

Namibia Pharmacovigilance Training Workshop Report: July 11-12, 2007, Rock Lodge Okahandja, Namibia

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Acronyms

ADR	Adverse drug reaction
AIDS	Acquired immune deficiency syndrome
ART	Antiretroviral therapy
DSP	Directorate of Special Programmes
DUS	Drug utilization studies
HIV	Human immunodeficiency virus
ICH	International conference on harmonization
I-TECH	International Training and education center on HIV/AIDS
MCC	Medicines Control Council
MDM	Medicos Del Mundo
MI	Medicines information
MoHSS	Ministry of Health and Social Services
MSH	Management Sciences for Health
MTP	Monitoring Training and Planning
NDP	National Drug Policy
PC&I	Pharmaceutical Control and Inspection
PVS	Pharmacovigilance system
TB	Tuberculosis
TC	Therapeutics Committee
THC&CSS	Tertiary Health Care and Clinical Support Services
TI	Therapeutics Information
TIPC	Therapeutic Information and Pharmacovigilance Centre
ToT	Training of Trainers
UMC	Uppsala Monitoring Center
WHO	World Health Organization
WHO-ART	WHO adverse reaction terminology

Background

Formal medicines information (MI) center and systems for monitoring and reporting adverse drug reactions (ADRs) had not existed in Namibia. The pre-assessment of the pharmaceutical management system in 2003 highlighted this deficiency as a serious impediment to the rational use of medicines in the country¹. The need for having medicines information center to provide unbiased and up-to-date information to health professions in the country has long been established. The National Drug Policy (NDP) of 1998 actually recommends the establishment of a drug information center and adverse reaction monitoring unit linked to the Medicines Control Council (MCC) to coordinate adverse reaction reporting and to manage data collection, analysis and dissemination². The Namibia Medicines and Related Substances Control Act, 2003 (Act. No. 13 of 2003) requires the reporting of ADRs by health professions. Thus, the establishment of a center to handle medicines information and ADR monitoring as proposed by the NDP becomes necessary to facilitate ADR reporting as stipulated by the act.

To address this gap, a working group was formed under the leadership of the Ministry of Health and Social Services (MoHSS) charged with the responsibility of developing and carrying out an implementation plan for the set-up of a center combining the twin functions of medicines information and pharmacovigilance. Members of this team are drawn from the MoHSS Directorate of Special Programs (DSP), Tertiary Health Care and Clinical Support Services (THC& CSS) and various development partners including Management Science for Health (MSH), Medicos del Mundo (MDM) and the International Training and Education Centre on HIV/AIDS (I-TECH). The working group developed an implementation plan detailing the office set-up plans, proposed functions, staff and a work plan for the center³. Subsequently, an office has been set up at the Windhoek Central Hospital (WCH), with a Medicines Information pharmacist engaged as coordinator to run the center.

The key objectives of the center are:

- To provide both proactive and query response therapeutics information to Namibian health professions
- To become a reference unit on pharmacovigilance by collecting and monitoring ADRs

Training, particularly on pharmacovigilance systems, is a key component of the implementation plan for the center. The plan proposes that the center staffs and other health professions should be trained on various aspects of medicines information and pharmacovigilance. Training for the center staffs is to focus on the processes of collecting, analysis and reporting of ADR. In this respect, it is envisaged that the center is to work closely with regional and international pharmacovigilance centers, and in particular, the World Health Organization (WHO) coordinating Centre for Drug Monitoring, the Uppsala Monitoring Center (UMC) in Sweden.

¹ Aboagye-Nyame, Francis, Laila Akhlaghi, and Michael Thuo. 2004. *Preassessment of the Pharmaceutical Management System, Republic of Namibia: Trip Report, August 18-26, 2003*. Submitted to the U.S Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.

² Ministry of Health and Social Services. 1998. *National Drug Policy for Namibia*.

³ TIPIC Implementation Working Group, 2006. *Implementation Plan for the setup of Therapeutics Information & Pharmacovigilance Centre in Namibia*.

Training of health professionals is aimed at equipping them with the skills and knowledge to facilitate their reporting of suspected ADRs. Other objectives of the trainings would be to raise awareness on issues of drug safety and create a reporting culture among Namibian health professionals.

The Namibia pharmacovigilance training forms part of the planned training and advocacy activities included in the center's work plan. This training was organized by RPM Plus Namibia, the MoHSS and other collaborators as a training of trainers (TOT) for a core group of individuals who are expected to serve as trainers in future pharmacovigilance trainings. The participants were drawn from MoHSS divisions and directorates involved in activities likely to benefit from a strengthened pharmacovigilance system in the country and also from the health facilities. This training covered all aspects of the programmatic implementation of a pharmacovigilance system. It was envisaged that the training would also expose participants to a wide range of topics in pharmacovigilance and provide a forum for the exchange of ideas on the functioning of the Therapeutic Information and Pharmacovigilance Centre (TIPC) and especially how the centers' activities can be expanded to involve regional teams in ADR monitoring and reporting.

Goal, Objective and Scope of Training

Goal

To strengthen pharmacovigilance and medicines information systems in the country in order to safeguard public health and improve rational medicine use through the provision of accurate and unbiased medicines information and monitoring of ADRs to support local decision making.

Specific Objectives:

At the end of the training, the trainees were expected to be able to:

1. Understand the benefits of pharmacovigilance systems (PVS) to the MCC, guidelines committees and policy makers
2. Be informed of the overview of PVS within the confines of the Therapeutics Information and Pharmacovigilance Center
3. Understand the importance of drug safety and pharmacovigilance in HIV/AIDS, TB and Malaria
4. Understand the newly developed Adverse Event Reporting System
5. Understand how to implement pharmacovigilance using the Monitoring, Training and Planning (MTP) approach

Scope of Training

The course was divided into four modules, each having a number of related sessions.

The modules are:

Module 1: Overview of Pharmacovigilance within the confines of the TIPC

- Session 1: Introduction–Pharmacovigilance and the MCC
- Session 2: Therapeutics Information and Pharmacovigilance Center- from concept to implementation
- Session 3: Therapeutic Consultation

Module 2: Importance of Drug safety and Pharmacovigilance on HIV/AIDS, TB and Malaria

- Session 1: Drug Safety and Pharmacovigilance I
- Session 2: Drug Safety and Pharmacovigilance II.
- Session 3: Drug Safety and Pharmacovigilance III
- Session 4: Pharmacovigilance in Special treatment programs 1
- Session 5: Pharmacovigilance in Special treatment programs 2

Module 3: Adverse Event Reporting System

- Session 1: Adverse Event Reporting System
- Session 2: From signal to regulation: Use of ADR report data

Module 4: Implementing Pharmacovigilance using the MTP approach

- Session 1: Effective Communication in Pharmacovigilance
- Session 2: MTP approach
- Session 3: Role of Therapeutics Committees (TC) in ADR Reporting

- Session 4: Program for implementation

Target audience for the training

This training was a TOT with the successful participants expected to become part of a core group of trainers for future trainings on pharmacovigilance. The participants were drawn from the MCC, DSP (HIV/AIDS, TB and Malaria programs), subdivisions Pharmaceutical Control and Inspection (PC&I), National Medicines Policy Coordination, Epidemiology division of Primary Health Care Services, representatives of Therapeutics Committees, Regional Management Teams and heads of Communicable Disease Clinics.

Expected Outcome

At the end of the training, it was expected that the participants would have developed adequate skills to:

1. Advocate for the TIPC and its functions
2. Lead efforts to increase interest in pharmacovigilance in their health facilities and workplaces
3. Function as resource persons for future pharmacovigilance training
4. Contribute to efforts in ADR data reporting and use in Namibia

WORKSHOP PROCEEDINGS

Participants

The training was attended by 13 participants. These were drawn from the sub-divisions Pharmaceutical Control & Inspection, National Medicines Policy Coordination, Directorate of Special Programs, Catholic health facilities, regional management teams/ therapeutics committees, health facilities and partner organizations (*See annexure 1*).

Facilitators

The facilitators of the training program included

1. Johannes Gaeseb, Chief Pharmacist of PC&I, MoHSS and Registrar of Medicines, MCC.
2. Augustine Odo, Coordinator of TIPC, MoHSS
3. David Mbirizi, MSH/RPM Plus Namibia
4. Charles Ouma, MSH/RPM Plus Namibia
5. Shabir Banoo, MSH/RPM Plus South Africa
6. Jude Nwokike, MSH/RPM Plus Arlington, VA, US

Below is a brief summary of session proceedings and discussion. The agenda of the workshop is attached at the end of this report. (*See annexure 2*).

Module 1: Overview of Pharmacovigilance within the confines of the TIPC

Session 1: Introduction- Pharmacovigilance and the MCC

Trainer: Johannes Gaeseb

Approximate duration: 15 minutes

This was the introductory session and laid the foundation of what was to be discussed during the rest of the sessions. This session highlighted the regulatory roles of the MCC and brought to the fore the importance of availability of safety information on medicines to guide regulatory decisions. The role of the pharmacovigilance and therapeutic information from experiences across the world was also elaborated and the envisaged roles of the TIPC in Namibia were discussed. The key message from this session was that a pharmacovigilance system that is working properly is essential if medicines are to be used safely, effectively and with confidence.

Session 2: Therapeutics Information and Pharmacovigilance Centre- from Concept to Implementation

Trainer: Charles Ouma

Approximate duration: 30 minutes

The objectives of this session were to:

1. Enable trainees to understand the objectives of setting up the TIPC
2. Inform the trainees of the implementation process of the TIPC
3. Discuss the functions of the TIPC

4. Discuss the link between Therapeutics Information (TI), PVS and rational medicine use

Summary of the session

This session provided a brief update of the set-up process of the center and the envisaged functions of both medicines information and pharmacovigilance. The participants were taken through the important milestones in the implementation of the TIPC including office set-up, acquisition of office equipment, medicines information references, staff recruitment and training, and the development of various PVS and MI tools. The presentation also sought to highlight the link and emphasized the relationship between medicines information, pharmacovigilance and rational medicine use.

Session 3: Therapeutic Consultation 1 & 2

Trainer: Charles Ouma

Approximate duration: 75 minutes

Therapeutics Consultation 1.

The objectives of this session were to:

1. Enable the trainees to understand common biases in scientific articles
2. Inform the trainees of the relevant skills needed for unbiased evaluation of published papers
3. Enable the trainees to understand common biases in scientific literature

Summary of the session.

This presentation elaborated on the TIPC role in providing both proactive and query response therapeutics information. This session gave an overview of the steps involved in the provision of therapeutic information. It also highlighted the need to develop critical appraisal skills, the specific areas to be considered when evaluating scientific papers and the common biases that may be encountered in such publications. The trainees were also informed of the components of a critical appraisal checklist.

Therapeutics Consultation 2.

The objectives of this session were to:

1. Enable the trainees to understand how to use the proposed therapeutic information request form
2. Demonstrate some of the tools for therapeutic consultation
3. Inform the trainees of the reference materials and other resources available at the center

Summary of the session

The first part of this session focused on explaining to the trainees the various elements of the Therapeutic Information form and the processes of completing it. The participants were also informed that requests for information to the center could be sent in a variety of ways including by phone, fax, e-mail, online completion of the request form or by physically visiting the center. The second part of session was a demonstration of the various features of one of the electronic databases- *the Micromedex* health care series acquired by the center for medicines information. This generated a lot of interest from the

trainees and discussions that ensued highlighted the potential use of the system in ensuring easy access to information for health professional in the country.

The session concluded with the trainees being informed of the other reference materials to be availed at the center including additional electronic databases, both on-line and print journals, and current reference texts.

Module 2: Importance of Drug Safety and Pharmacovigilance in HIV/AIDS, TB and Malaria

Session 1: Drug Safety and Pharmacovigilance I

Trainer: Jude Nwokike.

Approximate duration: 60 minutes

The objectives of the session were to:

1. Enable the trainees to understand pharmacovigilance and drug safety
2. Discuss the use of pharmacovigilance in regulatory decisions
3. Discuss the life-cycle approach to drug regulation

Summary of the session

This served as the introductory session into the science and practice of pharmacovigilance for the trainees. The purpose of the session was to enable trainees to understand the link between pharmacovigilance, drug regulation and public safety; and its importance in monitoring the safety of both new and older medicines, especially in public health programs such as HIV/AIDS, TB and Malaria. The need to develop Pharmacovigilance in Namibia to extend beyond mere ADR tracking and to include prevention or reduction in medicines use problems like drug-drug interactions, medication error, poor product quality and counterfeiting and lack of efficacy was emphasized. The session provided definitions and overview of pharmacovigilance, pharmacoepidemiology, drug utilization review studies and risk management. A key point brought out during the presentation was that the primary goal of pharmacovigilance is *to safeguard public health and improve rational use of medicines through efficient and timely collection, assessment and communication of risks and benefits to support local decision making*. The presentation also demonstrated the link between pharmacovigilance and regulatory systems and how monitoring of drug quality, efficacy, effectiveness and safety should go beyond clinical trial stages into real life use of the products in the population.

The trainees were informed that data emanating from pharmacovigilance activities should also guide regulatory decisions in the areas of label changes, product recalls and changes to prescriptions rights for products already in the market place. The concept of risk management and application of risk minimization strategies to reduce the occurrence of known adverse events when using medicines with a potential for serious adverse reactions was also discussed.

Session 2: Drug Safety and Pharmacovigilance II

Trainer: Shabir Banoo

Approximate duration: 60 minutes

The objectives of the session were to:

1. Discuss the purpose of pharmacovigilance
2. Describe vocabulary and terms used in pharmacovigilance
3. Enable the trainees to understand dictionaries used in pharmacovigilance
4. Describe the types of ADRs
5. Enable the trainees to understand who should report what and how
6. Describe reporting requirements
7. Discuss how to recognize ADRs
8. Discuss methods for determining causality
9. Understand tools for determining ADR causality

Summary of the session.

This session built on what was discussed in the first session on drug safety and pharmacovigilance and dealt with the more technical and practical aspects of pharmacovigilance. The first part of the presentation focused on familiarizing the trainees with the vocabulary and terms used in PV: adverse drug reaction, unexpected drug reaction, adverse event, side effect and signal. This was followed by a discussion on the types and classification of adverse drug reactions with examples of each provided. Discussions on the processes and procedures for reporting ADRs focused on the issues of who, what and how ADRs should be reported including the use of reporting forms. This discussion also touched on the factors that need to be considered when an ADR is suspected. It was emphasized that product quality problems or defects such as suspected contamination, questionable stability poor packing or labeling, and therapeutic failures should be reported. A provision for this has been made on the reporting forms. This session concluded with discussion on causality assessment including definitions, causality classifications and application of systematic methods such as the Naranjo algorithm in determining causality.

Session 3: Drug safety and Pharmacovigilance III

Trainer: Jude Nwokike

Approximate duration: 45 minutes

The objectives of the session were to:

1. Understand methods used in ADR reporting
2. Understand suitable methods to be used in ADR monitoring in Namibia

Summary of the session

The purpose of this session was to enable the trainees to understand the various methods used in ADR reporting and identify methods that may be effective for use in Namibia. The discussion on the methods touched on both passive surveillance (Spontaneous reporting) and active (Sentinel, Chart reviews, cohort studies, prescription event monitoring, pregnancy registries, case-control studies) methods. The advantages, disadvantages and limitations of

each of these methods were highlighted. Reference was also made on the applicability of data linkages in enabling the review of ADR reports archived in more than one database hence enabling a wider and more inclusive assessment of ADRs. The use of patient-initiated drug safety reporting and case-control studies in pharmacovigilance was also discussed. The session concluded with discussion on suitable methods for use in Namibia.

Session 4: Pharmacovigilance in Special Treatment Programs I

Trainer: Shabir Banoo

Approximate duration: 60 minutes

The objectives of the session were to:

1. Enable the trainees understand the importance of pharmacovigilance in public health programmes
2. Describe the unique needs for increased pharmacovigilance for HIV/AIDS, TB and Malaria programmes
3. Discuss strategies to integrate pharmacovigilance in public health programmes

Summary of session

This session focused on pharmacovigilance in new health programs - Antiretroviral therapy (ART), TB and Malaria programs. The purpose of the session was to introduce the trainees to pharmacovigilance in the context of public health programs and to highlight the unique needs of public health programs, in particular HIV/AIDS, TB and malaria programs. The specific objectives of pharmacovigilance and expected challenges in public health programs in ensuring appropriate patient care and safety were emphasized. The session concluded with an in-depth examination of the elements of a HIV/AIDS pharmacovigilance programme as an example of a public health pharmacovigilance programme.

Session 5: Pharmacovigilance in Special programmes II

Trainer: Shabir Banoo

Approximate duration: 60mins

The objectives of the session were to:

1. Understand the importance of pharmacovigilance in public health programs
2. Describe the unique needs for increased pharmacovigilance in HIV/AIDS, TB and Malaria programmes
3. Discuss strategies to integrate pharmacovigilance into public health programmes

Summary of the session

The purpose of this session was to enable the trainees have an understanding of the components of a functional national pharmacovigilance system using the example of the national pharmacovigilance system in South Africa. The session was also intended to give trainees an understanding of the structures responsible for monitoring and regulating drug safety in a country and their functions, and also enable them to identify major role players and stakeholders participating in pharmacovigilance activities. The structural and functional inter-relationships of a national pharmacovigilance program was then explained using the

example of the South African National Pharmacovigilance Programme citing MCC1, the National pharmacovigilance program, the various pharmacovigilance centres as well as the pharmaceutical industry, health workers and even patients as key players in the system.

Module 3: Adverse Event Reporting System

Session 1: Adverse Event Reporting System

Trainer: Jude Nwokike

Approximate duration: 60 minutes

The objectives of the session were to:

1. Enable the trainees to understand the critical information that should be contained in an ADR form
2. Enable the trainees be familiar with the proposed ADR tools for Namibia
3. Enable the trainees understand multidisciplinary approach to ADR

Summary of the session

The purpose of this session was to enable the trainees to understand tools used for pharmacovigilance. Discussions focused on critical information that should be contained in an ADR form and the proposed ADR tools for Namibia. The key data fields and minimum information required for ADR reporting were identified and reference made to the International Conference on Harmonization (ICH) E2B format for data elements required for individual case report forms. Trainees were also informed that ADR reporting should be encouraged and not having all data required to complete all fields of the forms should not deter reporting. Additionally, trainees were informed that timely reporting was, however, essential to help in the early recognition of signals. The ADR tools developed for Namibia, the Safety Yellow form and the Patient- Initiated Yellow form, were also presented to the trainees. The other tool highlighted during the presentation was the Therapeutics Information request form to be used for requesting information from the TIPC by health care workers. The features of the VigiFlow®, the Uppsala Monitoring Centre web-based report management tool, were highlighted to the participants. It is planned that this tool, which comes with the WHO Drug Dictionary, the International Classification of diseases (ICD 10) and the WHO Adverse Reaction Terminology (WHO-ART), will be availed to the center for submitting reports and accessing the WHO database. The session closed with discussions on the need to have a multidisciplinary approach involving all health workers and even consumers in pharmacovigilance activities. It was emphasized that it was critical to establish a pharmacovigilance advisory committee with the key responsibility of analyzing all case reports to determine the incidence and prevalence of known side effects and causality assessments of unknown ADRs. The reports generated would thus be used by the regulatory body to take regulatory decisions, inform the public, restrict or expand use of product and liaise with product sponsors.

Session 2: From Signal to Regulation: Use of ADR Report Data

Trainer: Shabir Banoo

Approximate duration: 60 minutes

The specific objectives of the session were to enable the trainees to:

1. Understand the steps in the use of ADR reports
2. Understand how ADR information is used for decisions
3. Describe how regulatory authorities, guideline committees and policy makers utilize information from ADR systems
4. Understand how to disseminate findings
5. Understand regulatory decisions that can be taken in response to pharmacovigilance findings

Summary of the session

The purpose of this session was to introduce the trainees to the regulatory implications of the safety findings of medicines. The introductory part of the session covered the elements of a pharmacovigilance system and this was linked to discussion on the pharmacovigilance process- *from data to signal analysis (process flows)*. The procedures for signal detection and hypothesis testing were also outlined to the trainees. The trainees were made aware of the importance of good communication in pharmacovigilance. This would include communication to reporters (acknowledging reports and giving feedback to reporters), and periodic communication to prescribers and other health care workers on medicine safety issues through bulletins and similar publications. The session concluded with discussions on possible regulatory decisions that a regulatory authority can make regarding safety findings including the issuing of ‘*Dear Doctor*’ letters, package insert revisions and drug recalls in case of serious safety concerns.

Module 4: Implementing Pharmacovigilance Using the MTP Approach

Session 1: Effective Communication in Pharmacovigilance

Trainer: Augustine Odo

Approximate duration: 30 minutes

The main objectives of this session were to:

1. Enlighten the trainees on the challenges involved in communicating ADR information to the public
2. Enable the trainees to understand roles health workers can play to improve ADR reporting culture

Summary of the session

The key message highlighted during the presentation was the pivotal role of effective communication in pharmacovigilance. The main areas of communication in pharmacovigilance were highlighted and the challenges of communicating drug safety information were identified and possible solutions suggested. The trainees were also made aware of the various tools and also available means of communication in pharmacovigilance and medicine information activities. The session concluded with discussions on strategies that can be applied to motivate health workers towards developing a reporting culture which

is critical for generating data for the pharmacovigilance activities, especially in monitoring drug safety.

Session 2: Improving Quality in Pharmacovigilance Systems: The MTP Approach

Trainer: Shabir Banoo

Approximate duration: 30 minutes

The objectives of this session were to:

1. Discuss why using the MTP approach is important for improving pharmacovigilance activities
2. Discuss the MTP process
3. Discuss practical considerations for implementation
4. Develop a plan of action for MTP implementation

Summary of the session.

The session dealt with definitions, importance and use of the MTP process as a performance improvement strategy in implementing pharmacovigilance activities. The trainees were taken through the three segments and activities of the MTP process, monitoring, training and planning, and the possible applicability of the tool in implementing pharmacovigilance. The session also covered the practical aspects of how to design, organize and implement an MTP process, with examples given on the use of the tool in solving identified problems. The session concluded with discussion on the key aspects that should be addressed to ensure the maximum impact of the MTP processes. These were identified as ensuring that the process is all inclusive, ensuring that there is a mechanism to implement, co-ordinate and drive the process, as well as ensuring that the strategies developed to address the problem (s) are feasible and the standards set achievable.

Session 3: Role of Therapeutics Committees (TC) in Pharmacovigilance

Trainer: Charles Ouma

Approximate duration: 60 minutes

The objectives of the session were to:

1. Discuss the roles of TCs in pharmacovigilance activities
2. Discuss strategies to improve TC activities in ADR, to address inappropriate medicine use and medication errors
3. Describe the potential roles in prescription event monitoring and drug utilization studies in pharmacovigilance

Summary of session

The session opened with discussions on the roles of TCs in ensuring safety in the use of medicines. The areas of responsibility of TC in ensuring safety were identified as monitoring and ensuring medicines quality, monitoring and addressing medication errors and monitoring and managing ADRs which may be caused by the medicine itself, medication errors or poor drug quality. Some of the measures that TCs can implement to prevent or reduce incidence of ADRs and medication errors were highlighted. PEM, an active ADR surveillance method,

was presented as an additional tool to spontaneous reporting that TCs can use in signal detection and validation, especially for new products that require heightened surveillance. The use of Drug utilization studies (DUS) in pharmacovigilance were also discussed in detail, especially its use in assessing medicine use to identify problems, hence enabling specific interventions to be implemented to prevent possible occurrence of ADRs resulting from irrational use.

Session 4: Implementation of the Therapeutics Information and Pharmacovigilance Centre in Namibia

Trainer: David Mabirizi

Approximate duration: 75 minutes

The objectives of the session were to:

1. Explain to the trainees their roles in national and regional pharmacovigilance trainings
2. Discuss how the trainees will participate in the launch of the TIPC and other activities of the center.

Summary of the session

This was the concluding session of the training and was meant to enable the trainees to understand their roles in the wider perspective of the implementation of the TIPC in Namibia. During the presentation, the various components of the TIPC implementation plan were highlighted with specific emphasis on the plan for national and regional trainings and the launch. Preparatory and planned activities for the launch of the center were also highlighted. Possible TIPC indicators to monitor the function and efficacy of the center were discussed in detail. The session concluded with the presentation of the detailed implementation plan for the center and a review of the roles of the TOT team in the center's activities.

Next Steps

Immediate Follow-up Activities

The next steps after this training include:

1. Trainees conducting advocacy and sensitization meeting in their regions
2. Making preparations for the national trainings scheduled for later in the year; It is expected that the TOT team will form a core group of trainers for the national team
3. Finalization of the acquisition of the remaining equipment and reference materials for the center so that it can become fully operational
4. Circulation of the draft PVS and MI tools for pre-testing; These tools will be submitted to MoHSS for approval and adoption after incorporating required changes identified during pre-testing
5. Plan for the official launch of the center

Recommendations

Pharmacovigilance is a new initiate in the Namibian health sector. A key activity of the center is therefore to conduct advocacy and sensitization meetings targeted at policy makers, managers and health workers to raise awareness and encourage participation in pharmacovigilance activities. It is therefore important that center be adequately supported so as to deliver the required results which will be critical in ensuring that pharmacovigilance is entrenched as a necessary service in the country's health system. In addition, since this is a new initiate in the country, it is important that the center develops partnerships with regional and international pharmacovigilance centers so as to benefit from the experience of these older centers and also share information.

Important Upcoming Activities or Benchmarks in Program

1. National Pharmacovigilance Training
2. Official launch of the center

Annex 1. Participants

No.	First Name	Last Name	Post	Postal Address	E-mail address	Contact Phone No.
Participants						
1.	Pascal	Rite	Pharmacist-PC&I	P.O Box 8034, Bachbrecht, Windhoek.	prite@mhss.gov.na	061-2032346 081-2719600
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Facilitators						
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3.	Jude	Nwokike	SPA, MSH/RPM Plus, US		jnwokike@msh.org	+1 7032481629
4.	Shabir	Banoo	SPA, MSH/RPM Plus, South Africa.	P.O Box 31931, Braamfontein, Johannesburg	sbanoo@msh.org	+ 27 83869854

Annex 2. Agenda



Namibia Pharmacovigilance Training (TOT)
Rock Lodge, Okahandja, Namibia
 July 11th & 12th, 2007

PROGRAM

Time (11/07/2007)	Events	Facilitator
8h30	Registration	All
9h00	1.1: Introduction	Medicines Control Council, MCC
9h15	1.2: Therapeutics Information and Pharmacovigilance Center – from concept to implementation	David Mbirizi/Charles Ouma
9h45	1.3: Therapeutic Consultation 1	T. N. Shidengi-Shivolo/C. N. Ipinge
10h15	1.3: Therapeutic Consultation 11	Charles Ouma
11h00	Tea break	All
11h15	2.1: Drug safety and Pharmacovigilance 1	Jude Nwokike
12h15	2.2: Drug safety and Pharmacovigilance 2	Shabir Banoo
13h15	Lunch	All
14h15	2.3 Drug safety and Pharmacovigilance 3	Jude Nwokike
15h00	2.4 Pharmacovigilance in special treatment programs 1	Shabir Banoo
16h00	2.5 Pharmacovigilance in special treatment programs 2	Shabir Banoo
17h00	End of day 1	All



Time (12/07/2007)	Events	Facilitator
8h30	3.1 Adverse Event Reporting System (AERS)	Jude Nwokike
9h30	3.2 From signal to regulation: Use of ADR report data	Shabir Banoo
10h30	4.1 Effective communication in Pharmacovigilance	Augustine Odo
11h00	Tea break	All
11h15	4.2 MTP Approach	Shabir Banoo
12h15	4.3 Role of Therapeutics Committees (TC) in ADR reporting	Charles Ouma
13h15	Lunch	All
14h15	4.4 Program for implementation 1	David Mabirizi
15h00	4.4 Program for implementation 11	Johannes Gaeseb
15h30	Discussions on the way forward	All
16h30	Vote of Thanks	Directorate of Special Programme



Annex 3. Training Evaluation
Namibia Pharmacovigilance Training- Course Evaluation
 July 11th & 12th, 2007. Rock Lodge Okahandja

		Participants												Average
		1	2	3	4	5	6	7	8	9	10	11	12	
A	OVERALL RATING OF THE COURSE	4.0		4.0	3.0	4.0			5.0	3.5			3.0	
B	ACHIEVEMENT OF THE COURSE'S OBJECTIVES													
1	Enabled understanding of the benefits of Pharmacovigilance within the confines of TIPCC, MCC, Guidelines committees and policy makers	5.0	4.0	4.0	3.0	4.0	5.0	4.0	5.0	5.0	4.0	5.0	3.0	
2	Enabled understanding of the importance of Drug safety and pharmacovigilance in Public Health Programs (HIV/ AIDS, TB, Malaria)	5.0	4.0	3.0	3.0	4.0	5.0	5.0	5.0	5.0	4.0	5.0	3.0	
3	Enabled understanding of how to implement a National Pharmacovigilance System including an Adverse Event Reporting System	5.0	4.0	4.0	4.0	4.0	4.0	4.0	5.0	5.0	4.0	5.0	3.0	
C	GENERAL APPRECIATION OF THE COURSE													
1	Overall satisfaction with the course	4.0	4.0	4.0	3.0	4.0	3.0	4.0	5.0	5.0	4.0	5.0	2.0	
2	Met training expectation and needs	5.0	4.0		3.0	4.0	3.0	4.0	5.0	5.0	5.0	5.0	2.0	
3	Facilitators clear and easy to understand	4.0	4.0	4.0	3.0	4.0	4.0	4.0	5.0	5.0	4.5	5.0	3.0	
D	COURSE CONTENT, FORM AT AND MATERIAL													
1	Difficulty of course content (1= Not difficult; 5= Very difficult)	2.0	1.0	2.0	2.0	2.0	4.0	2.0	1.0	1.0	3.0	1.0	2.0	
2	Course coverage of all essential topics	5.0	4.0	2.0	4.0	4.0	4.0	4.0	5.0	5.0	4.0		3.0	
3	Efficacy of sessions format and discussions	4.0	4.0	2.0	3.0	4.0	3.0	4.0	4.0	5.0	4.0		2.0	
4	Rating of materials for the course (Handouts, slides, supplementary)	5.0	4.0	2.0	4.0	4.0	4.0	4.0	5.0	5.0	5.0		2.0	
5	Relevance of topics covered	4.0	4.0	1.0	4.0	4.0	4.0	5.0	5.0	5.0	4.0		4.0	
E	COURSE ORGANIZATION													
1	Overall time management (scheduling, duration, punctuality)	3.0	2.5	4.0	2.0	4.0	4.0	3.0	5.0	5.0	3.0		3.0	
2	Time allocated to session	3.0	3.0	3.0	2.0	2.0	4.0	4.0	4.0	4.0	2.0		3.0	
3	Coordination of the sessions	4.0	4.0	4.0	4.0	4.0	5.0	5.0	5.0	5.0	5.0		3.0	
4	Meals and accomodation	5.0	3.0	4.0	4.0	3.0	5.0	2.0	4.0	4.0	4.0		4.0	
5	Conference room facilities	5.0	3.0	3.0	4.0	3.0		3.0	5.0	4.0	4.0		4.0	

Evaluation Scale: 1-Poor; 2- Fair; 3- Good; 4- Very Good; 5- Excellent

Average score(excluding D1)- 3.92

Lowest score: Time allocation to sessions: 3.1

Highest score: Coordination of sessions: 4.4 and Achievement of course's objectives with an overall score of 4.3

