RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Pharmacovigilance and Food Safety Monitoring Division	
Document Type: **Standard Operating Procedure**		Doc. Number	: DIS/SOP/….
RWANDA FDA Rwanda Food and Drugs Authority	Title: **CONDUCTING PHARMACOVIGILANCE ON SITE SUPERVISION**	Revision Number	:0
		Revision Date:	:21/05/2021
		Effective Date	:01/06/2024
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1.0 Purpose

1.1 The purpose of this SOP is to define the procedure for conducting Pharmacovigilance on site supervision for healthcare workers, Marketing Authorization holders and other stakeholders at their facilities.

2.0 Scope

This SOP shall apply to all pharmacovigilance onsite supervision.

3.0 Policy

3.1 Law N° 003/2018 of 9/2/2018 establishing Rwanda FDA and determining its mission, organization and functioning.

3.2 Regulation CBD/TRG/018 governing post market surveillance of regulated products

3.3 Guidelines for Post Marketing Surveillance of pharmaceutical products N° PSM/GDL/015

3.4 Rwanda FDA guidelines N° PSM/GDL/011 on Safety and vigilance of medical products and health technologies.

4.0 Definitions and Abbreviations

4.1 Definition

4.1.1 **Pharmacovigilance:** Science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other possible medicine related problems.

4.1.2 Adverse event means any untoward occurrence that may present during treatment with a pharmaceutical product which does not necessarily have a causal relationship with the treatment. An adverse event can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding, symptom or disease, temporally associated with the use of product whether or not related to the product)

4.2 Abbreviation

4.2.1 DTC stand for Drug and therapeutic committee located at the level of health facility mainly in the Hospitals.

4.2.2 ADR: Adverse drug reaction which is response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function.

5.0 Responsibility

5.1 The Director General is responsible for:

a) Approval of all pharmacovigilance onsite supervision activities
b) Approval for all materials to be used during Pharmacovigilance onsite supervision

5.2 Head of department of Food and Drugs Inspection and Safety Monitoring are responsible for:

a) Ensuring that all planned onsite supervision are prepared, and conducted in accordance to this present SOP
b) Monitoring and evaluation of all conducted onsite supervision

5.3 Chief Finance officer is responsible for:

a) Availing/ mobilizing funds for conducting onsite supervision activities

5.4 The Division manager of Pharmacovigilance and Food Safety Monitoring is responsible for:

a) Planning all annual pharmacovigilance onsite supervisions
b) Coordinating pharmacovigilance onsite supervision activities
c) Identifying staff for conducting onsite supervision
d) Ensuring availability of all materials to be used in pharmacovigilance onsite supervision
e) Selecting Health facilities where onsite supervision will be conducted

5.5 Analysts and Specialists are responsible for:

a) Preparation of the concept note of pharmacovigilance onsite supervision
b) Preparation of all materials to be used in pharmacovigilance onsite supervision
c) Conducting pharmacovigilance onsite supervision at selected Health facilities
d) Preparing the report of all conducted pharmacovigilance onsite supervision
e) Proposing any other required onsite supervision to the Division Manager of Pharmacovigilance and Food Safety monitoring

f) Collaborating with Drugs and Therapeutic committee (DTC) members in order to give technical support if deemed necessary.

6.0 Distribution

6.1 Director General
6.2 Head of Department
6.3 Chief of Finance Officer
6.4 Division Manager
6.5 Analysts and Specialists

7.0 Reference

EAC Sop for Preparation and conduct pharmacovigilance training

8.0 Safety Precautions

NA

9.0 Materials and equipment

9.1 Power point presentation
9.2 Suspected Poor quality products reporting forms
9.3 ADR/AEFIs reporting forms
9.4 Patient alert cards
9.4Email box of Pharmacovigilance and Food safety Monitoring Division **pv_sm@rwandafda.gov.rw**

10.0 PROCEDURES

10.1 The Division manager of Pharmacovigilance and Food Safety Monitoring shall:

a) Plan annual Pharmacovigilance onsite supervision to be conducted
b) Select health facilities where pharmacovigilance onsite supervision will be conducted
c) Ensure availability of all materials including to be used during pharmacovigilance onsite supervision
d) Select staff of Pharmacovigilance and Food Safety Monitoring who will conduct pharmacovigilance onsite supervision

10.2 PV&PMS Analyst and specialist shall prepare all materials to be used during

pharmacovigilance onsite supervision

10.3 PV&PMS Analyst and specialist shall prepare pharmacovigilance onsite supervision concept note

10.4 PV&PMS Analyst and specialist shall prepare and send letters to the Director General of health facilities at least 7days before conducting pharmacovigilance onsite supervision.

10.5 During onsite supervision PV&PMS Analyst and specialist have to:

i. Closely monitor all activities related to pharmacovigilance and advise DTC members to in order to improve pharmacovigilance activities
ii. Disseminate all tools related to pharmacovigilance activities to the health care providers
iii. Supervise all clinical services at health facility where onsite supervision shall be carried out

11.0 Document Revision History

Date of revision	Revision number	Author(s)	Changes made and/or reasons for revision
21/05/2021	0	QMS Specialist	First issue