RWANDA FOOD AND DRUGS AUTHORITY	Food and Drugs Inspection and Safety Monitoring Department	Pharmacovigilance and Food Safety Monitoring Division	
Document Type: **Standard Operating Procedure**		Doc. Number	: DIS/SOP/053
RWANDA FDA Rwanda Food and Drugs Authority	Title: **SIGNAL DETECTION AND MANAGEMENT**	Revision Number	:0
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1.0 Purpose

1.1 This standard operating procedure (SOPs) describes the process by which identification and management of safety signal for active substances is periodically conducted by Rwanda FDA

1.2 Provide guidance on the handling of validated and confirmed signals.

1.3 Ensure that all activities, from signal detection, analysis, prioritization and evaluation of signals, are handled in an efficient and consistent way

2.0 Scope

This SOP applies to signal detection and signal management as well as specific situations such as pandemic, however for such situations adapted processes and shorter timelines may apply.

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/016 governing pharmacovigilance of pharmaceutical products and medical devices

3.3 Guidelines PSM/GDL/011 on safety and vigilance of medical products and health technologies

4.0 Definitions and Abbreviations

4.1 Definitions

SIGNAL Reported information on a possible causal relationship between an adverse event and a drug the relationship being unknown or incompletely documented

previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information.

4.2 Abbreviations

ICSR	Individual Case Safety Report
SOP	Standard Operating Procedures
SVM	Signal Validation Meeting
ME	Medication errors
PV & FSM	Pharmacovigilance and Food Safety Monitoring
PV & PMS	Pharmacovigilance and Post Marketing Surveillance
QPPV	Qualified Person Responsible for Pharmacovigilance

4.0 Responsibility

4.1 The Director General is responsible for the overall approval of:
- i. All detected and validated signal for publication
- ii. All regulatory action taken due to detected and validated Signals

4.2 Head of department of Food and Drugs Inspection and Safety Monitoring is responsible to ensure that this procedure is adhered.

4.3 . Division manager of Pharmacovigilance and Food Safety Monitoring is the responsible for coordination of all activities related to signal detection and signal management

4.4 PV &PMS analyst and specialists are responsible for implementation of each steps of this procedure.

4.5 Pharmacovigilance Advisory committee is responsible for technical assistance during analysis of detected signal.

5.0 Distribution

5.1 Director General
5.2 Head of Food and Drugs Inspection and Safety Monitoring Department
5.3 Division Managers Pharmacovigilance and Food Safety Monitoring
5.4 Pharmacovigilance and Post Marketing Surveillance Analyst and specialists
5.5 Quality assurance Analyst

6.0 Reference

6.1 Guidelines PSM/GDL/011 on safety and vigilance of medical products and health technologies
6.2 EAC NMRA signal management SOP
6.3 European Medicines Agency Signal Management Standard Operating Procedure No. SOP/H/3065

8.0 Safety Precautions

NA

9.0 Materials and equipment

9.1 Records

9.1.1 Signal tracking register
9.1.2 Signal Validation Reports from Signal Validation Meeting (Signal assessment report template)
9.1.3 ADR/AEFI reporting Form

10.0 PROCEDURES

10.1 PV& PMS analyst and specialists shall regularly screen electronic reporting systems/ manual reporting system to identify potential signals and receive potential signal from other

sources (e.g., literature, other regulatory authorities, emerging safety issue, data generated from VigiBase etc.)

10.2 PV& PMS analyst and specialists shall enter the signal detected into a signal tracking registers

10.3 PV& PMS analyst and specialists shall perform signal validation by reviewing individual case safety reports (ICSR) forms, line listings or any other sources as relevant.

10.4 PV& PMS analyst and specialists shall immediately notify the supervisors if detected signal is considered urgent.

10.5 PV& PMS analyst and specialists shall prepare the signal validation report

10.6 PV& PMS analyst and specialists shall close the signal if no further immediate action is required

10.7 PV& PMS analyst and specialists shall send the proposed closed/monitored signal to the supervisors for review

10.8PV& PMS analyst and specialists shall conclude that the signal should be validated at the Signal Validation Meeting (SVM) if the signal require discussion

10.9 PV& PMS analyst and specialists shall send the list of the signals to the supervisor for discussion at the SVM.

10.10 PV& PMS analyst and specialists shall update the signal validated from SVM into signal tracking register

10.11 Division Managers Pharmacovigilance and Food Safety Monitoring shall send the validated signals to the Pharmacovigilance Advisory Committee with cover email or cover letter. If the signal is urgent this should be clearly identified on the subject of the e-mail or letter.

10.12 The Pharmacovigilance Advisory Committee shall submit the confirmed and non-confirmed signals report to the authority.

10.13 PV& PMS analyst and specialists shall Update the signal tracking register and end the procedure.

10.14 The authority shall publish confirmed signals if deemed necessary

10.15 The authority shall enforce regulatory action based on Signal recommendations from Pharmacovigilance Advisory committee

11.0 Document Revision History

Date of revision	Revision number	Author(s)	Changes made and/or reasons for revision
20/05/2021	0	PV & PMS Specialist	First issue