RWANDA FDA
Rwanda Food and Drugs Authority
P.O. Box 1948 Kigali
info@rwandafda.gov.rw
www.rwandafda.gov.rw

TERMS OF REFERENCE FOR THE NATIONALPHARMACOVIGILANCE ADVISORY COMMITTEE

1. Introduction

Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible medicine-related problems Pharmacovigilance (PV) plays a key role in the healthcare system through assessment, monitoring and discovery of drug interactions as well as their effects in human beings. Pharmaceutical and biotechnological medicines are designed to cure, prevent or treat diseases; however, there are also risks, particularly adverse drug reactions (ADRs) which can cause serious harm to patients. Thus, for safety medication, ADRs monitoring is required for each medicine throughout its life cycle, from pre-marketing including early stages of drug design, pre-clinical and clinical trials to post-marketing surveillance.

Reference made to the Law No 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority, especially in its article 8, paragraph 9, the Authority is mandated to conduct pharmacovigilance and post marketing surveillance for safety and quality of regulated products among other regulatory functions. Reference made is also made to the regulation No CBD/TRG/016 Rev_0 governing pharmacovigilance in Rwanda especially in its article 10.

WHO has set minimum requirements for functional National Pharmacovigilance System including National Pharmacovigilance Center, National Spontaneous Reporting System, and National Database for Collecting and Managing ADRs, National Pharmacovigilance Advisory Committee and clear communication strategy. In this regards, Rwanda FDA has established the National Pharmacovigilance Advisory Committee which will provide technical expertise related to drug safety monitoring.

2. Status of the National Pharmacovigilance Advisory Committee

A National Pharmacovigilance Advisory Committee is a key requirement for a functional national pharmacovigilance system. The National Pharmacovigilance Advisory Committee provides technical assistance on causality assessment, risk assessment, risk management, case investigation and, where necessary, crisis management including crisis related to medicine safety communication. Rwanda FDA has established the multidisciplinary national pharmacovigilance advisory committee to perform the advisory role in their relevant area of expertise to guide pharmacovigilance regulatory actions

3. Organization

The National Pharmacovigilance Advisory committee is multidisciplinary body and therefore composed by professionals from all disciplines of medical carrier as follows:

S/No	Profession	Number
1	Dermatologist	1
2	Internist	1
3	Division Manager PV & SM	1
4	Clinical Pharmacist	1
5	Pharmacist	1
6	Toxicologist	1
7	Surgeon	1
8	Cardiologist	1
9	Oncologist	1
10	Paediatrician	1
11	Pharmacologist	1
12	Veterinary	1
13	Gynaecologist	1

The Chairperson will be nominated by the Director General of Rwanda FDA, while Vice-Chairperson will be voted by the members of the committee in their first ordinary meeting and the Secretary will be the Division Manager for Pharmacovigilance and Safety Monitoring at Rwanda FDA. Each member will serve for a maximum of three (3) years. Any member who is absent for three (3) consecutive meetings without any notified reason should be replaced.

4. Duties and Responsibilities

4.1 National Pharmacovigilance Advisory Committee

The National Pharmacovigilance Advisory Committee will assess scientific, safety and pharmacovigilance documentation on individual medical products and health technologies formulating recommendations and advice to Rwanda FDA for appropriate and informed regulatory decisions.

The roles and responsibilities of the National Pharmacovigilance Advisory Committee include the following:

a) Provide guidance on risk identification/management on the use of medical products including the detection, assessment, minimization and communication relating to the risk of adverse reactions and guidance on set up risk management plan (RMP);

b) Provide technical assistance on causality assessment for the reported adverse drug reactions

c) Provide advice on the design of post-authorization safety studies (PASS) and pharmacovigilance audit/inspections;

d) Provide recommendations for urgent safety issues related to medicines and advice on the timing and message content for individual safety cases;

e) Provide advice for updating medical products list with safety concerns requiring additional monitoring;

f) Assess and advise on potential signals/alerts of adverse drug reactions and Suspected Poor-Quality products;

g) Advise on signal detection, investigation, analysis and management on medical products

h) Provide guidance on medicine safety communication required especially in case of crisis

i) Advise on medicine registration, renewal/variation of medicine taking into consideration their safety, efficacy and quality

4.2 Duties and Responsibilities of Chairperson

The Chairperson of the National Pharmacovigilance Advisory Committee will have the following responsibilities:

1. Represent the committee in different organizations/institutions and other relevant events;
2. Ensure the decisions of the committee are taken objectively and based on scientific evidence where applicable;
3. Follow up on implementation of the committee's recommendations;
4. Establish good relationship between the committee and the senior management team of Rwanda FDA
5. Present quarterly activity reports to management with copy to the Chairman of the Board of Directors of Rwanda FDA:
6. Convene and preside all regular and extraordinary committee meetings.

4.3. Deputy Chairperson of the Committee

The Deputy Chairperson of the Committee has the following duties and responsibilities:

1. Assist the Chairperson and replace him/her in case of absence;

2. Perform any other duties falling within the mission of the committee as may be assigned to him/her by the committee.

4.4. Duties and Responsibilities of Secretariat

The secretary of the National Pharmacovigilance Advisory Committee will have the following responsibilities:

1. Prepare the notice and agenda for all meetings and share them with all committee members at least seven working days before the meeting;
2. Prepare the minutes of all meetings and disseminate these to all members;
3. Follow up the action plan of the committee;
4. Ensure that the recommendations taken by the committee are submitted to the Director General of Rwanda FDA and with copy to the Board of Directors 's Chairperson;

Circulate all pertinent materials for meetings to all members and their task team at least seven (7) working days before the meeting.

5. Meeting of the National Pharmacovigilance Advisory Committee

The National Pharmacovigilance Advisory Committee will meet on quarterly basis and can have extraordinary meetings when deemed necessary. The Pharmacovigilance Advisory Committee may invite to its meetings person within or outside Rwanda FDA who can contribute for his/her specialized knowledge or expertise. The agenda items will be determined by the Chairperson in consultation with the secretariat and communicated in seven (7) working days before the meeting. The meetings of the Committee may be held physically or online using electronic platforms that help each member to provide his/her point of view on agenda items.

The Chairperson of the committee together with the Secretary will sign minutes of the meeting after gathering comments/observations from the all committee members present to the meeting. The quorum for a meeting of the committee is a seven (7) of its members. However, when a meeting is convened for the second time it takes place regardless of the number of its members present.

The minutes of the meetings shall be sent to the Director General, with copy to the Board of Directors 's Chairperson, of Rwanda FDA for implementation within five (5) working days after the meeting tenure.

The National Pharmacovigilance Advisory Committee can appoint punctual technical subcommittee for a specific task and correspondence will be addressed to Chairperson of the committee

6. Capacity building for the National Pharmacovigilance Advisory Committee

Rwanda FDA in collaboration with different partners will ensure that the capacity building for the committee members is included in capacity building plan of Rwanda FDA

Done at Kigali on ..11/10/2021

Dr. Emile BIENVENU
Director General