

# A Consultative Meeting Report for Pharmacovigilance

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## *Tanzania and Beyond*

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*October 2006*



## **A Consultative Meeting Report for Pharmacovigilance: Tanzania and Beyond**

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## CONTENTS

ACRONYMS .....	v
BACKGROUND .....	1
Summary of Key Presentations.....	2
Highlights from Group Discussion .....	8
Proposed Partnership and Activities .....	9
ANNEX 1. PROPOSED PHARMACOVIGILANCE (PV) ACTIVITY MATRIX .....	13
ANNEX 2. LIST OF PARTICIPANTS—PHARMACOVIGILANCE WORKSHOP, JULY 21– 22, 2006, BAGAMOYO, TANZANIA .....	15



## ACRONYMS

ACT	artemisinin-based combination therapy
ADDO	accredited drug dispensing outlet
ADR	adverse drug reaction
AQ	amodiaquine
AS/AQ	artesunate/amodiaquine
CDC	U.S. Centers for Disease Control and Prevention
CIMed	center for drug information
DHMT	district health management team
DIC	drug information center
IHRDC	Ifakara Health and Development Research Center
IPTi	Intermittent Preventive Treatment in infants
LLD	large linked database
MoH	Ministry of Health
MSH	Management Sciences for Health
PMI	President's Malaria Initiative
PV	pharmacovigilance
RPM Plus	Rational Pharmaceutical Management Plus
TADATIS	Tanzania Drug and Toxicology Information Services
SOPs	standard operating procedures
SP	sulfadoxine-pyrimethamine
STGs	standard treatment guidelines
TFDA	Tanzania Food and Drugs Authority
USAID	U.S. Agency for International Development
WHO	World Health Organization
ZDIC	zonal drug information center
ZMCP	Zanzibar Malaria Control Program



## BACKGROUND

In February 2006, the U.S. Agency for International Development (USAID) Mission in Tanzania, under the mandate of the President's Malaria Initiative (PMI),<sup>1</sup> requested assistance from the Rational Pharmaceutical Management (RPM) Plus Program of Management Sciences for Health (MSH) to assist the Tanzanian Food and Drugs Authority (TFDA) to improve their pharmacovigilance (PV) system. Specific attention is needed for the monitoring of adverse drug reaction (ADR) of artemisinin-based combinations (ACTs) in pregnant women in Tanzania.

The need to strengthen ADR reporting for this class of antimalarials is urgent for two reasons: (1) its safety profile in pregnant women has not been well established and (2) a policy change to use ACTs as first-line antimalarials to be implemented in Tanzania from July 2006 to May 2008.

As the first step, RPM Plus/MSH organized a two-day consultative meeting to assist TFDA in gathering ideas on how best to strengthen the ADR reporting of ACTs. The meeting focused on Tanzania's ADR reporting structure, specifically, its design and management. The meeting brought together participants from a diverse range of experience and expertise, including: TFDA; U.S. Centers of Disease Control and Prevention (CDC); Ifakara Health and Development Research Center (IHDRC); and PV experts from the national programs of Ghana, Mozambique, and Zanzibar, countries with relevant experience in ADR monitoring of antimalarials.

The key objectives of the meeting were to—

- Share experience and key lessons learned from ADR monitoring of antimalarials in pregnant women and related issues in Tanzania, Ghana, and Mozambique
- Identify gaps in ADR monitoring system in Tanzania
- Based on meeting discussion, assist TFDA in identifying key components 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 three small group discussions. RPM Plus/MSH 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 and IHRDC in Tanzania and PV programs of Ghana, Mozambique, and Zanzibar.

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<sup>1</sup> The President's Malaria Initiative (PMI). <<http://www.fightingmalaria.gov/>> (accessed Oct. 16, 2006).

## **Summary of Key Presentations**

### *Designing Sustainable Pharmacovigilance Systems (MSH)*

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

- Assessment of available resources (both financial and technical) 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 the Drug Regulatory Authority (i.e., regulatory, managerial, or educational). In this context, an effective national PV system requires the Drug Regulatory Authority 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 and standard operating procedures [SOPs]) for ADR reporting structure nationally, including those of public health programs

### *Pharmacovigilance System in Tanzania (TFDA)*

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 the Tanzania Drug and Toxicology Information Services (TADATIS), in Muhimbili National Hospital. Among the key functions of TADATIS were promoting, reporting, and analyzing ADRs, with reports submitted to the World Health Organization (WHO). In addition, it also provided pharmaceutical information and education for the public and health care workers about rational use and prescribing through radio, TV, bulletins, and newspapers.

In 1998, TADATIS was incorporated into the Ministry of Health (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 four zonal drug information centers (ZDICs) in Dar es Salaam (Muhimbili), Bugando, Mbeya, and Kilimanjaro.

TFDA has supported ZDIC activities by purchasing computers, as well as providing PV

awareness training for health care professionals. SOPs for ADR data handling have been developed for these ZDICs and the PV unit within TFDA.

However, underreporting remains a challenge due to the following factors—

- Lack of awareness on ADR by health care 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 standardized ADR reporting forms (“yellow card”) from health facilities

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

- Incorporate PV into health care teaching curricula (physicians, pharmacists, nurses, etc.)
- 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 nationwide
- Establish more zonal DICs

### *Monitoring Adverse Drug Reactions in Southern Tanzania (CDC/IHDRC)*

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 two reporting-related components—

- Yellow card system—design, training, follow-up, and reports
- Linked database approach

A two-day training program was designed to: (1) identify “ADR Monitors” from each district health management team (DHMT) and each hospital and (2) train staff from health facilities (1 dispensary; 2 health centers). Overall, it took two 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 three months to check the following—

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

After one year of implementation, there have been 47 ADR reports, five for age two and below with the rest coming from infants over two years of age. The key lessons learned include—

- Broad reporting criteria (all medicines, 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
- DHMT having a sense of ownership of the process and yellow card system is critical for success

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

LLD offers some advantages over the yellow card form system, namely it does not depend on—

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

However, LLD 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 (National PV Center of Mozambique)*

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 cards) and to encourage all health care providers to report.

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

- Adoption of a step-by-step approach toward implementation, beginning with pilot phase in two districts (Namaacha and Mtutuine)
- Formed close collaboration with the malaria control program 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 forms
- 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 know where forms are stored, how to fill out forms, 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, which might be attributed to poor product quality.

The challenges for the Mozambique PV program are—

- Flow of information—getting feedback information and reports sent to CIMed remains a barrier
- Underreporting—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
- Implementation has to be adapted to the context 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 the 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 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 and the 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 and Progress Indicators (National PV Center of Ghana)*

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 the WHO program for International Drug Monitoring in 2001. It is currently located within Department of Clinical Pharmacology & Therapeutics, University of Ghana Medical School. The center promotes ADR reporting through—

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

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 filling out an 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

#### *Zanzibar Pharmacovigilance Program (Zanzibar Malaria Control Program-ZMCP)*

The Zanzibar Malaria Control Program (ZMCP) started implementation of pharmacovigilance activities in 2004 by conducting ten training of trainers with several health care staff from health facilities in Pemba and Unguja. In Zanzibar, the main thrust for pharmacovigilance activities came after a change of malaria treatment policy to ACTs. However, since these activities started, very few ADR reports have been reported to the PV unit within ZMCP.

In order to understand the reasons for such low ADR reporting, the ZMCP, in collaboration with WHO, conducted a rapid assessment of PV activities in 42 health facilities in February 2006. The assessment focused on health care workers training in pharmacovigilance, availability of ADR reporting forms, frequency of suspected ADR events, and awareness on common ADR by health care workers.

The assessment identified the following problems—

- Availability of ADR reporting forms
- Lack of awareness on the need to report ADR among health care workers
- Low number of staff trained in pharmacovigilance
- Lack of regular follow up and supervision by pharmacovigilance focal person from ZMCP

The ZMCP is in the process of addressing the identified problems.

## **Highlights from Group Discussion**

The three 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 three 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” pharmaceutical safety data (i.e., baseline). This is especially crucial when a policy change is considered, e.g. change in STGs.
- The TFDA PV unit needs to network with active surveillance studies in the country—through public health programs, universities, hospitals, research centers, CDC/IHRDC—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 no 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 a “training of trainers” approach to build ADR awareness at district level; use of existing community-level programs, such as the accredited drug dispensing outlet (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.

## **Proposed Partnership and Activities**

The consensus of the participants is that—

A key gap in the ADR reporting system exists 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, such as at the DHMT and health facilities) and central levels (PV unit of TFDA).

It is proposed that MSH/RPM Plus, TFDA, NMCP, 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 address this gap, three major activities are proposed—

### 1. Strengthen passive surveillance (see ADR reporting scheme)

To achieve the above objectives, it is proposed that the following sub-activities be developed in two districts, one each in Ruvuma and Morogoro regions, (where MSH/RPM Plus, TFDA, CDC/IHRDC already have ongoing projects to leverage resources) to—

- Improve the ADR reporting system at the district level by focusing on the crucial linkage of: DHMT (especially district pharmacist), health facilities, and ADDOs
- Improve the ADR information flow between levels by providing training in guidelines and SOPs for ADR form distribution and collection (Figure 1)

### 2. Strengthen active surveillance network

Currently, there is weak coordination between TFDA and active surveillance research projects throughout the country, such as at hospitals, research centers, and universities. 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.

### 3. Develop communications and advocacy plan to address ADR as a medicine safety issue

The lack of awareness about ADR reporting and PV in general is a common problem among both health care professionals and the general public.

Having a clear communication strategy is crucial to address—

- A change in malaria treatment policy and
- ADR reporting must be a responsibility of both health professionals and general public

The proposed activities (Annex 1) build on the existing system by filling the gaps identified during the consultative process. 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, enhancing the oversight capability of TFDA in monitoring safety of medicines in the country.

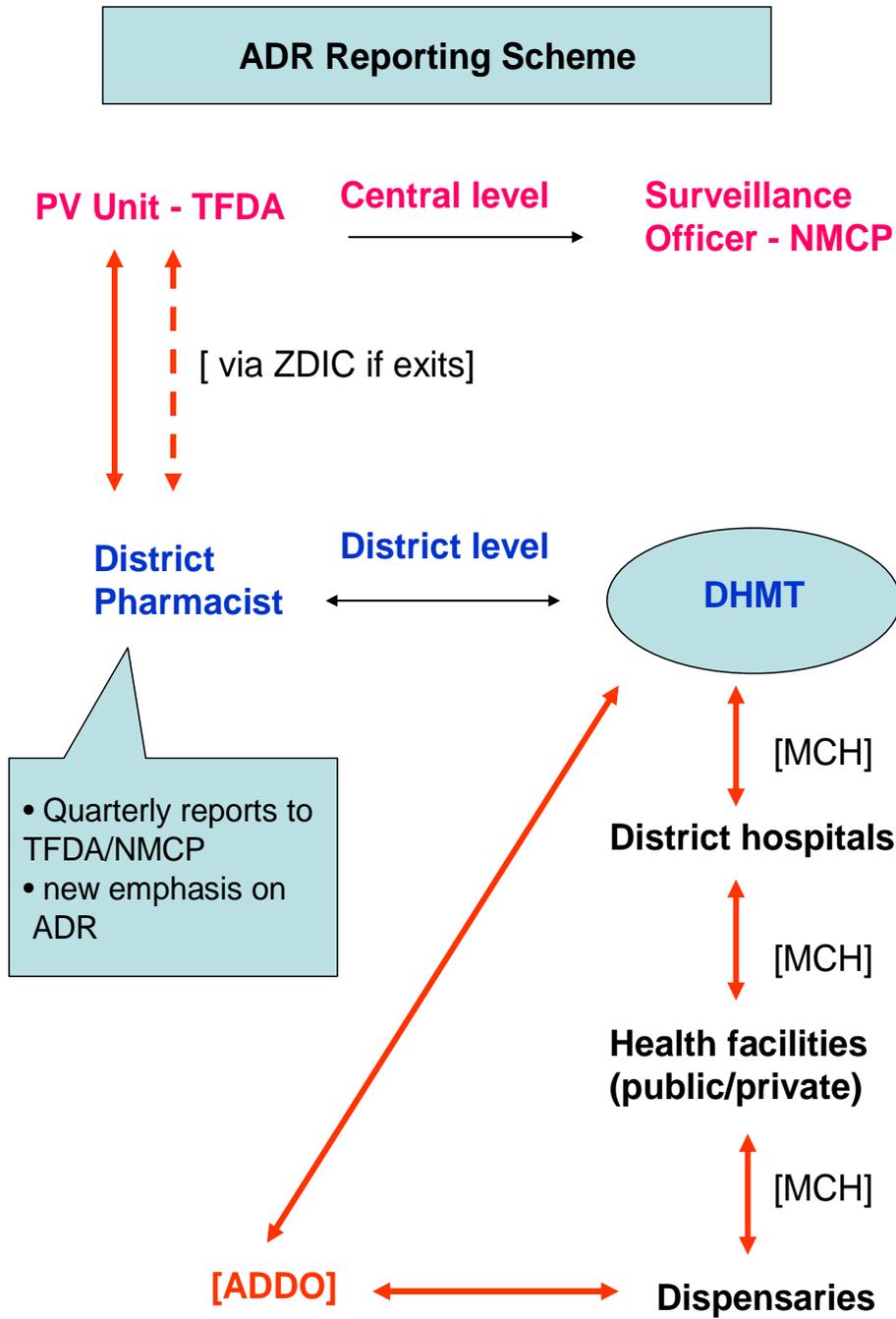


Figure 1. ADR reporting scheme



## ANNEX 1. PROPOSED PHARMACOVIGILANCE (PV) ACTIVITY MATRIX

Activity	Sub-Activity	MSH Role	TFDA Role	CDC/IHRDC Role	NMCP Role	Product(s)
<b>Project introduction and meeting proposal</b>	Develop concept paper to propose a pharmacovigilance consultative meeting: background/use of ACTs; ADR reporting needs	Lead role in developing first draft	Provide comments and suggestions	Provide comments and suggestions		Concept paper for improving ADR reporting
<b>Organize PV consultative meeting for key partners</b>	<ul style="list-style-type: none"> <li>• Share experiences and lessons learned from ADR monitoring of antimalarials in pregnant women in Ghana and Mozambique</li> <li>• Identify gaps in ADR monitoring system of ACTs in Tanzania</li> <li>• Assist TFDA in identifying key components for the design of a cost-effective PV system to monitor ADR of ACTs in pregnant women (and other medicines in the future)</li> </ul>	Support meeting costs; contribute to presentation; participate in discussion; organize meeting notes and prepare report	Contribute to presentations; facilitate and participate in meeting discussion	Contribute to presentations; participate in meeting discussion	Contribute to presentations; participate in meeting discussion	Meeting report
<b>PV activity planning</b>	Develop workplan for PV activities	Lead role	Provide comments and suggestions	Provide comments and suggestions	Provide comments and suggestions	Workplan
<b>Develop implementation strategies</b>	Key considerations— <ul style="list-style-type: none"> <li>• Select two pilot districts</li> <li>• Role of DHMT at district level</li> <li>• Role of health facilities and ADDO at district level</li> <li>• Strengthen TFDA's management of and response to ADR data</li> <li>• Establish or incorporate into existing committee ADR advisory group to take advantage of existing resources from active surveillance studies in Tanzania</li> <li>• Improve methods to monitor ACT use during pregnancy</li> </ul>	Provide TA	Lead role; provide staff to coordinate and facilitate planning	Provide TA	Coordination role; provide staff to work with partners; facilitate communication between NMCP and TFDA	Implementation document
<b>ADR training preparation</b>	Develop training materials, guidelines, and SOPs— <ul style="list-style-type: none"> <li>• Use of ADR reporting form</li> </ul>	Provide TA	Lead role in organizing training; develop guidelines	Provide TA	Coordination role; take advantage of	ADR training materials for district-level

*A Consultative Meeting Report for Pharmacovigilance: Tanzania and Beyond*

Activity	Sub-Activity	MSH Role	TFDA Role	CDC/IHRDC Role	NMCP Role	Product(s)
	<ul style="list-style-type: none"> <li>Distribution and collection of ADR reporting forms</li> <li>Management of reporting forms</li> <li>District-TFDA reporting mechanisms</li> </ul>		and SOPs from finalized training materials; develop training objectives and indicators		current trainings on ACT case management or pharmaceutical management for malaria to incorporate PV/ADR module	facilities
<b>ADR training at district level</b>	<ul style="list-style-type: none"> <li>Raise ADR awareness as drug safety issue among health care workers</li> <li>Orient staff on the use of SOPs for distribution and collection</li> </ul>	Support role in training; provide two staff; partial support of travel and training costs	Lead role in training; provide two staff; provide training facilities; support travel and training costs of TFDA staff	Provide TA		Training report: list of staff trained; training evaluations
<b>Monitoring &amp; Evaluation of pilot districts</b>	<ul style="list-style-type: none"> <li>Review of procedures for distribution and collection ADR forms</li> <li>Review of ADR forms collected</li> <li>Analysis of ADR data and impact of new ADR reporting structure</li> </ul>	Provide TA; support two–three rounds of evaluation costs	Lead role: provides supervision; periodic evaluations; share reports with all key partners	Provide TA	Coordination role: malaria focal person link with district pharmacist and DHMT	Technical and management performance reports
<b>Communications—Advocacy and outreach</b>	Develop communications and advocacy plan to reach— <ol style="list-style-type: none"> <li>Prescriber in health facilities, ADDOs dispensers, and CHMTs</li> <li>General public to address change in policy and the idea of reporting problems with medications</li> </ol>	Lead role in developing plan	Lead role in implementing plan; MSH to have supportive role in assisting with implementation	Provide TA	Coordination role; link NMCP communication activities on ACT safety with TFDA PV/ADR public awareness	Communications and outreach plan to identify objectives, key audiences, key messages, materials/collateral for achieving objectives

**ANNEX 2. LIST OF PARTICIPANTS—PHARMACOVIGILANCE WORKSHOP, JULY 21–22, 2006, BAGAMOYO, TANZANIA**

**List of Participants—Pharmacovigilance Workshop, July 21–22, 2006, Bagamoyo, Tanzania**

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*A Consultative Meeting Report for Pharmacovigilance: Tanzania and Beyond*

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