	TITLE: GUIDELINES PHARMACOVIGILANCE INSPECTIONS	
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PHARMACY BOARD OF SIERRA LEONE
PMB 322
CENTRAL MEDICAL STORES COMPOUND
NEW ENGLAND VILLE
FREETOWN

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The Pharmacy Board of Sierra Leone extends its sincere appreciation to all individuals and institutions that contributed to the development of this guideline for signal management. Special thanks to the Paul Ehrlich Institut in Germany for their valuable contribution to this guideline. This document is the result of collaborative efforts aimed at strengthening the national pharmacovigilance system and ensuring the continued safety of medicines in Sierra Leone

Executive summary

This guideline establishes the framework for conducting Pharmacovigilance (PV) inspections in Sierra Leone. It outlines the principles, procedures, and regulatory expectations for evaluating the adequacy, functionality, and compliance of pharmacovigilance systems implemented by Marketing Authorization Holders (MAHs), Clinical Trial Sponsors, and other regulated entities. The primary objective is to ensure that all medicinal products supplied in Sierra Leone are continuously monitored for safety and that risks to public health are identified, assessed, and appropriately managed.

PV inspections serve as a regulatory tool to verify that MAHs have established effective systems for collecting, analyzing, and reporting adverse drug reactions and other safety data in accordance with national legal provisions and globally accepted standards, including WHO and ICH Good Pharmacovigilance Practices (GVP). The guideline describes the different types of inspections, the inspection planning process, inspection conduct, reporting requirements, and corrective and preventive action (CAPA) expectations. It further outlines the roles of inspectors and inspected parties, documentation requirements, and procedures for maintaining transparency and integrity throughout the inspection lifecycle.

The inspection process is designed to be risk-based, prioritizing entities and products that present the greatest potential safety concerns. Findings identified during inspections are

categorized according to their severity, and entities are required to respond with appropriate remedial actions within defined timelines. Post-inspection follow-up, including verification of corrective measures, is an integral part of the regulatory oversight process. Failure to comply may result in sanctions, penalties, or enforcement actions as provided under the Pharmacy and Drugs Act and associated regulations.

Overall, the implementation of this guideline strengthens the national pharmacovigilance system by promoting accountability, improving data quality, enhancing signal detection, and supporting timely regulatory decision-making. It ensures that public health is protected through proactive surveillance and continuous evaluation of the benefit-risk profile of medicinal products used in Sierra Leone.

1.0 Introduction

In pursuance to the Pharmacy and Drugs act, 2001 this guideline is developed by the Pharmacy Board of Sierra Leone (PBSL), hereafter referred to as the Board, to provide guidance on the planning, conduct, reporting and follow-up of pharmacovigilance (PV) inspections in Sierra Leone and outlines the role of the different parties involved.

This guideline on Pharmacovigilance inspections in Sierra Leone was developed according to the guidance provided by the European Medicines Agency (EMA) Guideline on good pharmacovigilance practices (GVP) Module III – Pharmacovigilance inspections (Rev 1).

1.1. Background

In order to assure that marketing authorisation holders (MAHs) comply with pharmacovigilance (PV) obligations within Sierra Leone and to facilitate compliance, the Pharmacy Board of Sierra Leone (PBSL) shall conduct PV inspections of MAHs. Inspectors of PBSL are to inspect the premises, records, documents and PV system master file (PSMF) of the MAH or any firm employed by the MAH. The result will be used to help the manufacturer representatives and MAHs to improve compliance in relation to PV.

PV inspection programmes be implemented, which will include routine inspections scheduled according to a risk-based approach and will also incorporate "for cause" inspections, which have been triggered to examine suspected non-compliance or potential risk, usually with impact on a specific product(s).

The outcome of an inspection will be provided to the MAH who will be given the opportunity to comment on any non-compliance identified. Any non-compliance should also be addressed by the MAH in a timely manner through the implementation of a corrective and preventive action plan and submission of a compliance report.

Information on the conduct and outcome of PV inspections and follow-up and evaluation of the consequence may be made publicly available as part of the overall transparency of PV activities. The inspection will be conducted where PV activities of the Local representative of MAHs is located.

2.0 Objective

To ensure that manufacturer's representatives and MAHs comply with national law and regulation as well as international standards (reference to EU GVP modules or the SL Regulation/Act and/or ICH standards). PBSL PV requirements and to ensure compliance with these obligations, the Board shall conduct PV inspections.

3.0 Scope

This guideline contains direction on the planning, conduct, reporting and follow-up of PV inspections in the Sierra Leone and outlines the role of the different parties involved.

4.0 Requirements

4.1 Objectives of PV inspections

- To assess that the MAH has personnel, facilities and mechanisms in place to comply with PBSL PV requirements.
- To detect and document non-compliance to PBSL regulatory PV requirements which may be risky to public health in Sierra Leone.
- To use the inspection results to ensure that PV obligations are enforced.

4.2 Types of PV inspections

PV inspections will be done, which will include system and product –related, routine and "for cause", pre-authorisation, post-authorisation, announced and unannounced and re-inspections.

- **System and product-related inspections**

  PV system inspections are done to review personnel, procedures and facilities that are in place and to assess their compliance with PV regulatory obligations. Product specific examples maybe be utilized in the assessment to illustrate the proper functioning of the PV systems. Product related PV inspections focuses on PV issues of specific products and their safety activities, taking into consideration the relevant documentation, product – related activities. However, some aspects of the system that's related to the product may be assessed.

- **Routine and 'for cause" PV inspections**

  Routine PV inspections are scheduled before hand as part of the Board's inspection plan and it involves no specific trigger though it is risk analysis based. The kind of inspection is mostly system-based although one or more products can be selected to demonstrate practically the proper functioning and compliance of the system.

  For cause PV inspection, there is a specific trigger and an inspection is necessary to examine the issue. This inspection will primarily focus on specific PV processes or assessment that identifies compliance issues and their impact on specific product. Full system inspection may also be conducted due to the trigger. For cause inspections may arise when, for example, one or more of the triggers listed below are identified:

  — Risk-benefit balance of the product:
    - Suspension or product withdrawal without notifying PBSL
    - Delays or failure to identify or communicate a risk or a change in the risk-benefit ratio

- Communication of information on PV concerns to the public without prior notification to PBSL.

— Reporting obligation (expedited or periodic)

- Delays or omissions in reporting
- Poor quality or incomplete report
- Inconsistencies between MAH reports and other PV sources

— Requests from PBSL

- Failure to provide the requested information or data within the deadline specified by PBSL
- Poor quality or inadequate provision of data to fulfil request for information from PBSL

— Fulfilment of commitments:

- Concerns about the status or fulfilment of risk management plan (RMP) commitments
- Delays or failure to carry out specific obligation relating to the monitoring of product safety, identified at the time of the marketing authorisation.

- **Pre-authorisation PV inspections**

These are inspections conducted prior to the granting of marketing authorisation (MA). This kind of inspection is done to assess existing or proposed PV system in support of the MA application. They are not mandatory but maybe requested in specific situations. Due to product–specific safety concerns, it may be prudent to examine the applicant's ability:

— To implement product specific risk-minimisation activities, or

— to meet specific safety conditions which may be imposed; or

- To manage the routine safety monitoring for the product concern (e.g.- anticipated significant increase in adverse reaction reports where compared to previous products).

In some cases, a risk assessment based on a combination of product-specific and system-related issues may be performed before a pre-authorisation PV inspection is requested.

If the outcome of the pre-authorisation inspection raises concerns about the applicant's ability to comply with the PV requirements laid down by the Board, the following recommendations may be considered:

- non-approval of the marketing authorisation;
- a re-inspection prior to approval of the marketing authorisation to confirm that critical findings and recommendations have been addressed;
- granting of the marketing authorisation with the recommendation to perform an early post-authorisation PV inspection.
- imposition of safety conditions to the marketing authorisation based on the national Sierra Leone national PV regulations.

- **Post-authorisation inspections**

These are inspections conducted after a marketing authorisation has been granted and are intended to determine whether the MAH has complied with its regulatory obligations as stipulated by PBSL.

Announced and unannounced inspections

Usually inspections are done with prior notification to the MAH (routine) to ensure the availability of relevant documentation and personnel for the inspection. However, in some instance it may be prudent to do unannounced

inspections or to announce an inspection at very short notice (e.g. when the announcement could potentially compromise the goal of the inspections or when the inspections is conducted in a short time frame due to urgent safety reasons.

- **Re-inspection**

  These inspections are conducted on a routine basis as part of a routine inspections programme. Risk factors will be assessed in order to prioritise re-inspections. Early re-inspection may take place where significant non-compliance has been identified and where it is necessary to verify actions taken to address findings and to evaluate on going compliance with PV obligations. Early re-inspections may also be warranted when the MAH filed to implement appropriate corrective and preventive actions in response to an earlier inspection.

4.3 The inspection Program

The Board will perform PV inspections for manufacturer's representatives and MAHs based on using a risk-based approach.

The risk-based approach is used to determine the areas of risk, where risk is defined as the probability of an event occurring that will have an impact on the achievement of objectives, taking account of the severity of its outcome and/or likelihood of non-detection by other methods. The risk-based approach for PV inspections is focuses on the areas of highest risk to the organisation's pharmacovigilance system, including its quality system for pharmacovigilance activities, including factors posing the risk to public health, which is of prime importance.

The scheduling of PV inspections may feed into the risk assessment performed to prioritise inspections. Factors which may affect inspection scheduling may include but not limited to the following:

- New product on the market
- New MAH
- number of products issued marketing authorization by the Board;
- product portfolio;
- failure to provide details of the qualified person responsible for pharmacovigilance (QPPV) to the Board;
- number of products with known safety risks or new safety risk identified
- non-compliance with the Board's requirements (delayed submission of reports: ICSRs, PSURs/PBRERs, Risk Management Plans (RMPs), or safety variations Reference Safety Information (RSI): Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL); delayed submission of the responses to the Board requests, submission of the documents with unsatisfactory quality…etc)

- Awareness of non-compliance detected by PV department prioritise the areas that will be reviewed during inspection. The risk-based inspection programme should take into account historical areas with insufficient past PV inspection coverage, identified findings and CAPAs recommended to implement should be verified.
- High risk areas can be identified by implementing reliance and recognition mechanism, using information from any other competent authorities, international organizations like PICs, WHO, UMC, AUDA-NEPAD, etc.
- Any information obtained from MAH, persons responsible for pharmacovigilance activities in the country (QPPV or local representatives), importers related to the

product safety, efficacy or quality; complaints from consumers, or any issues raised by public concerns.

- Any information or concerns on the product quality, efficacy and safety received from Market Control department, CT department, MA department of the PBSL. Information that can be considered when preparing the inspection programme includes marketing authorisation status, MAH compliance with regulatory submissions, product-specific concerns raised by PV departments, intelligence, information from other regulators and inspection outcomes from other GXPs. Interactions and exchanges of information between PV departments, inspectors and other departments can take place both pre- and post-inspection. This can be on an ongoing basis, as and when the information becomes available, or in response to a specific request.
- PV inspection should be undertaken in line with the risk-based inspection programme updated and approved by the Board every year.

- PV inspections will be planned according to the identified priority areas mentioned above, but not limited to it. The leading inspector will assesses the risks relevant to the area under review and employs the most appropriate risk-based approach in the annual inspection plan, provides the inspection plan for approval to the head of department.
- The inspection programme should be based on an appropriate risk assessment and should focus on:
  - the quality system for pharmacovigilance activities;
  - critical pharmacovigilance processes;
  - key control systems relied on for pharmacovigilance activities;
  - areas identified as high risk,
  - after controls have been put in place or mitigating action taken.

The risk-based approach used in PV inspection planning and conduction will help to allocate the resources efficiently in response to the emerging public health risk, to improve the protection of public health where there is a potential risk.

4.4 Inspection process

PV inspections should be well planned, coordinated, conducted, reported, followed-up and documented in accordance with prescribed inspection procedure.

Planning: PV inspections planning should be based on a systematic and risk-based approach (see above) to make the best use of surveillance and enforcement resources whilst maintaining a high level of public health protection. In order to ensure that the inspection resources are used in an efficient way, the scheduling and conduct of inspections will be driven by the preparation of an inspection programme.

Factors which may be taken into consideration, as appropriate, by the competent authorities when
establishing PV inspection programmes include, but are not limited to:

- inspection related:
  - compliance history identified during previous PV inspections or other types of inspections (GCP, GMP, GLP and GDP);
  - – re-inspection date recommended by the inspectors or assessors as a result of a previous inspection;
- product related:
  - product with additional PV activities or risk-minimisation activities;
  - authorisation with conditions associated with safety, e.g. requirement for post-authorisation safety studies (PASS) or designation for additional monitoring;
  - product(s) with large sales volume, i.e. products associated with large patient exposure in Sierra Leone;

- product(s) with limited alternative in the market place;

- MAH related:
  - MAH that has never been subject to a PV inspection;
  - MAH with multiple products licensed for marketing in Sierra Leone;
  - resources available to the MAH for the PV activities they undertake;
  - MAH with no previous marketing authorisations in the EU;
  - negative information and/or safety concerns raised by competent authorities, other bodies outside Sierra Leone or other areas (i.e. GCP, GMP, GLP and GDP);
  - changes in the MAH organisation, such as mergers and acquisitions;
- PV system related:
  - MAH with sub-contracted PV activities (function of the qualified person responsible for PV in the EU (QPPV), reporting of safety data etc.) and/or multiple firms employed to perform PV activities;

A preliminary notification to the MAH about the scheduled inspections and pertinent documents to facilitate the inspection may be requested by the Board at least 21 days to the scheduled date of inspection. The date for the inspection will be agreed with the MAH.

The Board may request for the following documents prior to the inspection. This may include but not limited to;

i. Curriculum vitae, job descriptions and training records for QPPV and any other employee the Board considers relevant.
ii. Contract between the MAH and the QPPV.
iii. Organization charts/organograms (with names and job titles).
iv. Procedural documents (e.g. Standard Operating Procedures, working instructions, job descriptions, terms of reference etc.)
v. Standard training material and presentations.

vi. Minutes of meetings specific to PV
vii. Individual adverse reaction cases files and adverse event reports
viii. Recent PSURs/PBRERs for marketed products
ix. Contacts and agreements with third parties and list of distributors
x. Sierra Leone specific RMPs for selected products when applicable
xi. Line listings of adverse reaction reports;
xii. Summary report of ADRs
xiii. Pharmacovigilance System Master File (PSMF) to reflect Sierra Leone's PV system including but not limited to human resource for PV, organizational chart for PV, job description of the QPPV and other staff involved in PV, information relating to the QPPV, SOPs and other work instructions. For details refer to EU GVP Module IV.

4.5 Conduct of inspection:

PV inspection activities should verify, by examination and evaluation of objective evidence, the appropriateness and effectiveness of the implementation and operation of a PV system, including its quality system for PV activities. The inspection may be conducted at the MAHs location, and if a third party is involved in any PV activity, their site may also be inspected by the Board.

The inspection will normally commence with an opening meeting and end with a closing meeting. The MAH has the right to choose which members of staff participate in these meetings but shall include the QPPV. Reporting and follow-up of deficiencies found during the Board's PV inspection is graded as follows:

Critical: A deficiency in PV systems, practices or processes that could either adversely affect the rights, safety or well-being of patients or that poses a potential risk to public health or that represents a serious violation or regulatory offence of the pharmacy and Drugs Act and the applicable PBSL guidelines.

Major: A deficiency in PV systems, practices or processes that could either potentially adversely affect the rights, safety or well-being of patients or that could potentially pose a risk to public health or that represents a violation of the Pharmacy and Drugs Act and the applicable PBSL guideline

Minor: A deficiency in PV systems, practices or processes that would not be expected to adversely affect the rights, safety or well-being of patients. Lots of minor non-compliance may add up to a major non-compliance.

In general, preliminary findings will be communicated at the closing meeting. An inspection report is then prepared and reviewed internally to ensure consistency of classification of deficiencies prior to issue of the final report. The report is sent to the MAH, usually within 30 working days of the site visit or the date of the provision of the last document requested. It should be noticed that the factual matter contained in the inspection report relates only to those things that the inspection team sees and hears during the inspection process.

4.6 Closure of inspection

The inspection can be closed by:

- Routine closure of inspection with final meeting and a discussion of the findings which will be provided in the inspection report.
- Inspection can be terminated due to product specific issues
- Inspection can be terminated due to failure to provide documents and logistical issues etc. that will cause legal consequences to the MAHs, respective sanctions and penalties (see below).

4.7 Responding to Findings

Following the issue of the inspection report, the MAH is requested to respond to any deficiencies identified and to provide the Board with an appropriate corrective action

plan (CAP) within 14 working days or a deadline to be determined by the Board based on the magnitude of non-compliance identified and a corrective action report (CAR) within 45 working days on receipt of PV inspection report.

The MAH may be required to provide report and where necessary evidence of the progress and completion of the action plan. There may be re-inspections at an appropriate time to verify the progress and success of these remedial actions.

Note that, in some circumstances, the manufacturer's representative of MAH may be required to take immediate action to address a critical or major finding, for the protection of public health and safety.

4.8 Record management and archiving of inspection files

Responsibilities

The lead inspector is responsible for inspection files. The general layout of these files should be in accordance with the format as described in the appendices to this guideline. All entries in the files should be made or completed at the time each action is taken and should be added in chronological order within the sections of the appendix. The lead inspector should ensure that all copies of relevant data/documents are collected so that the information can be incorporated into a single inspection file and filed properly during the conduct of the inspection.

Storage

It is the responsibility of the involved inspectorates to store the inspection files under conditions that prevent accidental or premature destruction of the documents according to Sierra Leone national requirements. The inspection files should be stored safely in a suitable archive for the whole retention period and only authorised personnel shall have access to the archives. Documents may be stored electronically, onto human readable media or other new media as changes in technology demand. If documents are to be archived using electronic or optical

media, the methods for transferring the data to these media should be validated. A suitable backup strategy must be implemented to prevent loss or destruction of data. There must be a possibility to generate hardcopies throughout the period of retention.

Confidentiality and security

PBSL is responsible for ensuring the correct application of applicable data protection requirements. Access will only be provided to parties that are deemed necessary to have access, unless otherwise is indicated by legislation. Whenever PBSL grants access to the inspection file(s) or parts thereof, this access should be recorded. If copies of documents are required these may be provided, subject to confidentiality, to the parties mentioned above. The parties in receipt of the documents then bear full responsibility for ensuring their continued confidentiality.

Retention period and destruction

The inspection files should be maintained for at least 25 years or as determined by national requirements, whichever retention period is longer. After this time, the inspection files could be removed from the archives for destruction. The signature of the person who is responsible for the destruction of the inspection file and the date of the destruction has to be recorded and should be kept in the archives for unlimited time.

4.9 Joint Inspections

Joint inspections involving both assessors and inspectors can provide on-the-job training opportunities for both PV assessors and inspectors. Whilst inspectors expertise includes an in-depth understanding of the legislation and guidance, product specific knowledge which can be important for determining the public health impact of an inspection finding lies with the assessor. The presence of an assessor during an inspection allows real-time access to

this information and also provides an opportunity for assessors to see how the broader PV system contributes to the submissions such as PSURs, RMPs and ICSRs that they frequently assess. The collaboration between an assessor and inspector on product specific issues can contribute to the decision making process with regards to inspection outcomes and post-inspection actions.

Identification of opportunities for joint inspections

Due to resource limitations and considerations of workload it is often not possible for an assessor to participate in every PV inspection. Therefore NCAs can define which inspection scenarios would benefit the most from the presence of an assessor and which would provide the better training opportunities. Criteria could include:

- Has the inspection been triggered as a result of a product specific concern?
- Does the MAH portfolio include:
  - Products for which additional PV activities are required (e.g. additional monitoring, risk minimisation measures)?
  - Novel or niche products?
- Does the PV department have any ongoing concerns regarding the quality of MAH submissions (such as PSURs, ICSRs, Post-Authorisation Safety Study (PASS) protocols etc.)?

The decision may require input from both PV departments and inspectors and therefore inspection schedules created by inspectorates should be shared with PV departments. This will allow timely decision making and allocation of resource and workload.

4.10 Post-Inspection interactions

Following the conduct of an inspection, if findings have been identified that have the potential to impact the benefit-risk profile of a product, recommendations for interaction within PBSL to discuss implications of the management of PV inspection findings which may impact the robustness of the benefit-risk profile of the concerned

medicinal products. Impact on robustness of the product(s) benefit-risk profile(s) in this case is considered to refer not only to cases where the benefit-risk profile itself might be altered, but also to cases where deficiencies in the PV system may have occurred with potential to impact the safety profile of the MAHs authorised product. For example, a failure to update risk-minimisation measures and/or failure to communicate safety information to healthcare professionals (HCPs) and patients.

PBSL established the mechanisms for information sharing within the organization (MA, MC, CT, QA departments, etc). Information on the following findings may be useful to assessors when performing benefit-risk assessments of a product;

- violation of the provisions regarding the recording and reporting of ICSRs, such as lack of submission, incorrect seriousness assessments, incorrect coding;
- inadequate literature searches, and inclusion of literature cases in the safety database and submission;
- signal analysis performed by the MAH was not in accordance with the provisions, failure to implement necessary actions identified in the signal management process.

PBSL may disseminate information between external stakeholders (MAH, pharmaceutical companies, importers, PICs, WHO, UMC, any other competent authorities, MoH, public, etc) in a timely manner. Inspection report (see below) will be shared with MAH, QPPV and/or their representatives in the country and PBSL website, mass media, official letters to competent authorities will be used to disseminate relevant information.

4.11 Regulatory sanctions

The following regulatory sanctions shall be applied in the case of non-compliance;

a. Non-compliant manufacturer representative or MAH may be inspected to determine the extent of non-compliance and then re-inspected to ensure compliance is achieved.
b. The Board may issue a formal warning reminding MAH of their PV regulatory obligations.
c. The non-compliant MAH may be placed on high risk leading to additional monitoring and re-training.
d. Product recalls e.g. where important safety warnings have been omitted from product information;
e. Deferral of application for registration of product(s) or delays in approval of new products until corrective and preventive or actions have been implemented or the addition of safely conditions to new approvals.
f. The Board may consider making public a list of MAHs found to be seriously or persistently non-compliant
g. Suspension of the Marketing Authorization
h. Revocation of the Marketing Authorization
i. Administrative penalties, usually in the forms of fines as stipulated in the fines schedule

4.12 Penalties

Non-adherence to the requirements of these guidelines by manufacturer representatives and MAH will result in the Board imposing sanctions.

Sanction	Description	Penalty / Consequence
Re-inspection of non-compliant MAH	Inspection conducted to verify the extent of non-compliance and confirm	Cost of re-inspection borne by MAH; CAPA required within 30–90 days.

	corrective actions.	
Formal warning letter	Issued for first-time or administrative non-compliances.	Written warning with deadline for compliance (usually 30 days); recorded in compliance history.
Placement on High-Risk List	Applied when an MAH demonstrates repeated weak PV systems.	Increased inspection frequency, mandatory re-training, affects new product approvals.
Product recall	Used when safety warnings or critical information is missing or risk to patients is identified.	MAH must recall at its own cost and provide recall execution and monitoring reports.
Deferral of product registration or approval	Applied when poor PV performance makes it unsafe to approve additional products.	New product approvals paused until full compliance is demonstrated (3–12 months).
Public listing as non-compliant	Used when MAH repeatedly ignores regulatory directives.	Company listed publicly to warn stakeholders and procurement agencies.
Suspension of Marketing Authorization	Applied when non-compliance poses a serious risk to public health.	Product cannot be imported, sold, or distributed until compliance is restored.
Revocation of Marketing Authorization	Used for severe, persistent, or deliberate violations.	Product is permanently removed from the market; company may be blacklisted.

Administrative fines / penalties	Applied according to severity and recurrence of violations.	Based on fines published by the Board

4.13 Inspection Fees

PV inspection fee(s) (and inspectors' expenses where applicable) will be charged for inspection of new MAH in accordance with the fees published by the Board.

5.0 Glossary

Adverse drug reaction (ADR)	A response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for modification of physiological function.
adverse event/adverse experience	Any untoward medical occurrence in a patient or clinical investigation subject administered a medicinal product and 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 for example), symptom or disease temporarily associated with the use of the medicine.
Board	Pharmacy Board of Sierra Leone (PBSL)

Drug	A drug is a pharmaceutical product, used in or on the human body for the prevention (prophylaxis) mitigation, diagnosis and or treatment of disease, or for the modification of physiological function. This definition includes prescribed medicines, over-the counter medicines, vaccines, herbal medicines, traditional medicines and biologicals (including blood and blood-related products e.g. sera, plasma) and cosmetics, medical devices and nutritional agents.
Expedited reporting	This is the immediate reporting and in not more than 7 calendar days, of a serious adverse reaction to the Board.
Important identified risk and important potential risk	An identified risk or potential risk that could have an impact on the risk-benefit balance of the product or have implications for public health. What constitutes an important risk will depend upon several factors, including the impact on the individual, the seriousness of the risk and the impact on public health. Normally, any risk that is likely to be included in the contraindications or warnings and precautions section of the product information should be considered important.
Local distributor or local agent	A person or company authorized by the Board to manufacture, import, receive as donation, distribute or sell a medicinal product in Sierra Leone.
Local representative	The company or legal entity that represents the MAH in Sierra Leone and performs functions delegated by the MAH.
Manufacturer	A person or a body who sells a product under their own name, or under a trademark, design, trade name or other name or mark owned or controlled by the person or the body, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the product, or for assigning to it a purpose, whether those tasks are performed by that person or not
Marketing	A person or company authorized by the Board to manufacture, import,

authorization holder (MAH)	receive as donation, distribute or sell a medicinal product in Sierra Leone.
missing information	Information about the safety of a medicinal product which is not available at the time of submission of a particular risk management plan and which represents a limitation of the safety data with respect to predicting the safety of the product in the marketplace. Examples of missing information include populations not studied (e.g. pregnant women or patients with severe renal impairment) or where there is a high likelihood of off-label use period.
Post Authorisation Safety Studies (PASS)	Any study relating to an authorized medicinal product conducted with the aim of identifying, characterizing or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures. A PASS may be interventional or non-interventional.
Periodic benefit risk evaluation report (PBRER)	An update of the world-wide marketing experience of a medicinal product at defined times with focus on formal evaluation of benefit in special population at defined times during post-registration.
Periodic safety update report (PSUR)	A regular update of the world-wide safety experience of a medicinal product at defined times during post-registration period.
Pharmacovigilance (PV)	The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.
Pharmacovigilance system master file (PSMF)	A detailed description of the PV system used by the MAH with respect to one or more authorised medicinal products.
Qualified person	An individual named by the MAH and approved by the Board as the

responsible for pharmacovigilance (QPPV)	person responsible for ensuring that the MAH meets its legal obligation in accordance with PBSL PV regulatory obligations in Sierra Leone.
Quality system requirements	Those characteristics of a system that are likely to produce the desired outcome, or quality objectives
Quality management system of a PV system	The organisational structure, responsibilities, procedures, processes and resources of the PV system as well as appropriate resource management, compliance management and record management.
Risk management plan (RMP)	A systematic approach and set of PV activities and interventions designed to identify, characterize, prevent or minimize risks relating to medicinal products, and the assessment of effectiveness of those intervention and how these risks will be communicated to the Board and the general population.
Safety concern	An important identified risk, important potential risk, or important missing information.
Serious adverse drug experience	Serious adverse drug experience is an adverse drug experience that — (A) results in — (i) death (ii) an adverse drug experience that places the patient at immediate risk of death from the adverse drug experience as it occurred (not including an adverse drug experience that might have caused death had it occurred in a more severe form); (iii) inpatient hospitalization or prolongation of existing hospitalization; (iv) a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; or a congenital anomaly or birth defect; or (B) based on appropriate

	medical judgment, may jeopardize the patient and may require a medical or surgical intervention to prevent an outcome described under subparagraph (A**).**
Side effect	It is any unintended effect of a pharmaceutical product occurring at doses normally used in human, which is related to the pharmaceutical properties of the drug." Such effects may or may not be beneficial. Side effects are related to the known properties of the drug and can often be predicted. All drug related reactions, including side effects and suspected adverse drug reactions, are of central interest in PV. HPCs must therefore report all drug related problems to the NPC.
Serious risk	Serious risk means a risk of a serious adverse drug experience
Spontaneous report or Spontaneous notification	Unsolicited communication by a patient, a consumer or healthcare professional to the Board, MAH or local representative or an organization that describes a suspected adverse reaction in a patient, a consumer who is given one or more medicines and which is not derived from a study or any organized data collection systems where adverse event reporting is actively sought.

5.1 Abbreviations

ADR Adverse Drug Reaction

CAPA Corrective and Preventative Action

CT Clinical Trials

EMA European Medicines Agency

EU European Union

GVP Guideline on Good Pharmacovigilance Practices

HCP Healthcare Professionals

ICSR Individual Case Safety Report

MA Marketing Authorisation

MC Market Surveillance and Control

MAH Marketing Authorisation Holder

NCA National Competent Authority

RSI Reference Safety Information

PIL Patient Information Leaflet

PV Pharmacovigilance

PSUR Periodic Safety Update Report

PASS Post-authorisation Safety Study

PSMF Pharmacovigilance System Master File

Quality Assurance

QPPV Qualified Person Responsible for Pharmacovigilance

QMS Quality Management System

RMP Risk Management Plan

SmPC Summary of Product Characteristics

6.0 REFERENCES and INFORMATION SOURCES

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6.1 Legislations and guidelines used to develop this guideline:

- Directive 2001/83 EC as amended
- Regulation 726/2004 European Commission (EC) as amended

- Commission Implementing regulation 520/2012
- Good Pharmacovigilance Practice (GVP) Modules (specifically GVP Module III – Pharmacovigilance Inspections)
- Pharmacovigilance Inspection Union Procedures
- SCOPE WP7 Survey Report: Interaction with Pharmacovigilance Assessors.

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