DRUG SAFETY MONITORING MANUAL

FOR

PHARMACY BOARD OF SIERRA LEONE
PHARMACOVIGILANCE DEPARTMENT

P.M.B 322
SIERRA LEONE

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CONTENT

Background
Mandate
Mission
Vision
Functions
Units
Organogram
Staff Profile
Standard Operating Procedures (SOPs)
Job descriptions

Guidelines
Operational forms

BACKGROUND

Access to new essential medicines for malaria, HIV/AIDS, and tuberculosis (TB) has dramatically improved in many developing countries through the efforts of global health initiatives. With the increased access, lifesaving medicines are now available to many. The large population covered and the use of new medicines provides the potential for not only benefits to the local population but also harm. The possibility of harm is high—especially if adverse reactions are not monitored pursuant to a strategy aimed at good reporting and early detection, review, and management.

The Pharmacovigilance/Safety Monitoring Department of the Pharmacy Board of Sierra Leone was established in 2005 and later on became an associated member of the World Health Organization (WHO) International Safety Monitoring programme. This was followed by full membership in 2007 making Sierra Leone the 87th member of the WHO International Safety Monitoring programme.

Definition and Scope of Pharmacovigilance

The WHO defines Pharmacovigilance as the science and activities relating to the detection, assessment, understanding, and prevention of adverse reactions to medicines or any other medicine-related problems. There is incomplete understanding of the safety of new medicines at the point of registration. Data on the safety of new medicines are mainly derived from pre-authorization clinical trials in controlled settings. Though data on safety are collected during clinical trials of new medicines, the limitations of clinical trials—including restricted exposure, narrow perspective, and short duration—make it imperative to monitor for safety and effectiveness when the product is used in large populations. Post marketing surveillance (PMS) is crucial to quantify previously recognized ADRs, identify unrecognized adverse drug events, and evaluates the effectiveness of medicines in real-world situations as well as to decrease mortality and morbidity associated with adverse events. The aims of Pharmacovigilance for the Drug Safety Monitoring department are to—

Improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions

Improve public health and safety in relation to the use of medicines

Detect problems related to the use of medicines and communicate the findings in a timely manner

Contribute to the assessment of benefit, harm, effectiveness and risk of medicines, leading to the prevention of harm and maximization of benefit

Encourage the safe, rational, and more effective (including cost-effective) use of medicines

Promote understanding, education, and clinical training in Pharmacovigilance and its effective communication to the public.
Overall, Pharmacovigilance is important to ensure product stewardship and safeguard public health. The implementation of a comprehensive Pharmacovigilance system requires efforts beyond data collection on adverse events and should include risk evaluation, minimization, and communication. Spontaneous ADR reporting and other forms of data collection for early warning on drug safety are part of the *risk identification* process. *Risk minimization* and *communication* are the preventive part of Pharmacovigilance and include strategies for mitigating known risks, communication of drug safety information, and promotion of rational use of medicines.

MANDATE

The Pharmacovigilance Department derived the mandate to ensure the safety of regulated products from the Pharmacy and Drugs Act. The Department shall continually monitor the safety of the products regulated under the Pharmacy and Drugs Act by analysis of the adverse effect or event reports and by any other means and take appropriate regulatory action when necessary

VISION

The vision of the Pharmacovigilance Department is to improve nationwide patient safety and wellbeing by reducing the risk of medicines used by patients and the general public.

MISSION

To ensure the patients and the general public obtain the best outcome from their medical intervention or treatment. This is achieved by;

Creating awareness and educating health professionals and the general public on the need to monitor and report adverse events to medicines and other products regulated by the Pharmacy Board of Sierra Leone.

Ensuring that Marketing Authorization Holders continually monitor their products on the Sierra Leone market

FUNCTIONS

The Pharmacovigilance/Safety Monitoring Department has four Units viz the Clinical practice, Public Health, Clinical trial and Post market surveillance units.. The Broad objectives of the Department are monitoring of product safety, creation of awareness amongst the general public and healthcare professionals about the need to report adverse events.

Clinical Practice Unit

The Unit is responsible for ensuring compliance by manufacturer's representatives of the requirements in the Pharmacy and Drugs Act. This is done through activities including conduct of:

Pharmacovigilance Inspections for hospitals and manufacturer's representatives and review of safety information submitted e.g. Risk Management/Pharmacovigilance/ Plans for new products.

The unit is also responsible for Pharmacovigilance promotional activities in healthcare facilities and to the general public. This is done through sensitization activities organized for these stakeholders and the generation of Information Education and Communication (IEC) materials for them.

Coordination of causality assessment

Public Health Unit

The Unit is responsible for ensuring incorporation of Pharmacovigilance into Public Health Programmes (PHPs) and ensuring the successful implementation of safety monitoring activities undertaken in collaboration with the PHPs.

This Unit is also responsible for the management and maintenance of the database of safety information (Adverse Events, ADR, AEFI). This includes ensuring availability and accessibility of reporting forms (Adverse Drug Reaction (ADR) and Adverse Events Following Immunization (AEFI))

The unit also coordinates Pharmacovigilance promotional activities for PHPs and for the general populace. This is done through sensitization activities organized for these stakeholders and the generation of Information Education and Communication (IEC) materials for them.

Clinical Trial Unit

The unit is responsible for the regulation of clinical trials in Sierra Leone. This involves but not limited to evaluation of clinical trial applications, Good Clinical Practice(GCP) inspection and monitoring.

Post Market Surveillance Unit

This department is responsible for the coordination of Post Market Surveillance (PMS) activities in collaboration with Drug Evaluation and Registration Department, Quality Control Laboratory Department, Distribution Chain Inspection Department, Enforment and Narcotics Department and Factory Inspectorate and Import Control Department.

STAFF PROFILE

The Department has Three Pharmacists(All with Post graduate qualifications) coordinating drug Safety Monitoring activities,

1. Pharm Onome Abiri- Head/Principal Regulatory Officer
2. Pharm Tima brewah-Head of unit Public Health Pharmacovigilance
3. Pharm Emmanuel Margao: Head of unit clinical Practice Pharmacovigilance

The department is also supported by 4 clinical regulatory officers that are medical doctors and one clinical regulatory consultant that is a physician consultant.

The department is also supported by an expert committee on drug safety that serves as a Technical Advisory Committee consisting of two (2) consultant physicians, one(1) consultant surgeon, one (1) public health specialist, one (1) consultant pathologist, one (1) community pharmacist, one(1) hospital pharmacist, one(1) industrial pharmacist and the secretary which is the head of department.

STANDARD OPERATING PROCEDURES (SOPs)

1. Procedure for writing SOP
2. SOP for Post Market Surveillance (PMS)
3. SOP for uploading ICSR via vigiflow to Uppsala Monitoring Centre database.
4. SOP for sending PMS samples to the laboratory
5. SOP for Good Clinical Practice (GCP) inspection
6. SOP for evaluating clinical trial protocol
7. SOP for causality assessment of ADR
8. SOP for PVG inspection of hospitals
9. SOP for responding to complaints

JOB DECRIPTIONS

- **PRO**
- **RO**
- **CLINICAL OFFICERS**
- **CLINICAL REGULATORY CONSULTANT**