

## Initiation and Implementation of a Pharmacovigilance System in Rwanda

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## **About SPS**

The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines.

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## TABLE OF CONTENTS

|   |    |
|---|----|
| Acronyms .....  | iv |
| Background .....  | 1  |
| Objectives .....  | 3  |
| Approaches .....  | 4  |
| Stakeholders' Awareness .....   | 4  |
| Legal Framework and Tools to Support PV and MI System.....  | 5  |
| Pharmacovigilance, Medicine Information, and the National Pharmacovigilance and<br>Medicine Information Center..... | 6  |
| Developing Staff Capacity .....   | 8  |
| National Adverse Event and Medicine Poor Quality Reporting System.....  | 10 |
| Results.....  | 12 |
| Stakeholders Awareness .....  | 12 |
| Legal Framework and Tools to Support Pharmacovigilance and Medicine Information<br>System.....                      | 12 |
| Findings of this Assessment.....  | 12 |
| Developing Staff Capacity .....   | 15 |
| TOTs for PHPs, Referral Hospitals, and District Hospitals.....  | 16 |
| Supportive Tools for AE and MPQ Reporting .....   | 19 |
| Illustration of the Contribution of PV to Patient Safety .....  | 20 |
| Challenges.....   | 23 |
| Conclusion and Recommendations.....   | 24 |
| Annex 1. AE notification forms (French and English) .....   | 25 |
| Annex 2. MPQ Notification Form (French and English) .....   | 26 |
| Annex 3. Patient Alert Card (English and Kinyarwanda).....  | 27 |
| Annex 4. Ministerial Instruction Establishing DTCs in all Hospitals .....   | 28 |
| Annex 5. Terms of Reference of DTC.....   | 29 |

## ACRONYMS

|         |  |
|---------|--|
| AE      | adverse event  |
| AEFI    | adverse event following immunization                       |
| AIDS    | acquired immunodeficiency syndrome                         |
| BUFMAR  | Bureau des Formations Medicales Agrées du Rwanda           |
| CAMERWA | Central d'Achats des Medicaments Essentiels du Rwanda      |
| CDC     | Centers for Disease Control and Prevention                 |
| CHUB    | Centre Hospitalo-Universitaire de Butare                   |
| CHUK    | Centre Hospitalo-Universitaire de Kigali                   |
| DTC     | Drug and Therapeutics Committee                            |
| FDA     | US Food and Drug Administration                            |
| HIV     | human immunodeficiency syndrome                            |
| MCH     | maternal and child health                                  |
| MI      | medicine information                                       |
| MoH     | Ministry of Health   |
| MSH     | Management Sciences for Health                             |
| MPQ     | medicine poor quality                                      |
| NMRA    | National Medicine Regulatory Authority                     |
| NPMIC   | National Pharmacovigilance and Medicine Information Center |
| NUR     | National University of Rwanda                              |
| PEPFAR  | President's Emergency Plan for AIDS Relief                 |
| PEV     | Programme Elargie de Vaccination                           |
| PHP     | public health program                                      |
| PMI     | Presidential Malaria Initiatives                           |
| PNILP   | Programme National Intégré de lutte contre le Paludisme    |
| PNILT   | Programme National Intégré de lutte contre la Tuberculose  |
| PTF     | Pharmacy Task Force  |
| PV      | Pharmacovigilance  |
| RBC     | Rwanda Biomedical Center                                   |
| SCPS    | Service de Consultation Psycho-Sociale                     |
| SPS     | Strengthening Pharmaceutical Systems [Program]             |
| TB      | Tuberculosis   |
| TOT     | training of trainers                                       |
| TRAC    | Treatment and Research AIDS Center                         |
| UMC     | Uppsala Monitoring Centre                                  |
| WHO     | World Health Organization                                  |

## BACKGROUND

The problems with medicines use are many—they may differ in pharmacological, pathological, epidemiological and legal respects; and may have different consequences in such areas as scientific study, regulation, or rational use. Pharmacovigilance (PV) is concerned with adverse effects and interactions as well as problems relating to ineffectiveness, inappropriate use, counterfeiting, and dependence or poisoning.<sup>1</sup>

A pivotal event in PV occurred in 1961 when an Australian obstetrician, William McBride, reported a 20 percent increase in fetal malformation and the appearance of a hitherto rare malformation, phocomelia (literally “seal limbs”), in association with the use of the hypnotic thalidomide during pregnancy. This drug had not been adequately screened for teratogenic effects, but similar malformations were subsequently shown in rabbits and in rats (at high doses).

The impact was devastating in Western countries (Germany, the United Kingdom, Australia, and the United States) with over 5,000 children born with phocomelia. In the United States, the Kefauver-Harris amendment to the US Federal Food and Drugs Act that required premarketing submission of both efficacy and safety data to the Food and Drug Administration (FDA) was passed in 1962. During the 1960s, in the aftermath of the thalidomide disaster, national PV centers were established in a number of countries around the world. New centers continue to be established, now mainly in developing countries.

Rwanda, like most developing countries, benefits from the increased availability and accessibility of new medicines and fixed-dose combination formulations to treat epidemic diseases (HIV/AIDS, malaria, and tuberculosis [TB]) and the use of other essential medicine through community health programs and other health facilities. However, the lack of experience with these products creates concerns about medicine safety. This highlights the need to identify and evaluate adverse events (AEs) and product quality to better understand and prevent possible risk, improve treatment protocols and patient safety. This concern was expanded to other essentials medicines and vaccines which are need also a close safety monitoring. Rwanda had planned to address these issues through a PV and medicine information (MI) system.

The World Health Organization<sup>2</sup> defines PV as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems.” Its major aims are<sup>3</sup>—

- Early detection of hitherto unknown adverse reactions and interactions
- Detection of increases in frequency of (known) adverse reactions
- Identification of risk factors and possible mechanisms underlying adverse reactions
- Estimation of quantitative aspects of benefit/risk analysis and dissemination of information needed to improve drug prescribing and regulation

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<sup>1</sup> Meyboom, Ronald H. B., Marie Lindquist, and Antoine C. G. Egberts. June 2000. An ABC of Drug-Related Problems; *Drug Safety* 22:415–423;

[http://www.who.int/medicines/areas/quality\\_safety/safety\\_efficacy/trainingcourses/abc\\_course.pdf](http://www.who.int/medicines/areas/quality_safety/safety_efficacy/trainingcourses/abc_course.pdf).

<sup>2</sup> WHO. 2002. *The Importance of Pharmacovigilance: Safety Monitoring of Medicinal Products*. Geneva: WHO. <http://apps.who.int/medicinedocs/en/d/Js4893e/>

<sup>3</sup> WHO. 2000. Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring. *Safety Monitoring of Medicinal Products: Guidelines for Setting Up and Running a Pharmacovigilance Center*. <http://apps.who.int/medicinedocs/en/d/Jh2934e/>

In many countries, the National Medicine Regulatory Authority (NMRA) is responsible for ensuring the quality, safety, and efficacy of the medicines available in the country through activities such as medicine registration, quality control testing, and PV.

Despite the fact that Rwanda does not have an NMRA, the Pharmacy Task Force (PTF) within the Ministry of Health (MoH) temporarily performs those activities by elaborating pharmacy policies and monitoring their implementation. This task force has a desk that coordinates PV, MI, and rational medicine use activities.

In 2009, a midterm PV diagnostic assessment was conducted to provide evidence-based options analysis and feasible recommendations that reflect local realities, priorities, and resource availability. These recommendations have been used to orient system implementation.

In many countries, the national drug authority is responsible for ensuring the quality, safety, and efficacy of the medicines available through activities such as medicine registration, quality control testing, and PV. Although Rwanda is in the process of establishing a national drug authority, it is not yet functional. Despite the fact that Rwanda does not have a national drug authority or experience in PV interventions, the President's Emergency Plan for AIDS Relief (PEPFAR) under COP08, with Presidential Malaria Initiatives (PMI) and the Global Fund, funded the implementation of a PV system in Rwanda to be hosted by the PTF. The Strengthening Pharmaceutical Systems (SPS) Program helped the PTF, the National Malaria Control Program (PNILP, also known as Programme National Intégré de lutte contre le Paludisme), and other in-country counterparts develop a national plan for PV beginning in FY07 in close collaboration with the US Centers for Disease Control and Prevention (CDC) and the MoH. During the COP08/MOP08 implementation period, Rwanda identified the establishment of an AE notification system as one of its highest priorities.

## OBJECTIVES

The main objective was to assist MoH in establishing and implementing a functional PV and MI system.

Specific objectives were to—

- Conduct a stakeholder’s awareness meeting for common understanding on the importance and need of medicine safety monitoring system in Rwanda
- Develop a legal framework and tools to support the PV and MI system
- Establish a national PV and MI center and initiate international collaboration with other medicine safety networks
- Build capacity of health care professionals in PV and MI activities
- Establish a national AE and medicine poor quality (MPQ) reporting system

## APPROACHES

With increased access to essential medicines comes a greater need to monitor and promote the safety and effectiveness of these medicines. Few developing countries, however, have the structures, systems, or resources in place to support medicine safety activities, and countries often lack unbiased, evidence-based information to help guide treatment decisions and promote rational (that is, safe, effective, and cost-effective) use of medicines. In addition, sustained budgetary support for PV and medicine safety activities is generally lacking.

Different approaches were used in the establishment and implementation of a PV and MI system at different levels with different stakeholders. These approaches included assessments, stakeholders meetings, training courses, workshops, field visits and continued remote follow up, elaboration and implementation of tools and guidelines, and assessment studies.

The SPS Program has developed a conceptual framework and operational approach to strengthen PV systems<sup>4</sup>.

### Stakeholders' Awareness

PV and medicine safety system initiation and implementation activities began in 2007 with the development of a concept paper by MoH/PTF with technical assistance from SPS. This PV conceptual framework and operational approach defined strategic approaches and proposed interventions necessary for the establishment of the PV system; this document has been produced for decision makers, especially the PTF in MoH and its collaborating partners (Rwanda Biomedical Center [RBC], WHO, CDC, SPS).

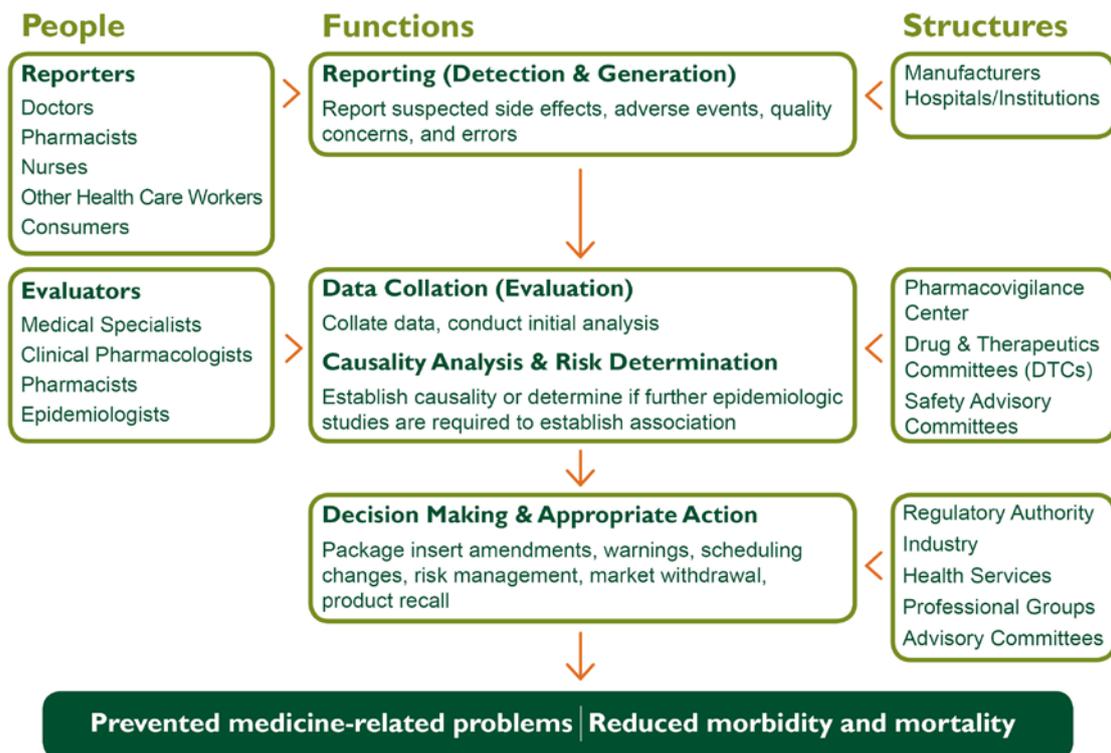
One of the recommendations in the concept paper was an awareness workshop on PV, attended by all stakeholders. The goal of the workshop was to provide stakeholders with a general understanding of the PV system and how to implement it in Rwanda. In this workshop, the strategic plan and the skeleton of the PV system scheme were adopted. The workshop was organized in May 2008 and was facilitated by a consultant from Agence du Medicament Madagascar; 30 people from PTF, WHO, the National University of Rwanda (NUR), PNILP, Programme Elargie de Vaccination (PEV), Programme National Intégré de lutte contre la Tuberculose (PNILT), Centre Hospitalo-Universitaire de Kigali (CHUK), Centre Hospitalo-Universitaire de Butare (CHUB), Hôpital National Psychiatrique-Ndera, La Rwandaise d'Assurance Maladie, Military Medicine Insurance, Laboratoire Pharmaceutique du Rwanda (LABOPHAR), Service de Consultation Psycho-Sociale (SCPS), Central d'Achats des Medicaments Essentiels du Rwanda (CAMERWA), Bureau des Formations Medicales Agrées du Rwanda (BUFMAR), CDC Atlanta, DELIVER, and SPS participated in the workshop.

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<sup>4</sup> *Concept Paper and Framework for Strengthening Pharmacovigilance Capacity in Resource-Limited Countries*; SPS Rwanda office, May 2008

## Legal Framework and Tools to Support PV and MI System

The figure below illustrates the components of a comprehensive, ongoing PV system. It describes functions such as monitoring, detecting, reporting, evaluating, and documenting medicine safety data. It proposed interventions and capturing information from reporters (prescribers, health care workers, other health care professionals, and consumers) and providing them educational feedback.



**Figure 1. The pharmacovigilance framework**

Once the information has been collected, evaluators, such as epidemiologists or pharmacologists, should analyze it to determine the AE's severity, probable causality, and preventability. A number of resources (e.g., Naranjo, French, and WHO algorithms) can be used for causality analysis.

Significant data must be communicated effectively to a structure or entity that has the authority to take appropriate action, whether at the facility, national, or even international levels. The entity may be a hospital's Drug and Therapeutics Committee (DTC), the national PV center, if one exists, or the WHO Program for International Drug Monitoring (Uppsala Monitoring Centre [UMC]). The final function in the framework is appropriate action.

In 2007, to maximize synergy among stakeholders, SPS supported MoH in identifying a country-level coordinating institution as the principal step in establishing a PV system. In 2008, all the stakeholders (PTF, Treatment and Research AIDS Center [TRAC] Plus Malaria and HIV Units, WHO, SPS, the United States Government/PMI, and CDC) agreed that PTF should lead and host the PV system, and, in 2010, the Minister of Health established the

National Pharmacovigilance and Medicine Information Center (NPMIC) to be temporarily hosted by PTF in its rational medicine use and MI desk.

In 2009, after stakeholders identified the leader of the PV system, PTF, in collaboration with SPS, conducted the midterm diagnosis assessment of PV in the country to identify strengths, weaknesses, and gaps to be addressed. The findings of this assessment orient further actions to implement the PV system in Rwanda.

### **Box 1. National Medicine Policy**

The goal of the drug policy is to improve the health of the Rwandese by making available and accessible, geographically and financially, effective drugs with assurance of their quality and rational and safe use by prescribers, dispensers, and patients.

**Policy objective number 5 is: To promote the rational use of medicines by both health providers and the community and to ensure patient safety through proactive PV and appropriate MI.**

### **Box 2. Guidelines for PV and MI in Rwanda**

The purpose of these guidelines is to help health workers with the continuous process of surveillance of safety and efficacy of pharmaceutical products used in clinical practice. These guidelines specifically address what, why, when, where, and how to report.

**These guidelines for the national PV system in Rwanda have been developed to complement and support the efforts of educating all health care workers on this important concept and to enhance our efforts in ensuring that safe, efficacious, and quality medicines are made available to all Rwandans.**

In 2009, PTF in collaboration with WHO and SPS developed the National Medicine Policy and its strategic plan for three years. This policy highlighted the importance of a functional PV system. The PV and MI guidelines were then developed and approved at the general senior management meeting in 2011.

Instructions on AE and MPQ reporting systems were disseminated to all hospitals and public health programs (PHPs) beginning in March 2011. District hospitals began sending in AE reports to PTF/NPMIC in May 2011.

## **Pharmacovigilance, Medicine Information, and the National Pharmacovigilance and Medicine Information Center**

The PV center is the cornerstone of the entire system, so it should be established early.

WHO recommends minimum requirements for any national PV system<sup>5</sup>—

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<sup>5</sup> WHO and GF. 2010. *Minimum Requirements for a Functional Pharmacovigilance System*; [http://www.who.int/medicines/areas/quality\\_safety/safety\\_efficacy/PV\\_Minimum\\_Requirements\\_2010\\_2.pdf](http://www.who.int/medicines/areas/quality_safety/safety_efficacy/PV_Minimum_Requirements_2010_2.pdf)

- A national PV centre with designated staff (at least one full time), stable basic funding, clear mandates, well-defined structures and roles, and collaboration with the WHO Programme for International Drug Monitoring
- A national spontaneous reporting system with a national individual case safety report form (i.e., an AE reporting form)
- A national database or system for collating and managing AE reports
- A national PV advisory committee to provide technical assistance on causality assessment, risk assessment, risk management, case investigation, and, where necessary, crisis management including crisis communication
- A clear communication strategy for routine and crises communication

WHO has identified the following functions for a national PV system—

- To promote PV in the country, notably, to collect and manage AE reports and reports of medication errors and suspected counterfeit/substandard drugs
- To collaborate and harmonize with existing AE collection activities within the country (e.g., national disease control program, MoH, etc.) as well as with international cohorts monitoring AEs in defined patients or populations
- To identify signals of medicine safety, i.e., unknown or poorly characterized AEs in relation to a medicine or a combination of medicines and/or its use
- To undertake assessment of risk and options for risk management
- To identify quality problems in medicines that result in AEs and to generally support the identification of medicine quality issues
- To provide effective communication on aspects related to medicine safety, including dispelling unfounded rumors of toxicity attributed to medicines and/or vaccines
- To apply resulting information from PV for the benefit of PHPs, individual patients, and national medicines policies and treatment guidelines
- To develop and maintain drug utilization information
- To identify issues associated with unregulated prescribing and dispensing of medicines

Because NPMIC coordinates national PV activities, these functions provide the basis of its terms of reference.

As mentioned earlier, MoH/PTF is hosting NPMIC until an official medicine regulatory authority is established. SPS has supported MoH/PTF by—

- Developing standard operating procedures for receiving and managing AE notifications and MI requests
- Developing tools to analyze the quality of notifications reported to NPMIC
- Developing the template of a “Dear Doctor” letter for sending feedback to those who report AEs and to provide MI to health care professionals
- Developing databases for management of AE and MPQ notifications and MI requests
- Providing access, as an associate member of UMC, to all tools developed by this center for PV and MI activities (Vigilflow, HINARI, Vigimed, CemFlow, ViGIBASE-DRL, etc.)
- Providing equipment needed to perform NPMIC activities (computers, camera, fax machine, etc.)
- Providing training of trainers to PTF staff on PV and MI activities (two people who work in the desk of MI, rational medicine use, and PV)

### **Developing Staff Capacity**

Medication safety is a concept that everyone can understand. The key is to make everyone from regulators to health care providers and consumers realize that they all have a role to play in helping to make medicines safer. PV topics should be part of the training curricula for health care professionals, both pre-service and in-service, and the NMRA should make sure that PV training materials are harmonized and implemented nationwide.

All health care providers should realize that reporting AEs and MPQ are part of their professional responsibility. Voluntary reporting requires health care providers to participate actively in a culture of safety reporting.

Barriers to reporting AEs and MPQ to the national PV center include lack of awareness by health care professionals and the public on the importance of AEs and MPQ reporting and the low percentage of staff trained in PV.

The NMRA and PV center can build awareness among different stakeholders through training and outreach. Outreach activities may include communicating with professional groups (e.g., professional organization newsletters), health care providers in-service (e.g., a lunch-time seminar), and the public (e.g., billboards about the dangers of counterfeit medicines). Involving the media is a good way to reach everyone who reads a newspaper or listens to the radio.<sup>6</sup>

In Rwanda, SPS has assisted MoH with building staff capacity through in-service and pre-service training. In 2008, MoH, WHO, and SPS sent four people from MoH/PTF, NUR, and

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<sup>6</sup> September 2009. *Supporting Pharmacovigilance in Developing Countries; The Systems Perspective*; MSH/SPS; [http://www.msh.org/projects/sps/SPS-Documents/upload/SPS\\_PV\\_Paper.pdf](http://www.msh.org/projects/sps/SPS-Documents/upload/SPS_PV_Paper.pdf)

SPS to Morocco to be trained in initiation of a PV system in resource-limited countries.<sup>7</sup> Since 2009, SPS has been assisting MoH in developing a PV training manual based on the national context and needs. These training materials have been adapted to all levels of the Rwanda health care system and are available both in French and English.<sup>8</sup>

In September 2009, a training of trainers was conducted to constitute a core team of 27 people; this training was facilitated by two international experts (one each from the University of Washington and SPS headquarters) and other national experts from SPS and MoH. This core team will assist PTF in rolling out the cascade training on PV. The core team was composed of individuals from PTF, Malaria Unit/TRAC Plus, TB Unit/TRAC Plus, TRAC, the Maternal and Child Health (MCH) Program, NUR, SCPS, the Rwanda National Laboratory, university teaching hospitals, King Faysal Hospital, Ndera Psychiatric Hospital, CAMERWA, BUFMAR, UNIPHARMA (private pharmacy), Population Services International, Association Rwandaise des Pharmaciens, Association des Medecins du Rwanda, and Association Nationale des Infirmiers du Rwanda.<sup>9</sup>

In October 2010, the training of trainers for 177 health care providers was conducted at all 41 district hospitals. Participants were DTC members (two medical doctors, one hospital pharmacist, one nurse, and one data manager). The training aimed to constitute a team of trainers for each hospital who are members of the DTC/PV subcommittee.<sup>10</sup>

After the training of trainers at district hospitals, MoH, with support from SPS and the malaria program, organized and supervised on-the-job-trainings in all district hospitals from February to May 2011. These one-day trainings aimed at capacitating health care providers and increasing their awareness on the reporting and management of AEs and MPQs to improve rational medicine use. In total, 2,396 participants from all 41 district hospitals received this training.<sup>11</sup>

In September 2011, the adapted training of trainers in PV for PHPs and referral hospitals was conducted; 22 people from referral hospitals and 18 people from PHPs attended the training. Participants from referral hospitals will constitute a core team of trainers and will be members of PV committees in their respective hospitals. Participants from PHPs will be the focal point of PV and train their colleagues.<sup>12</sup>

SPS assisted the NUR pharmacy department in integrating antimicrobial resistance, rational medicine use, and PV courses into the existing curricula, which began using the new modules in 2011.

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<sup>7</sup> Ingabire, Penelope and Anicet Nyawakira. Juin 2008. *Rapport de Mission: Formation en Pharmacovigilance a Rabat au Maroc*

<sup>8</sup> Nyawakira, Anicet, Buki Gege. February 2011. *Guide du Participant dans la formation des formateurs en pharmacovigilance*

<sup>9</sup> Mireille, Muhimpundu, Jude Nwokike, Patrick Gaparayi. November 2009. *Rwanda Central Training of Trainer on Pharmacovigilance*

<sup>10</sup> Nyawakira, Anicet, Ruzindaza Alexis, Ines Buki Gege, Murindahabi Monique. March 2011. *Training Report: Rwanda National Training of Trainer on Pharmacovigilance*

<sup>11</sup> Nyawakira, Anicet, Ines Buki Gege, Ruzindaza Alexis, Nathalie Ngabo. June 2011. *Report of On-the-Job Training on Adverse Event Reporting System at District Hospital Level*

<sup>12</sup> Nyawakira, Anicet, Ines Buki Gege, Ruzindaza Alexis, et al. October 2011. *Report of the Training of Trainers in Pharmacovigilance for Public Health Program and Referral Hospitals*

## National Adverse Event and Medicine Poor Quality Reporting System

In many countries, the reporting of AEs related to medicine is voluntary, but in an increasing number of countries, some legal reporting obligations on health care professionals have been established (although a penalty is not usually associated with failure to report). Little information is available regarding the advantages and disadvantages of such obligations. In addition, in many countries, it is mandatory for pharmaceutical companies to report suspected adverse drug reactions to the health authorities.<sup>13</sup>

Rwanda, as have many limited-resource countries, has chosen to use the spontaneous or voluntary reporting system for PV. Spontaneous reporting is the voluntary reporting by health care professionals of any suspicion of AEs related to medicines.

To provide a legal and clear framework for the AE and MPQ reporting system, SPS assisted PTF/MoH in developing the national guidelines for PV and MI that clearly describe the reporting system and the roles and responsibilities of each intervener, including marketing authorization holders.<sup>14</sup> To implement this reporting system, SPS assisted PTF in developing, printing, and disseminating reporting tools (table 1) to all district and referral hospitals and all PHPs.

**Table 1. Reporting Tools Disseminated**

| <b>Tools</b>  | <b>District hospitals (all)</b> | <b>Referral hospitals (all)</b> | <b>PHPs (all)</b> | <b>Total</b> |
|---|---------------------------------|---------------------------------|-------------------|--------------|
| Set of 50 AE notification forms (book) in English           | 0                               | 45                              | 33                | 78           |
| Set of 50 AE notification forms (book) in French            | 246                             | 55                              | 66                | 367          |
| Set of 50 MPQ notification forms (book) in English          | 0                               | 45                              | 33                | 78           |
| Set of 50 MPQ notification forms (book) in French           | 246                             | 55                              | 66                | 367          |
| Flyers with instructions on the reporting system (English)  | 1230                            | 200                             | 330               | 1760         |
| Posters with instructions on the reporting system (English) | 410                             | 60                              | 65                | 535          |
| Patient alert cards (in English)                            | 2460                            | 400                             | 400               | 3260         |
| Patient alert cards (in Kinyarwanda)                        | 0                               | 600                             | 600               | 1200         |

Each service in the district and referral hospitals received its own set (book) of notification forms for AEs and MPQs.

In the district hospitals, the reporting system is decentralized in a manner that is analogous to its PV unit, which consists of two physicians (medical doctors), one pharmacist, one nurse, and one data manager for management of reported data. Of the two physicians, one chairs this unit and reports all notifications to PTF/NPMIC.

The referral hospitals have not yet established their own PV units. During the training of trainers in October 2011, the PHPs agreed to use the existing reporting channels in the district

<sup>13</sup> Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring. 2000. *Safety Monitoring of Medicinal Product; Guidelines for Setting Up and Running a Pharmacovigilance Centre*. <http://apps.who.int/medicinedocs/en/d/Jh2934e/>

<sup>14</sup> 2011. *Guidelines for Pharmacovigilance and Medicine Information System in Rwanda*, Rwanda Ministry of Health

hospitals because their staffs are working in the existing health facilities (district hospitals and health centers). For special cases where the report shall be submitted directly to their PHP headquarter, a focal point have been identified to work closely with the NPMIC and for information exchange.<sup>15</sup>

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<sup>15</sup> Nyawakira, Anicet, Ruzindaza Alexis, Busingo Bel'Ami, et al. October 2011. *Report of Training of Trainers in Pharmacovigilance for Referral Hospitals and Public Health Programs* (in process)

## RESULTS

### Stakeholders Awareness

To involve all stakeholders in PV implementation, a workshop was conducted with the following results—

- An action plan for 2008-2009 for establishment of a PV system in Rwanda
- A first draft of an AE notification form
- The first draft of an AE reporting scheme
- The core team to implement recommendations from this workshop. Its members were from PTF, PEV, PNILP, Association des médecins du Rwanda, WHO, NUR, SCPS, PSMI, and SPS
- Recommendations to—
  - Finalize the AE notification form
  - Develop the PV and MI guidelines
  - Develop the PV training curricula and modules for in-service and pre-service health care professionals
  - Organize cascade trainings to enrich all health care professionals

### Legal Framework and Tools to Support Pharmacovigilance and Medicine Information System

In 2009, a diagnosis assessment of the PV system was conducted by PTF/MoH in collaboration with SPS. The assessment was conducted with the PV indicator-based assessment tool to provide feasible recommendations that reflect local realities. Findings of this assessment enable MoH to better orient actions for implementation of the PV and MI system. This assessment was conducted at PTF, PHPs (PNILP, TRAC, PNILT), and the MoH/MCH Program) and hospitals (Kanombe Military, Rwinkwavu, CHUB, Nyanza District, King Faysal, CHUK, Gisenyi District, and Ruhengeri District<sup>16</sup>).

### Findings of this Assessment

#### Strengths

Drafts of the following documents were available—

- National Medicine Policy (PV-related policy being part of this one)

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<sup>16</sup> Nyawakira, Anicet, Alex Ruzindaza, Felix Hitayezu, Denise Murekatete, Mohan Joshi, and Jude Nwokike. Out briefing June 2009. *Assessment of Pharmacovigilance and Medicine Safety System in Rwanda*

- Food and Medicine Act
- Guidelines for Medicines Safety Surveillance in Rwanda
- Notification system (including the AE form)
- In-service training curriculum on PV, rational medicine use, and AMR
- Pharmacy antiretroviral therapy register, which is AE data collected longitudinally

The following activities have been initiated—

- Proposal for a NPMIC
- Active surveillance studies initiated in PHPs
- Increase the number of DTCs, several of which were already addressing PV-related issues
- Actions taken locally based on six WHO drug alerts (e.g., market withdrawal of Viracept)

***Constraints (June 2009)***

| <b>Constraints</b>  | <b>Impact</b>   |
|---|---|
| No approved medicine policy   | Addressing medicine safety is not viewed as obligatory                      |
| Food and Medicine Act and related regulations not in place                        | Enforcement not possible; marketing authorization holders do not report AEs |
| PV center, guidelines, and notification system not approved                       | PV activities cannot be operationalized                                     |
| Lack of in-service and pre-service training on PV                                 | Health care providers have limited skills to monitor AEs                    |
| Lack of medicine safety information services                                      | Health care providers and patients are not informed                         |
| No organized system to improve or monitor patient safety relating to medicine use | Incidence of AEs cannot be used to prevent future occurrences               |
| Discrete and uncoordinated PV activities  | Inefficient use of resources  |
| PHPs do not consistently track and consolidate AE and treatment failure data      | No data to inform guidelines decision (e.g., changing D4T)                  |
| Concerns about drug quality   | Patient loss of confidence in the health delivery system                    |

***Opportunities (June 2009)***

- MoH and other stakeholders are highly committed to the issue of PV in Rwanda
- National PV team exists to oversee and guide implementation
- NPMIC has been temporarily established at the PTF/rational medicine use and PV desk
- PV-related trainings, DTC involvement in PV activities, and medicine use surveys are considered highly relevant by key informants
- Some facilities have risk management strategies for high-alert medicines

- Some PHPs are already tracking AEs in patient treatment files (TRAC Plus: HIV and malaria divisions)
- DTCs are already envisioned as “decentralized units” for NPMIC
- Besides MoH, other bodies, such as PEPFAR, PMI, the Global Fund, CDC, USAID, and WHO, are leveraging funding
- Drug quality study for artemisinin-based combination therapy (ACT) is currently being conducted in collaboration with the University of Liverpool
- Active surveillance of ACT use in pregnancy has been set up
- Plan underway for revision of NUR’s pharmacy curriculum, thus providing opportunity for inserting PV topics

### ***Recommendations for Immediate Action***

- Approve national medicine policy, legal provisions, and guidelines
- Establish NPMIC as early as possible
- Focus on active surveillance—
  - ACT in pregnancy
  - Safety monitoring within the community health worker program
  - AE data in HIV/AIDS program to inform guideline revision
- Strengthen the national PV committee to ensure better coordination of PV activities
- Strengthen DTCs to monitor medicine safety and treatment failure
- Develop system for tracking suspected treatment failure
- Establish a multidisciplinary medicines safety committee to assist NPMIC on technical matters
- Prepare an initial core group of in-country experts and trainers by providing a training of trainers (TOT)
- Initiate a cascade of trainings led by the TOT-exposed trainers
- Work with NUR to adequately address PV topics in the pharmacy curriculum
- Implement locally suitable strategies to stimulate reporting on drug-related AEs
- From early on, emphasize medicines safety by putting in place risk minimization systems, protocols, and standard operating procedures

- Catalyze effective communications and information flow between PTF/NPMIC, DTCs, health facilities, community health workers, the private sector, patients, and consumers
- Integrate a monitoring and supervision plan

To support the establishment of a functional PV system, PTF, with assistance from SPS, has developed guidelines for a PV and MI system. These guidelines contain the scheme of the system and the roles and responsibilities of each intervener in the scheme.

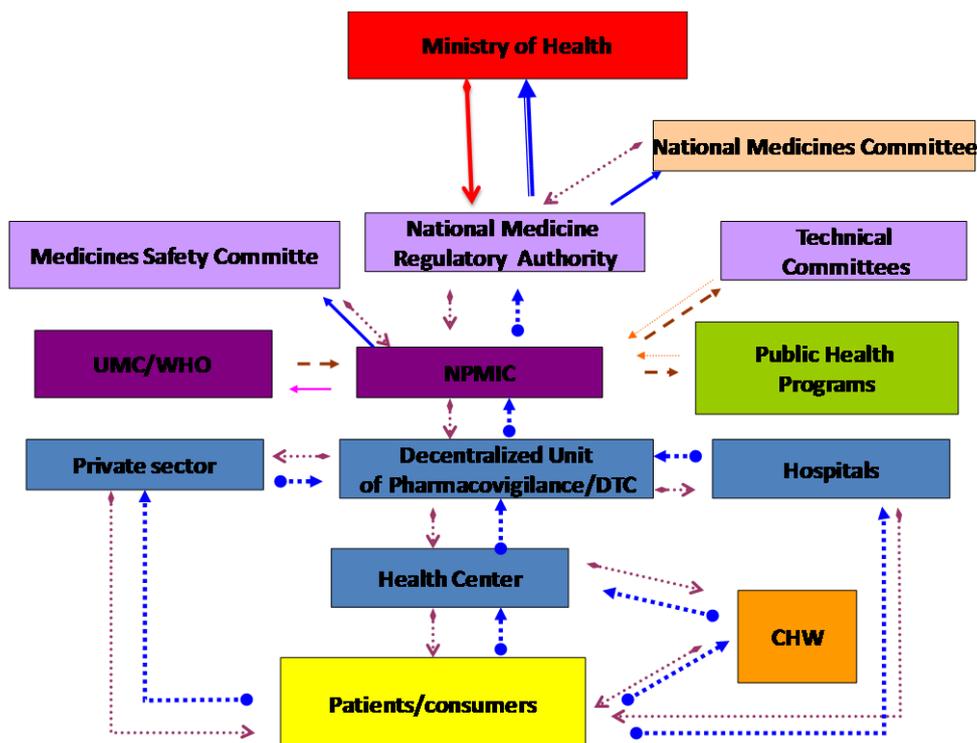


Figure 2. National PV and MI system (adopted by MoH in February 2011)

### Developing Staff Capacity

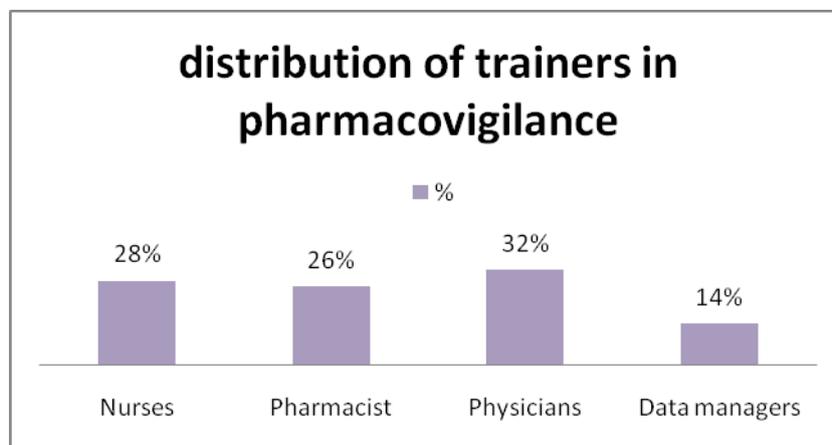
Trainings were among the strategies identified for building staff capacity. These trainings have been organized to reach the greatest number of health care providers.

With support from SPS, the team trained in Morocco developed the PV training curricula.<sup>17</sup> In April 2009, during a workshop, a team composed of 19 people from PTF, TRAC Plus (HIV, malaria, and TB units), NUR's pharmacy department, CHUK (referral hospital), CAMERWA, JSI DELIVER, and SPS developed the PV training module.<sup>18</sup> This module has been adapted to all health system levels for its use in cascade trainings.

<sup>17</sup> Nwokike, Jude. February 2009. *Establishing Medicine Safety System in Rwanda Trip Report: 29–31 October, 2008*

<sup>18</sup> Aline, Mukerabirori and Nyawakira, Anicet. May 2009. *Report of the Workshop on the Development of Training Module of Pharmacovigilance*

These cascade trainings started with a TOT of a national core team of trainers that will assist PTF in rolling out cascade trainings. A total of 27 health care professionals from different institutions were trained. **As result of this training, 72 percent of TOT participants have greatly contributed to training multidisciplinary health providers from district and referral hospitals and PHPs and have supervised on-the-job trainings in district hospitals.**



**Figure 3. Distribution of trainers (from PHPs and hospitals) according to their professions**

### **TOTs for PHPs, Referral Hospitals, and District Hospitals**

The objectives of these TOTs were to capacitate these institutions with skilled staff who can train their colleagues, to constitute a PV unit in hospitals, and to provide a focal point of PV activities in PHPs.

- The staff trained in the TOTs constituted the PV unit in their respective district hospitals (one pharmacist, two physicians, one nurse, and one data manager)
- All 41 district hospitals have conducted on-the-job training for their staff; the average number of people trained per hospital was 60. The total number of health care providers trained in all district hospitals was 2,396.



Figure 4. Number of people in on-the-job training in each district hospital

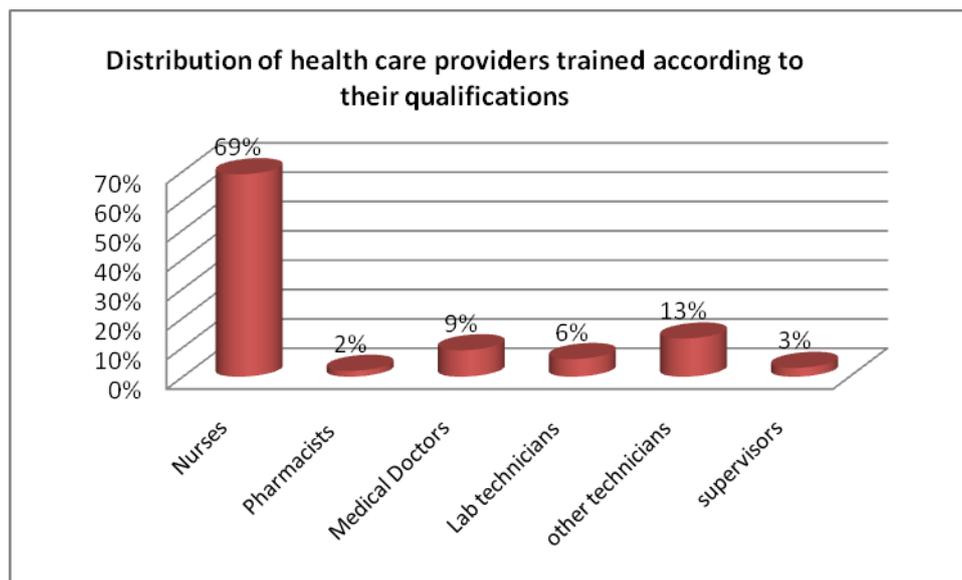


Figure 5. Distribution of health care providers trained in district hospitals according to their professions

- In referral hospitals, 27 staff were trained as trainers in PV (CHUK: 5; CHUB: 11; King Faysal: 8; Ndera Psychiatric Hospital: 3). Ndera Hospital organized on-the-job training for 100 staff; CHUK, CHUB, and King Faysal are planning to do the same.
- PHPs have already initiated PV activities (adverse events following immunization [AEFIs] for PEV; Sentinel Site for Malaria Division, ART sites with *fiche de visite a la Pharmacie* for HIV division, etc.), but their activities are not coordinated with the

national PV system and are not well used to inform decision making. The purpose of the TOTs was to constitute a pool of trainers and to discuss the harmonized PV system. As the result of this training, focal points for PV activities were identified in each PHP—

- MCH/PEV: officer in charge of PEV surveillance
  - RBC/TB division: TB supervisor
  - RBC/HIV division: HIV/AIDS commodities supply chain analyst
  - RBC/malaria division: drug logistic officer
- The work done in PEV, HIV, TB, and malaria programs in existing health facilities and the national AE reporting system can be applied to products managed by these programs—
    - In each hospital, the PEV supervisor normally reports only serious AEFIs to PEV. The supervisor can use NPMIC notification forms to report any AEs related to vaccines to the PV unit in the hospital; the report then follows the normal channels of AE reporting. For serious AEFIs reported to PEV, the PV focal point in PEV informs NPMIC.
    - HIV, TB, and malaria programs will use the existing AE reporting system and NPMIC will share the information with the concerned program.
  - Since 2008, SPS has been assisting NUR’s pharmacy department to integrate a PV component in its curriculum; as of now, 246 finalist students have received this course and some of them have conducted operational research on PV (box 3).

**Box 3. Impact of Introduction of PV in NUR**

Some senior pharmacy students have begun to conduct safety surveillance, especially on ART.

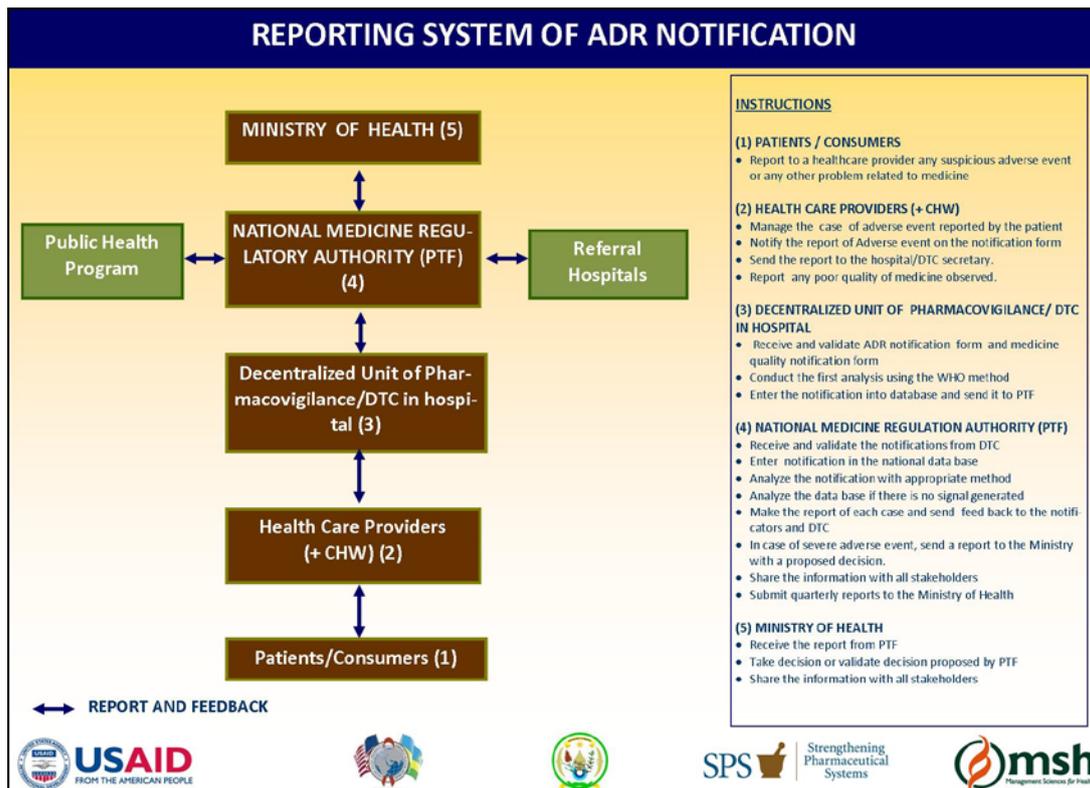
In 2010, a pharmacy student conducted an assessment of ART to determine the most probable causes of AE in people living with HIV/AIDS under ART; among the results, he found that zidovudine is the major cause of nephrotoxicity.

In 2011, another student conducted a case series study on patients under the first regimen based on tenofovir (TDF). The results showed that 88 percent of AEs appeared during the 15 days after taking the TDF-based regimen; the most common AEs are digestive disorders followed by central nervous system disorders. The combination of TDF and efavirenz seems to be a risk factor for these AEs.

## Supportive Tools for AE and MPQ Reporting

The cascade trainings of health care providers were supported by tools to strengthen the reporting system.

The following tools have been disseminated to PHP and district and referral hospitals—training materials, instructions on the reporting system, notifications tools, and patient alert cards.



**Figure 6. Instructions on AE and MPQ reporting system were disseminated as flyers and posters to all hospitals and PHPs in March 2011**

These tools enabled health care providers report 23 AEs and 10 MPQs to NPMIC during on-the-job trainings (box 4).

#### **Box 4. AE and MPQ Notifications Reported to NPMIC/PTF as of September 2011**

##### **AEs sent to NPMIC**

Notifications of AEs were sent to NPMIC from February 2011 (starting with 2 notifications) until September 2011, for a total of 23 notifications. The most notifications were sent in April (5), June (6), and August (4). District hospitals that have reported more AEs are Nyamata (6), Remera-Rukoma (7), and Kibilizi (3); at Kibilizi, all 3 notifications were related to self-intoxication for the purpose of suicide.

The medicines that are most suspected to cause AEs are bupivacaine (5 notifications), nevirapine (4), tenofovir (2), and co-trimoxazole (2); the diseases most associated with these reports are HIV positives, 39 percent; diabetes, 4.3 percent; epilepsy, 4.3 percent; hypertension and cardiac diseases, 9 percent.

##### **MPQs sent to NPMIC**

MPQs were sent to NPMIC from April 2011 until September 2011, for a total of 10 notifications. The period with the most notifications was July with 3. District hospitals that have reported MPQs are Nemba (5) and Nyamata (3). The medicines which are most reported are furosemide (2), nitrofurantoin (2), clomipramine (2), obstetrics gloves (1), tenofovir (1), valproic acid (1), and dexamethasone (1).

Furosemide's poor qualities were detected after therapeutic failures were noticed. Most MPQs are detected by health care providers (9/10) but patients can also detect them (1/10).

#### **Illustration of the Contribution of PV to Patient Safety**

With the initiation of PV activities and awareness of all stakeholders, some specific activities related to medicine safety have been conducted and have informed decision making.

##### **Case of Mortin (Co-trimoxazole 480 mg)**

In July 2008, TRAC Plus noticed that several HIV-infected patients receiving co-trimoxazole had developed sudden symptoms of skin rash, pruritis, and/or abdominal pain. Affected patients included pre-ART patients as well as those on ART. Initial efforts focused on case finding in the Kigali area; by July 28, 2008, TRAC Plus, in collaboration with SPS and PTF, had identified and characterized 28 suspected cases reported from health facilities.

Following the initial characterization of these 28 suspected cases and concern of possible Mortin exposure, distribution of Mortin was suspended at the end of July; samples of the product were sent to South Africa for laboratory analysis, an assessment of the drug manufacturing process was completed, and an epidemiologic investigation was conducted.

The objectives of the investigation were—

1. To determine whether symptoms of rash/pruritis and abdominal pain were occurring at higher rates than expected
2. To identify risk factors for the rash/pruritis and abdominal pain syndrome

The investigation was conducted with assistance from the African Field Epidemiology Network (AFENET) and CDC through different methods, such as clinic site visits, determination of case rates, statistical analysis, rates of symptoms, and laboratory analysis of Mortin, and to enhance the quality and completeness of data collected.

In conclusion, a true increase in the overall incidence of pruritis/rash or abdominal pain among HIV-infected patients in recent months did not occur. The small percentage of patients

exposed to Mortin at the time of their presentation, along with the unremarkable laboratory analysis of Mortin, did not provide sufficient evidence to implicate Mortin as the causative agent of the described symptoms.

In light of the findings from this epidemiologic investigation and the laboratory analysis, further investigation of an association of Mortin with the reported symptoms is not warranted at this time. Given the lack of evidence implicating Mortin and the benign clinical course of patients presenting with pruritis/rash, cautious redistribution of Mortin with close monitoring was recommended.

### ***Case of APO-TriAvir***

Since 2008, Rwanda has benefited from trade-related aspects of intellectual property rights (TRIPS) agreements to procure APO-TriAvir generic ARV from the company APOTEX.

In March 2009, patients reported the instant disintegration of Apo-TriAvir tablets when swallowed and a consequent abnormal bitterness compared to another formulation of the ARV generic (Duovir-N) prescribed and dispensed before the introduction of Apo-TriAvir.

A survey was conducted among patients on APO-TriAvir to confirm this bitterness, and laboratory analyses of the quick disintegration were performed at the NUR quality control laboratory of medicines. Findings of the survey and the quality control results confirmed the abnormal bitterness of Apo-TriAvir (72 percent) and the quick disintegration of the tablets once swallowed. Tablets were in conformity to the European Pharmacopoeia before the stability tests. Upon storage at 33, 75, and 97 percent relative humidity, the tablets lost their hardness and changed color.

The abnormal bitterness could cause poor adherence to ART among patients treated with the medicine.

Disintegration time was drastically reduced in a relatively high humidity from 9 min 12 sec ( $\pm 19.8$  sec) to 7 min 20sec ( $\pm 1.1$  sec) and 1 min 50 sec ( $\pm 0.0$  sec).

This survey was conducted by PTF/NPMIC in collaboration with TRAC Plus and NUR with assistance from SPS. Recommendations were given to MoH for a decision—stopping procurement from this company until the formulation is changed.

The pictures below shows two examples of notification reports sent to NPMIC from district hospitals.



## CHALLENGES

The implementation of a PV system in Rwanda has met different challenges. The main challenge is the lack of regulatory authority in which the PV center activities shall be performed. Other connected challenges are related to—

- Barriers to reporting AEs and MPQs to the NMRA or the national PV center which include—
  - Lack of understanding by health care staff on the importance of AE reporting
  - Within the PTF and PHPs, PV is not emphasized enough
  - Lack of technical and financial resources at the facility to collect and analyze data
  - Weak organizational structure at the PTF, leading to lack of regular follow-up and supervision of health facilities
- Management of MPQ reports—MPQ is reported to PTF/NPMIC but the management of these reports is not yet done. This management needs the coordination of many other interveners including medicines procurement and distribution institutions and the Rwanda Bureau of Standards, etc.
- Lack of a medicine registration system to identify medicines available in Rwanda and those who are the marketing authorization holders
- Lack of adequate human resources and infrastructure for NPMIC—
  - To be fully functional, a national PV and MI center needs at least 3 people—one in charge of PV, one in charge of MI, and one technical contact for the UMC and other PV centers (it could be also a data manager)
  - SPS had provided NPMIC with the necessary equipment to better perform assigned activities, but NPMIC still needs sufficient space for routine activities, a call center, a filing room, an adequate filing system, etc.
- Absence of a National Medicine Safety Committee; a multidisciplinary advisory committee is desirable to support the PV centre with regard to the quality of data collection and assessment, the interpretation of the data, and the publication of information
- Lack of a clear communication strategy; providing high-quality information to health care professionals is a basic task of a PV centre and a major instrument in the stimulation of reporting. For this purpose and for the assessment of case reports, the center should have access to a comprehensive and up-to-date literature information database. In urgent cases of sufficient importance, Dear Doctor letters may be used. Until now, PTF/NPMIC did not have a clear communication strategy, which impacts on the implementation of the PV and MI system and the dissemination of decisions taken.

## CONCLUSION AND RECOMMENDATIONS

From 2007 until now, about 80 percent of required activities to initiate a PV and MI system have been achieved—structures and systems are in place, immediate intervener staff have been trained, and tools to report and manage AEs, MPQs, and MI are available and disseminated country wide. However, there is still a lot to do in the implementation. MI and MPQ reports' management needs to be improved, and NPMIC staff needs to be more capacitated to fully perform their duties.

To strengthen and establish a fully function system, the following are recommended—

- The reporting system needs to be expanded to all levels. MPQ and AE reporting systems are established at district hospitals. The PV and MI system needs to be integrated in the private sector and district pharmacies and the systems expanded to health center and community levels.
- NPMIC staff still needs clear roles and defined responsibilities. With the increase in the number of MPQ reports, AE reports, and MI requests expected at NPMIC, 2 additional staff are needed per WHO/UMC requirements: 1 coordinator in charge of PV activities, 1 staff in charge of MI, and 1 technical staff in-charge of communication.
- Many efforts have been invested to capacitate NPMIC staff to be able to initiate the PV and MI system and train health care providers on the reporting system; now, staff must be capacitated on causality assessment and epidemiological investigations related to medicine safety.
- NPMIC needs enough space for filing and managing the notification reports and also space for a documentation center to provide easy access to scientific information.
- A toll-free line (call center) should be implemented so the public and health professionals can request and access MI.
- A clear management mechanism for MPQ notifications must be designed.
- A clear communication strategy for PV and MI must be designed.
- A National Medicine Safety Committee must be put in place and its members trained, as well as the PTF/NPMIC staff, on causality assessment methods.

# ANNEX 1. AE NOTIFICATION FORMS (FRENCH AND ENGLISH)

**REPUBLIQUE DU RWANDA**  
  
**MINISTRE DE LA SANTE**

**Centre National de Pharmacovigilance et d'Information Pharmaceutique**  
**Fiche De Notification Des Evénements Indésirables**  
**A. Informations sur le patient**

|   |  |   |  |                |
|---|--|---|--|----------------|
| Adresse du patient  |  | Village:  | Secteur  |                |
|   |  | Cellule:  | District   |                |
| Autres adresses disponibles (téléphone/email...)  |  |   |  |                |
| N° d'identification du patient (N° fiche, consultations, etc.)  |  | Date naissance / ou Age                             | Poids (Kg)   | Taille (en cm) |
| Grossesse: <input type="checkbox"/> Oui <input type="checkbox"/> Non <input type="checkbox"/> Pas connu   |  | Si oui, Age gestationnel (en Semaine d'aménorrhée): | La femme enceinte est: <input type="checkbox"/> Primipare <input type="checkbox"/> Multipare |                |
| Le patient a-t-il une (des) maladie(s) chronique(s)? <input type="checkbox"/> Oui <input type="checkbox"/> Non <input type="checkbox"/> Pas connu   |  | 1   |  |                |
| Si Oui, lesquelles (compléter ci devant et en bas si nécessaire)  |  | 2   |  |                |
| 3   |  | 4   |  |                |
| Facteurs de risque associés (encadrer): tabac, alcool, l'historique clinique du patient, antécédent familial, les allergies, ...). Décrivez les autres facteurs associés si il y en a (ajouter une feuille supplémentaire si nécessaire): |  |   |  |                |

**B. Informations sur les événements indésirables susceptibles d'être dus au produit de santé**

Description de l'événement indésirable:

|   |   |  |
|---|---|--|
| Date et heure de début de réaction  | Début d'apparition de la réaction (en heures/jours) | Date et heure d'arrêt de réaction si applicable      |
| INFORMATION SUR LE PRODUIT DE SANTÉ SUSPECTÉ  |   |  |
| Nom du produit en DCI ou nom vernaculaire, forme et dosage:   |   | Nom de la spécialité/fabricant:                      |
| Date de fabrication:  | Date d'expiration:                                  | No de Lot/batch N°:                                  |
| Le produit est-il prescrit? <input type="checkbox"/> Oui <input type="checkbox"/> Non   |   |  |
| Four quelle raison le produit a-t-il été prescrit (indication):   |   |  |
| Dose Prescrite:   | Fréquence prescrite:                                | Durée du traitement                                  |
| Dose prise:   | Fréquence de prise par jour:                        |  |
| Date/ si possible heure de début de prise du produit:   |   | Date/ si possible heure d'arrêt de prise du produit: |
| Voie d'administration utilisée par le patient:  |   | Détails sur la dilution (si applicable):             |
| Où est-ce que le patient s'est-il procuré le produit? est-ce la première fois que le produit suspecté est pris? <input type="checkbox"/> Oui <input type="checkbox"/> Non Si Non l'a-t-il déjà apparu auparavant? <input type="checkbox"/> Oui <input type="checkbox"/> Non |   |  |
| Y a-t-il eu des mesures prises pour gérer/traiter l'événement indésirable? <input type="checkbox"/> Oui <input type="checkbox"/> Non  |   |  |
| Si oui, spécifier les mesures prises pour gérer l'effet indésirable observé (traitement médicamenteux, vitamines, arrêt du traitement, conseils, changement de traitement...)   |   |  |

**C. Autres produits utilisés** Y a-t-il d'autres produits utilisés par le patient?  Oui  Non Si oui compléter le tableau ci-dessous  
*(Ajouter une feuille supplémentaire si nécessaire)*

| Nom du produit  | 1 | 2 | 3 |
|---|---|---|---|
| Indication  |   |   |   |
| Posologie utilisée par le patient                       |   |   |   |
| Voie d'administration telle que utilisée par le patient |   |   |   |
| Date (et si possible heures) de début                   |   |   |   |
| Date (et si possible heures) d'arrêt                    |   |   |   |

**D. Informations sur le notificateur**

|                  |                                      |
|------------------|--------------------------------------|
| Nom et Prénom *  | Lieu de travail / FOSA*              |
| Qualification ** | Téléphone de lieu de travail/ FOSA * |
| Adresse postale: | Date*                                |
| Email:           |                                      |

**Votre appui au système de pharmacovigilance est grandement apprécié.**  
 La soumission d'une plainte n'implique en aucun cas que le médicament ou le prestataire des soins ont causé ou contribué à l'apparition de cet événement. Toute information est strictement confidentielle et le personnel du système de pharmacovigilance ne mettra jamais en public l'identité du rapporteur en réponse à une quelconque demande publique. L'information que vous fournissez contribuera dans l'amélioration de la qualité des soins et la sécurité d'utilisation du médicament. Une fois remplie, veuillez envoyer cette fiche au Centre National de Pharmacovigilance ou au sous comité de Pharmacovigilance dans l'hôpital qui vous en a fourni.

**REPUBLIC OF RWANDA**  
  
**MINISTRY OF HEALTH**

**National Center for Pharmacovigilance and Medicine Information**  
**Adverse Event Notification Form**  
**A. Patient Information**

|  |  |  |             |   |
|--|--|--|-------------|---|
| Patient address  |  | Village:   | Sector      |   |
|  |  | Cell:  | District    |   |
| Other available address (cell phone/email...)  |  |  |             |   |
| No of patient file/dossier   |  | Date of birth / or age   | weight (Kg) | height (cm)   |
| Sex <input type="checkbox"/> F <input type="checkbox"/> M  |  |  |             |   |
| Pregnancy? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know  |  | If yes, precise the age of the pregnancy (menstruation weeks): |             | The program was taken in: <input type="checkbox"/> primiparous <input type="checkbox"/> multiparous |
| The patient has any chronic diseases? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know   |  | 1  |             |   |
| If yes, precise these diseases in the follow place (you can add another paper if needed)   |  | 2  |             |   |
| 3  |  | 4  |             |   |
| Associate risk factors (tick on the following ones): tobacco use, alcohol use, clinical background, familial history, allergies ... Describe any other risk factors if applicable (you can add a new paper on this if needed): |  |  |             |   |

**B. Information on adverse events related to suspected health product**

Description of the adverse event:

|  |   |   |
|--|---|---|
| Date and time of when adverse reaction started   | Time to onset of reaction (hours/days)    | Date and time when reaction stopped           |
| INFORMATION ON THE SUSPECTED HEALTH PRODUCT  |   |   |
| Name of the product in DNS (or local name) (if plant medicine), form and dosage:   |   | Brand name/manufacturer:                      |
| Manufacturer date:   | Expired date:                             | Batch No.:                                    |
| The product was prescribed? <input type="checkbox"/> Yes <input type="checkbox"/> No   |   |   |
| If the product was prescribed, indicate the reason why:  |   |   |
| Dosage Prescribed:   | Frequency of daily dosing prescribed:     | Treatment duration                            |
| Dosage taken:  | Frequency of daily dosing use by patient: |   |
| Date/ time of the starting taking the suspected product:   |   | Date/ time the suspected product was stopped: |
| The administration route used by patient:  |   | Details on the dilution (if applicable):      |
| Where patient has been provided with the product? Is it the first time the patient has taken the suspected product? If no, did he experiment the same reactions the last time he take this product? <input type="checkbox"/> Yes <input type="checkbox"/> No |   |   |
| Is there any measure taken to manage / treat this adverse event? <input type="checkbox"/> Yes <input type="checkbox"/> No  |   |   |
| If yes, indicate these measures (pharmaco therapy, refer the patient, stop the treatment, change the treatment, etc...)  |   |   |

**C. Other product used: Is there any other product used by patient?  Yes  No If yes, fill the table below**  
*(Add a new page if needed)*

| Name of the Product                                    | 1 | 2 | 3 |
|--|---|---|---|
| Indication   |   |   |   |
| Dosage used by patient                                 |   |   |   |
| Administration route used by patient                   |   |   |   |
| Date (time if applicable) of start to take the product |   |   |   |
| Date (time if applicable) of stop to take the product  |   |   |   |

**D. Information on the notifiator**

|                  |   |
|------------------|---|
| Name * and Email | Place of Work/ Health Facility*                 |
| Qualification ** | Phone number/ yours or for the Health Facility* |
| PO box:          | Date*   |

**Your support in this pharmacovigilance program is appreciated.**  
 Submission of a complaint does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to an event. All information is held in strict confidence and programme staff is not expected to and will not disclose reporter's identity in response to any public request. Information supplied by you will contribute to the improvement of medicine safety and therapy in Rwanda. Once completed please send to: National Pharmacovigilance and Medicine Information Center or to the Drug and Therapeutic Committee (DTC) of the hospital which is near of you.

# ANNEX 2. MPQ NOTIFICATION FORM (FRENCH AND ENGLISH)

REPUBLIQUE DU RWANDA



MINISTÈRE DE LA SANTÉ

## Centre National De Pharmacovigilance et D'information Pharmaceutique

Fiche De Notification Sur La Qualité Des Médicaments

**A. Informations sur le rapporteur**

Veuillez cocher dans la case suivante votre statut:  1. patient  2. Professionnel de la santé  3. autres (spécifier):

Adresse du rapporteur: Village: \_\_\_\_\_ Secteur: \_\_\_\_\_  
 Cellule: \_\_\_\_\_ District: \_\_\_\_\_

Autres adresses disponibles (téléphone/ email, lieu de travail etc...): \_\_\_\_\_

Le rapporteur a-t-il pris le médicament?  Oui  Non

**B. Identification du produit**

Nom de spécialité: \_\_\_\_\_ Non générique:  Oui  Non  
 Numéro de lot: \_\_\_\_\_ Date de fabrication: \_\_\_\_\_ Date de péremption: \_\_\_\_\_

Date d'acquisition/achat: \_\_\_\_\_ Nom du producteur et son pays d'origine: \_\_\_\_\_

Nom du fournisseur (nom de l'hôpital, pharmacie, etc...): \_\_\_\_\_ Adresse du distributeur: \_\_\_\_\_

**Formulation du Produit (cocher sur le cas échéant)**

| Formulation du Produit (cocher sur le cas échéant)                   | Plaintes à l'encontre Du Produit (cocher sur le cas échéant) |
|--|--|
| <input type="checkbox"/> Comprimé Oral/ Capsule                      | <input type="checkbox"/> Changement de couleur               |
| <input type="checkbox"/> Suspension buvable                          | <input type="checkbox"/> Agglomération/ grumeaux             |
| <input type="checkbox"/> Sirop                                       | <input type="checkbox"/> Vaseux (formes solides)             |
| <input type="checkbox"/> Injection                                   | <input type="checkbox"/> Changement d'odeur                  |
| <input type="checkbox"/> Poudre pour reconstitution d'une suspension | <input type="checkbox"/> Séparation des composants           |
| <input type="checkbox"/> Poudre pour reconstitution d'une injection  | <input type="checkbox"/> Effritement                         |
| <input type="checkbox"/> Coques nasale                               | <input type="checkbox"/> Mauvaise étiquette                  |
| <input type="checkbox"/> Goutte Oculaire                             | <input type="checkbox"/> Conditionnement incomplet           |
| <input type="checkbox"/> Solution adhésive                           | <input type="checkbox"/> Autres: _____                       |
| <input type="checkbox"/> Crème/ gel/ pommade                         |  |
| <input type="checkbox"/> Autres: _____                               |  |

Descrivez en détail votre plainte: \_\_\_\_\_

**C. Condition de stockage**

Le produit requiert-il une réfrigération?  Oui  Non Autres: détailler \_\_\_\_\_

Le produit est-il disponible à la Formulation Sanitaire?  Oui  Non

Le produit est-il retourné par le patient après qu'il ait été dispensé?  Oui  Non

La conservation/ stockage du produit est-elle convenue aux directives du producteur ou du MS/SENE?  Oui  Non

**D. Circonstance et moment de détection du problème de la qualité du produit**

A quel moment avez-vous constaté que le médicament avait un problème de qualité?

| A quel moment avez-vous constaté que le médicament avait un problème de qualité?         | Dans quelle circonstance avez-vous constaté ce problème de qualité  |
|--|---|
| <input type="checkbox"/> Avant la prise du médicament                                    | <input type="checkbox"/> A la suite d'une complication de l'état d'un patient/ami(e)/ parent après la prise du médicament |
| <input type="checkbox"/> Au cours de la prise du médicament                              | <input type="checkbox"/> A la suite d'une hospitalisation du patient après la prise du médicament                         |
| <input type="checkbox"/> A la fin de la prise du médicament                              | <input type="checkbox"/> A la suite d'une plainte du patient  |
| <input type="checkbox"/> Quand un proche (parent ou ami/ e) a pris ce médicament         | <input type="checkbox"/> A la suite d'un constat personnel dans le lieu de stockage du médicament                         |
| <input type="checkbox"/> Quand un patient que vous traitez/ soignez a pris ce médicament |   |
| <input type="checkbox"/> Autres: spécifiez: _____  |   |

Si vous ou quelqu'un d'autre avez déjà pris ce médicament avez-vous constaté des symptômes/signes cliniques suspects?  Oui  Non

Si oui veuillez remplir la fiche de notification des événements indésirables.

Votre appui au système de pharmacovigilance est grandement apprécié. La soumission d'une plainte n'implique en aucun cas que le médicament ou le prestataire des soins ont causé ou contribué à l'apparition de cet événement. Toute information est strictement confidentielle et le personnel du système de pharmacovigilance ne mettra jamais en public l'identité du rapporteur ou réponse à une question que demandez publiquement. L'information que vous fournissez contribuera dans l'amélioration de la qualité des soins et la sécurité d'utilisation du médicament. Un fois remplie, veuillez envoyer cette fiche au Centre National de Pharmacovigilance ou au sous comité de Pharmacovigilance dans l'hôpital qui vous est proche.

REPUBLIC OF RWANDA



MINISTRY OF HEALTH

## National Center for Pharmacovigilance and Medicine Information

Medicine Poor Quality Notification Form

**A. Information on the notifier**

Please tick on your status:  1. Patient  2. Health care professional  3. Other (specify)

Address of notifier: Village: \_\_\_\_\_ Sector: \_\_\_\_\_  
 Cell: \_\_\_\_\_ District: \_\_\_\_\_

Any other available address (cell phone/ email, ...): \_\_\_\_\_

Is the notifier has consumed the reported product?  Yes  No

**B. Product identity**

Brand Name: \_\_\_\_\_ Generic name: \_\_\_\_\_  
 Batch/ lot number: \_\_\_\_\_ Date of manufacture: \_\_\_\_\_ Date of expiry: \_\_\_\_\_

Name of distributor/ supplier: \_\_\_\_\_ Name of manufacturer: \_\_\_\_\_  
 Distributor/ supplier's address: \_\_\_\_\_

**PRODUCT FORMULATION (tick appropriate box)**

| PRODUCT FORMULATION (tick appropriate box)                       | COMPLAINT (tick appropriate box/ boxes)       |
|--|---|
| <input type="checkbox"/> Oral tablet/ capsule                    | <input type="checkbox"/> Colour change        |
| <input type="checkbox"/> Oral suspension/ syrup                  | <input type="checkbox"/> Separating           |
| <input type="checkbox"/> Injection                               | <input type="checkbox"/> Powdering/ crumbling |
| <input type="checkbox"/> Ointment                                | <input type="checkbox"/> Clumping             |
| <input type="checkbox"/> Powder for reconstitution of suspension | <input type="checkbox"/> Moulding             |
| <input type="checkbox"/> Powder for reconstitution of injection  | <input type="checkbox"/> Change of odour      |
| <input type="checkbox"/> Eye drop                                | <input type="checkbox"/> Mislabelling         |
| <input type="checkbox"/> Ear drop                                | <input type="checkbox"/> Incomplete pack      |
| <input type="checkbox"/> Nebuliser solution                      | <input type="checkbox"/> Other: _____         |
| <input type="checkbox"/> Cream/ ointment/ liniment/ paste        |   |
| <input type="checkbox"/> Other: _____                            |   |

Describe complaint in detail: \_\_\_\_\_

**C. Storage conditions**

Does the product require refrigeration?  Yes  No Others details (if necessary): \_\_\_\_\_

Was the product available at facility?  Yes  No

Was product dispensed and returned by client?  Yes  No

Was the product stored according to manufacturer/ MoH recommendations?  Yes  No

**D. Circumstance and time of poor quality detection**

At which time did you notice that the poor quality problem?

| At which time did you notice that the poor quality problem? | In which circumstance did you notice the poor quality problem?   |
|---|--|
| <input type="checkbox"/> Before taking the product          | <input type="checkbox"/> When I notice complication of my patient/ relatives after he or she took this product |
| <input type="checkbox"/> While I took the product           | <input type="checkbox"/> When a patient was hospitalized after taking this product                             |
| <input type="checkbox"/> After I took the product           | <input type="checkbox"/> After a complaint of patient who is under this medication                             |
| <input type="checkbox"/> When relative took the product     | <input type="checkbox"/> When my patient took this product   |
| <input type="checkbox"/> When my patient took this product  | <input type="checkbox"/> Other: _____  |
| <input type="checkbox"/> Other: _____                       |  |

Have you experienced any adverse event or did you receive any complaint after taking this medicine?  Yes  No

If you or any other person has already take this medicine and experienced any health problem, please complete the adverse event notification form.

Your support in this pharmacovigilance program is appreciated. Submission of a complaint does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to an event. All information is held in strict confidence and programme staff will not disclose reporter's identity in response to any public request. Information supplied by you will contribute to the improvement of medicine safety and therapy in Rwanda. Once completed, please send to: National Pharmacovigilance and Medicine Information Center or to the Drug and Therapeutic Committee (DTC) of the hospital which is nearest you.

## ANNEX 3. PATIENT ALERT CARD (ENGLISH AND KINYARWANDA)



MINISTRY OF HEALTH

### PATIENT ALERT CARD

|  |
|--|
| Patient name: .....  |
| Date of birth: ..... Gender: M <input type="checkbox"/> F <input type="checkbox"/> |
| Height: .....  |
| ID/passport numb <input type="checkbox"/> .....                                    |
| Place of issue of the alert card: PV subcommittee of Hospital.....                 |
| Date when the card was issued: ...../...../.....                                   |
| Responsible medicine: .....  |
| Types of intolerance:<br>.....   |

*Please hold always this card with you to be presented to any health care provider in any consultation session.*

*Itwaze iteka iyi karita kandi wibuke kuyereka muganga mu gihecyose ugiye kwivuza.*

Signature and stamp of PV subcommittee



MINISTERI Y'UBUZIMA

### IKARITA MPURUZA Y'UMURWAYI

|  |
|--|
| amazina y'umurwayi.....  |
| Igihe yavukiye cyangwa imyaka: .....                                   |
| Igitsana : Gabo <input type="checkbox"/> Gore <input type="checkbox"/> |
| Uburebure: .....   |
| Nimero y'indagamunyu/pasiporo: .....                                   |
| Aho icyo karita yandikiwe: Ibitaro bya.....                            |
| Itariki icyo karita yandikiweho: ...../...../.....                     |
| Ubwoko b'ingaruka mbi yatewe n'umuti: .....                            |
| Izina/ubwoko ry'umuti wateye icyo kibazo: .....                        |

***Itwaze iteka iyi karita kandi wibuke kuyereka muganga mu gihecyose ugiye kwivuza.  
Kashe y'ibitaro handikiwe ino karita***

## ANNEX 4. MINISTERIAL INSTRUCTION ESTABLISHING DTCS IN ALL HOSPITALS

REPUBLIC OF RWANDA



MINISTRY OF HEALTH  
Web site : [www.moh.gov.rw](http://www.moh.gov.rw)  
B.P.84 KIGALI

Kigali, 19 JUN 2009

N° 20/...../PH/RDU/AN/2009

1586

**Director of Referral Hospital (all)**  
**Director of District Hospital (all)**

**RE: Establishment of Drug and Therapeutics Committees and the Hygiene Committees in all Hospitals**

Dear Sir/Madam,

In order to improve the quality of care and services provided in your health facilities and in the response of implementing the National Health Sector Policy, the Ministry of Health is recommending among other mechanisms the establishment of two key hospital committees: Drug and Therapeutics Committee and Hygiene Committee.

The Drug and Therapeutics Committee (DTCs) aims at improving the quality of care through promoting the rational use of medicines and other health commodities while Hygiene Committee (HCs) strive for improving hygiene and preventing nosocomial infections or other accident due to poor hygiene.

Therefore, we ask you to put in place these committees in your hospital, to inform the Ministry of Health about members of those committees and to ensure that they are functioning as per their terms of reference herein attached. Each month, the hospital Director shall provide a copy of the report of the activities of these committees at the Ministry of Health for follow up.

For more details about these committees, please contact the concerned services at the Ministry of Health:

- for Drug and Therapeutics Committees, contact the Task Force of Pharmacy,
- for the committee of hygiene, contact the Task Force of Environment Health.

Sincerely,

**Dr. SEZIBERA Richard**  
Minister of Health



## ANNEX 5. TERMS OF REFERENCE OF DTC

REPUBLIQUE DU RWANDA



MINISTERE DE LA SANTE

### Term of Reference of Hospital Drug and Therapeutics Committee

#### 1. Definition

A drug and therapeutics committee is a multi-disciplinary committee appointed by the Hospital Managing Director, which mainly aims at improving quality of patient care and health outcomes by:

- ✓ selecting effective, safe, high-quality, and cost-effective pharmaceuticals for the hospital;
- ✓ improving drug use, including antimicrobial use;
- ✓ managing antimicrobial resistance;
- ✓ increasing staff, patient and public knowledge about drugs,
- ✓ decreasing adverse drug reactions and medication errors
- ✓ Improving drug procurement and inventory management
- ✓ Control and management of drug expenditures

#### 2. Status

The drug and therapeutics committee is a committee appointed by the Managing Director of the Hospital. Its activities will be accountable to the Office of the Managing Director of the Hospital, whereby its chairman is responsible of those activities.

#### 3. Organization

The Drug and Therapeutics Committee is a multi-disciplinary committee and therefore it shall be composed by members from medical and paramedical staff as well as from the administration. The committee will be constituted by the following core members:

1. Clinical Director or Medical Chief of Staff who is the Chairperson
2. Head of Pharmacy Department, who is the Secretary
3. Administrator, Member
4. Chief of Nursing, Member
5. Head of Gynecology and Obstetrics Department or his representative, Member
6. Head of Surgical Department or his representative, Member
7. Head of Internal Medicine Department or representative, Member
8. Head of Pediatrics Department or his representative, Member
9. Head of Outpatients Department or his representative, Member
10. Head of Dermatology Department/representative, Member

11. Head of Ear, Nose and Throat Department or his representative, Member
12. Head of Anesthesia Unit or his representative Member
13. Head of Intensive Care Unit or his representative Member
14. Head of Laboratory Department or his representative Member
15. Staff in charge of community health insurance scheme, Member
16. Staff in charge of hygiene and environment, Member
17. District Pharmacist, member.

Each member of the committee will serve for a maximum of two years renewable once and departments may suggest to the managing director to replace their representatives in the committee if need be.

The vice-chairperson shall be a physician from any of above said clinical departments and be appointed by DTCs members.

The committee will assign a minutes' keeper from the secretaries of the hospital. The minutes' keeper will work closely with the secretary of the committee in organizing the minutes of the committee.

#### **4. Duties and Responsibilities**

##### **4.1 Duties and responsibilities of the Committee**

The DTC will have following responsibilities:

- Prepare and conduct periodical review of the list of medicines and other medical commodities for the hospital with reference to the national list of essential drugs.
- Formulate recommendations to the pharmacy department in all activities related to the selection, quantification, procurement, distribution and dispensing of drugs and other medical commodities for the hospital.
- Follow up the implementation of the National Standard Treatment Guidelines and Formulary to comply with the morbidity pattern observed in the hospital.
- Develop a system of monitoring rational use of drugs in the hospital and make recommendations of its improvement.
- Put in place strategies to contain antimicrobial resistances
- Participate in preventing and managing nosocomial infections
- Initiate and/or coordinate studies on problems related to rational use of drugs, proper distribution, and labeling of medications.
- Elaborate mechanisms for the prevention and management of Medication Errors in the Hospital.
- Serve as the decentralized unit of the National Pharmacovigilance and Medicines Information Center as per defined terms of reference of that decentralized unit in the Guidelines of Pharmacovigilance and Medicines Information.
- Design and organize continuing educational programs regarding the promotion of rational drug use to medical personnel, to other health workers and to the public.
- Participate actively in updating the National List of Essential Drugs, National Formulary and the National Treatment Guidelines.

- Prepare its annual plan of action and budget and report its activities to the Hospital Management Committee every quarter, with copies to the Hospital Managing Director.
- Coordinate all activities related to pharmaceutical marketing by medical representatives in the hospital and other means of medicines promotion in accordance with the existing norms and regulations.
- Evaluate its annual performance

The Committee is responsible to make close follow-up of the implementations of its approved recommendations by the hospital management and the entire staff. If any staff does not implement the adopted DTC recommendations, the committee will discuss the recommendations with the staff again and urge the hospital management to take necessary measures.

#### **4.2. Duties and Responsibilities of the Chairperson**

The chairperson of the DTC will have the following responsibilities:

1. Ensure the recommendations of the DTC are applied.
2. Ensure that decisions of the committee are taken objectively and based on scientific evidence where applicable
3. Establish good relationship between the committee and the management of the hospital
4. Delegate to his deputy chairperson his responsibilities once he is to be absent.
5. Present quarterly activity reports to the hospital management committee with copy to the Hospital Managing Director.
6. Represent the committee in the Hospital Management Committee meetings and other relevant events.
7. Call regular and extraordinary meetings.
8. Chair the meetings.

#### **4.3 Duties and Responsibilities of the Secretariat**

The secretary of the DTC will have the following responsibilities:

1. In consultation with the chairperson, prepare the notice and agenda for all meetings and share them with all committee members at least seven days before the meeting.
2. Prepare the minutes of all meetings together with the minutes keeper and disseminate these to all members.
3. Follow up the action plan of the committee.
4. Conduct literature searches and disseminate the material at least seven days before the committee meets.
5. Ensure that the decisions taken by the committee are submitted to the Hospital Managing Director for his/her notification.
6. Circulate all pertinent materials for meetings to all members and their task team at least one week before the meeting.
7. Acknowledge the receipt of ADR reports.

#### **4.4 Duties and responsibilities of a Member**

Each member of the committee is responsible to:

1. Actively participate in the DTC meetings and other activities

2. Propose issues that need to be discussed
3. Each member should give prior notification if he or she is unable to attend the next meeting.

Any member who is absent in three consecutive meetings without any notified reason should be replaced

**4.5. Duties and responsibilities of Pharmacovigilance Decentralized Unit: Sub Committee of DTC**

1. This sub-committee will be composed by four members:
  - One Physician who will act as Chairperson
  - The pharmacist of hospitals
  - The Chief of Nursing
  - One Supervisor of Health Facilities
2. The sub committee will ensure all activities related to pharmacovigilance in his area of operation; these activities are:
  - Implement recommendations of the *Guidelines for Medicines Safety Surveillance in Rwanda* in health facilities within its catchment area.
  - Ensure the ready availability of the adverse event and medicine information request notification forms in all health facilities
  - Collect, validate and transmit all notifications and requests to National Pharmacovigilance and Medicines Information Center (NPMC)
  - Ensure that health workers are trained and are familiar with the completion of the notification forms
  - Using the platform of the DTC sensitize health workers on the need for medicine safety monitoring
  - Collaborate with the NPMC on a regular basis on all medicine safety related issues
  - Identify and develop proposals for the implementation of interventions to address all medicine safety and irrational use issues in health facilities within their catchment area

**5. Meetings of the DTC**

- The DTC will meet every month for the first six months and every quarter then after and can have extraordinary meetings when necessary.
- The committee may invite to its meetings persons within or outside the hospital who can contribute from their specialized knowledge or experience.
- Issues to be discussed will be determined jointly by the chairperson and the secretary.

- Agenda will be prepared and submitted to members of the committee in sufficient time before the meeting at least seven days before the meeting.
- Minutes of the meeting will be signed by the chairman of the committee together with the secretary and be sent to the committee members for comments seven days after the meeting and be sent to the hospital Management then after.
- Minutes shall be maintained in the secretariat of the hospital
- Recommendations of the DTC will be presented to Hospital Management Committee for adoption and implementation.
- The quorum for any meeting is at least 50 percent of the membership plus one person of committee
- DTC members can appoint punctual technical subcommittees for a specific task in their routine activities.
- Correspondence will be addressed to the secretariat of the committee.

**6. Motivating Members/Budget**

The Management Committee of the Hospital shall determine motivational mechanism(s) that can give equal chance for all members of the committee in conformity with existing norms. The DTC budget for its activities must be allocated to the Hospital budget as it is for other similar committees.