	TITLE: Pharmacovigilance System, Pharmacovigilance System Master File, and Qualified Person Responsible for Pharmacovigilance	
Rev No: 00	**Doc No: PBSL/GL/055**	Version no. 01
Issue date: 25 Nov 2025	**Effective date: 28 Nov 2025**	Approved by: Registrar

Adopted By PBSL	
Start of public Consultation	
End of public Consultation	
Agreed by QMS committee	
Approved by Board	

PHARMACY BOARD OF SIERRA LEONE

PMB 322

CENTRAL MEDICAL STORES COMPOUND

NEW ENGLAND VILLE

FREETOWN

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Acknowledgement

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 provides an integrated framework for the establishment, implementation, and oversight of pharmacovigilance systems by Marketing Authorization Holders (MAHs) in Sierra Leone. It consolidates three interrelated components—the Pharmacovigilance (PV) System, the Pharmacovigilance System Master File (PSMF), and the role and requirements of the Qualified Person Responsible for Pharmacovigilance (QPPV)—into a single, coherent regulatory reference to ensure effective monitoring of the safety, quality, and benefit-risk balance of medicinal products across their lifecycle.

The guideline outlines the minimum regulatory expectations for MAHs to develop and maintain a functional pharmacovigilance system capable of collecting, managing, and evaluating safety data from both clinical use and post-marketing settings. It emphasizes the need for robust organizational structures, clearly defined responsibilities, transparent communication channels, and adequate resourcing to ensure ongoing product safety surveillance in compliance with national laws and aligned with international best practice standards.

The Pharmacovigilance System Master File (PSMF) serves as the central documentation repository that describes the MAH's PV system, including governance arrangements, standard operating procedures, data handling processes, risk management measures, and quality assurance activities. MAHs are required to keep the PSMF complete, accurate, and readily accessible to the Pharmacy Board of Sierra Leone (PBSL) for inspection or regulatory review.

A Qualified Person Responsible for Pharmacovigilance (QPPV) must be appointed by each MAH to oversee the PV system's performance. The QPPV must possess the appropriate professional competence and authority to ensure that safety concerns are identified, evaluated, and appropriately communicated, and that risk minimization and safety reporting obligations are fulfilled in a timely and consistent manner.

Ultimately, this guideline supports PBSL's mandate to safeguard public health by ensuring that all medicinal products marketed in Sierra Leone are continuously monitored for safety, and that emerging risks are detected early and managed effectively. The implementation of these requirements will strengthen the national pharmacovigilance system, promote transparency, enhance regulatory decision-making, and contribute to improved patient safety outcomes.

Section 1: Pharmacovigilance System

1. Introduction

Pharmacovigilance (PV) systems are used by the marketing authorisation holder (MAH) to fulfil the specific PV tasks and responsibilities designed to monitor the safety of marketed medicinal products and detect any change to their risk-benefit balance. The national PV center of the Pharmacy Board of Sierra Leone is ISO 9001:2015 certified for quality management systems and likewise maintains a PV system to fulfil its PV activities. For performing their PV activities, marketing authorisation holders, shall establish and use quality systems that are adequate and effective for this performance. By following the overall quality objectives in section 4.4 and the guiding principle in section 4.5 to meet the needs of patients, healthcare professionals and the public in relation to the safety of medicines, the application of the quality system should be adapted to how crucial each PV task is for fulfilling the quality objectives for each medicinal product covered by a quality system. The guidance on quality systems in this Module is consistent with the:

- General principles of the ISO 9000 Standards on good quality management practices, specifically the ISO 9001:2015, standards on quality management systems, issued by the International Organization for Standardization (ISO).
- European Medicines Agency (EMA) Guideline on good pharmacovigilance practices (GVP) Module I – Pharmacovigilance systems and their quality systems.

2. Objective

To ensure the establishment and maintenance PV quality systems for MAHs.

3. Scope

This guideline contains directions for the establishment and maintenance of quality assured PV systems for MAHs.

4. Requirements

4.1 Pharmacovigilance system

A PV system is defined as a system used by an organisation to fulfil its legal tasks and responsibilities in relation to PV and designed to monitor the safety of authorised medicinal

products and detect any change to their risk-benefit balance A PV system, like any system, is characterised by its structures, processes and outcomes.

4.2 Quality, quality objectives, quality requirements and quality system

For the purpose of GVP, the quality of a PV system can be defined as all the characteristics of the system which are considered to produce, according to estimated likelihoods, outcomes relevant to the objectives of PV. In general terms, quality is a matter of degree and can be measured. Measuring if the required degree of quality has been achieved necessitates pre-defined quality requirements. Quality requirements are those characteristics of a system that are likely to produce the desired outcome, or quality objectives. Specific quality objectives and quality requirements for the specific structures and processes of the PV systems are provided in other PBSL PV guidelines as appropriate. The quality system is part of the PV system and consists of its own structures and processes. It shall cover organisational structure, responsibilities, procedures, processes and resources of the PV system as well as appropriate resource management, compliance management and record management.

4.3 Quality cycle

The quality system shall be based on all of the following activities:

- quality planning: establishing structures and planning integrated and consistent processes;
- quality adherence: carrying out tasks and responsibilities in accordance with quality requirements;
- quality control and assurance: monitoring and evaluating how effectively the structures and processes have been established and how effectively the processes are being carried out; and
- quality improvements: correcting and improving the structures and processes where necessary.

4.4 Overall quality objectives for pharmacovigilance

The overall quality objectives of a PV system are:

- complying with the legal requirements for PV tasks and responsibilities;
- preventing harm from adverse reactions in humans arising from the use of authorised medicinal products within or outside the terms of marketing authorisation or from occupational exposure;
- promoting the safe and effective use of medicinal products, in particular through providing timely information about the safety of medicinal products to patients, healthcare professionals and the public;
- contributing to the protection of patients' and public health.

4.5 Principles for good pharmacovigilance practices

With the aim of fulfilling the overall quality objectives in section 4.3, the following principles should guide the design of all structures and processes as well as the conduct of all tasks and responsibilities:

- The needs of patients, healthcare professionals and the public in relation to the safety of medicines should be met.
- Upper management should provide leadership in the implementation of the quality system and motivation for all staff members in relation to the quality objectives.
- All persons within the organisation should be involved in and support the PV system on the basis of task ownership and responsibility in a degree according to their tasks and assigned responsibilities.
- All persons involved with the entire organisation should engage in continuous quality improvement following the quality cycle described in section 4.3.
- Resources and tasks should be organised as structures and processes in a manner that will support the proactive, risk-proportionate, continuous and integrated conduct of PV.

- All available evidence on the risk-benefit balance of medicinal products should be sought and all relevant aspects, which could impact on the risk-benefit balance and the use of a product, should be considered for decision-making.
- Good cooperation should be fostered between MAHs, public health organisations, the national PV centre, patients, healthcare professionals, and other relevant bodies in accordance with the applicable legal provisions.

4.6. Responsibilities for the quality system within an organisation

A sufficient number of competent and appropriately qualified and trained personnel shall be available for the performance of PV activities. Their responsibility should include adherence to the principles defined in section 4. For the purpose of a systematic approach towards quality in accordance with the quality cycle, managerial staff (i.e. staff with management responsibilities) in any organisation should be responsible for:

- ensuring that the organisation documents the quality system as described in section 4.9.3
- ensuring that the documents describing the quality system are subject to document control in relation to their creation, revision, approval and implementation;
- ensuring that adequate resources are available and that training is provided (see section 4.7);
- ensuring that suitable and sufficient premises, facilities and equipment are available (see section 4.8);
- ensuring adequate compliance management (see section 4.9.1);
- ensuring adequate record management (see section 4.9.2);
- reviewing the PV system including its quality system at regular intervals in risk-based manner to verify its effectiveness and introducing corrective and preventive measures where necessary;
- ensuring that mechanisms exist for timely and effective communication, including escalation processes of safety concerns relating to medicinal products within an organisation;

- identifying and investigating concerns arising within an organisation regarding suspected nonadherence to the requirements of the quality and PV systems and taking corrective, preventive and escalation action as necessary;
- ensuring that audits are performed.

In relation to the management responsibilities described above, upper management within an organisation should provide leadership through:

- motivating all staff members, based on shared values, trust and freedom to speak and act with responsibility and through recognition of staff members' contributions within the organisation; and
- assigning roles, responsibilities and authorities to staff members according to their competencies and communicating and implementing these throughout the organisation.

4.7. Training of personnel for pharmacovigilance

Achieving the required quality for the conduct of PV processes and their outcomes by an organisation is intrinsically linked with the availability of a sufficient number of competent and appropriately qualified and trained personnel.

All personnel involved in the performance of PV activities shall receive initial and continued training. For MAHs, this training shall relate to the roles and responsibilities of the personnel as described in section 3.

The organisation shall keep annual training plans and records for documenting, maintaining and developing the competences of personnel. Training plans should be based on training needs assessment and should be subject to monitoring. The training should support continuous improvement of relevant skills, the application of scientific progress and professional development and ensure that staff members have the appropriate qualifications, understanding of relevant PV requirements as well as experience for the assigned tasks and responsibilities. All staff members of the organisation should receive

and be able to seek information about what to do if they become aware of a safety concern.

There should be a process in place within the organisation to check that training results in the appropriate levels of understanding and conduct of PV activities for the assigned tasks and responsibilities, or to identify unmet training needs, in line with professional development plans agreed for the organisations as well as the individual staff members.

Adequate training should also be considered by the organisation for those staff members to whom no specific PV tasks and responsibilities have been assigned but whose activities may have an impact on the PV system or the conduct of PV. Such activities include but are not limited to those related to clinical trials, technical product complaints, medical information, terminologies, sales and marketing, regulatory affairs, legal affairs and audits. Appropriate instructions on the processes to be used in case of urgency, including business continuity, shall be provided by the organisation to their personnel.

4.8. Facilities and equipment for pharmacovigilance

Achieving the required quality for the conduct of PV processes and their outcomes is also intrinsically linked with appropriate facilities and equipment used to support the processes. Facilities and equipment should include office space, information technology (IT) systems and (electronic) storage space. They should be located, designed, constructed, adapted and maintained to suit their intended purpose in line with the quality objectives for PV and also be available for business . continuity. Facilities and equipment which are critical for the conduct of PV should be subject to appropriate checks, qualification and/or validation activities to prove their suitability for the intended purpose. There should be processes in place to keep the IT systems up-to-date accordingly.

4.9 Specific quality system procedures and processes

4.9.1 Compliance management by marketing authorisation holders

For the purpose of compliance management, MAHs shall have specific quality system procedures and processes in place in order to ensure the following:

- the continuous monitoring of PV data, the examination of options for risk minimisation and prevention and that appropriate measures are taken by the MAH;
- the scientific evaluation of all information on the risks of medicinal products as regards patients' or public health, in particular as regards E reactions in human beings arising from use of the product within or outside the terms of its marketing authorisation or associated with occupational exposure;
- the submission of accurate and verifiable data on serious and non-serious adverse reactions to the Board within the legally required time-limits;
- the quality, integrity and completeness of the information submitted on the risks of medicinal products, including processes to avoid duplicate submissions and to validate signals;
- effective communication by the MAH with the Board including communication on new or changed risks, the PV system master file, risk management systems, risk minimisations measures, periodic safety update reports, corrective and preventive actions and post-authorisation safety studies;
- the update of product information by the MAH in the light of scientific knowledge;
- appropriate communication of relevant safety information to healthcare professionals and patients.

4.9.2 Record management

The organisation shall record all PV information and ensure that it is handled and stored so as to allow accurate reporting, interpretation and verification of that information. A record management system shall be put in place for all documents used for PV activities, ensuring their retrievability as well as traceability of the measures taken to investigate safety concerns, of the timelines for those investigations and of decisions on safety concerns, including their date and the decision-making process. The record management system should support:

- the management of the quality of PV data, including their completeness, accuracy and integrity;
- timely access to all records;
- effective internal and external communication; and
- the retention of documents relating to the PV systems and the conduct of PV for individual medicinal products, in accordance with the applicable retention periods.

In addition, MAHs shall establish mechanisms enabling the traceability and follow-up of adverse reaction reports. In this context, it should be ensured that the fundamental right to personal data protection is fully and effectively guaranteed in all PV activities in conformity with legal provisions. The purpose of safeguarding public health constitutes a substantial public interest and consequently the processing of personal data should be justified if identifiable personal data are processed only where necessary and only where the parties involved assess this necessity at every stage of the PV process. As part of a record management system, specific measures should therefore be taken at each stage in the storage and processing of PV data to ensure data security and confidentiality. This should involve strict limitation of access to documents and to databases to authorised personnel respecting the medical and administrative confidentiality of the data. There should be appropriate structures and processes in place to ensure that PV data and records are protected from destruction during the applicable record retention period. The record management system should be described in a record management policy.

4.9.3 Documentation of the quality system

All elements, requirements and provisions adopted for the quality system shall be documented in a systematic and orderly manner in the form of written policies and procedures, such as quality plans, quality manuals and quality records. A quality plan documents the setting of quality objectives and sets out the processes to be implemented to achieve them. A procedure is a specified way to carry out a process and may take the format of a standard operating procedure and other work instruction or quality manual. A

quality manual documents the scope of the quality system, the processes of the quality system and the interaction between the two. A quality record is a document stating results achieved or providing evidence of activities performed.

In order to have a systematic approach, the organisation should define in advance:

- quality objectives specific to their organisations in accordance with the overall quality objectives provided under section 4.4 and the structure- and process-specific quality objectives; and
- methods for monitoring the effectiveness of the PV system (see section 6 below.).

The quality system shall be documented by:

- documents on organisational structures and assignments of tasks to personnel (see sections 4.9.4 and 4.9.5 below);
- training plans and records (see section 4.7 above); shall be kept and made available for audit and inspection.
- instructions for the compliance management processes (see section 4.9.1 above.)
- appropriate instructions on the processes to be used in case of urgency, including business continuity (see section 4.9.1);
- performance indicators where they are used to continuously monitor the good performance of PV activities;
- reports of quality audits and follow-up audits, including their dates and results.

It is recommended that the documentation of the quality system also includes:

- the methods of monitoring the efficient operation of the quality system and, in particular, its ability to fulfil the quality objectives;
- a record management policy;
- records created as a result of PV processes which demonstrate that key steps for the defined procedures have been taken;

- records and reports relating to the facilities and equipment including functionality checks, qualification and validation activities which demonstrate that all steps required by the applicable requirements, protocols and procedures have been taken;
- records to demonstrate that deficiencies and deviations from the established quality system are monitored, that corrective and preventive actions have been taken, that solutions have been applied to deviations or deficiencies and that the effectiveness of the actions taken has been verified.

4.9.4 Additional quality system documentation by marketing authorisation holders

In addition to the quality system documentation, MAHs shall document:

- their human resource management in the PV system master file (PSMF) (see section 2 of this guideline)
- job descriptions defining the duties of the managerial and supervisory staff;
- an organisational chart defining the hierarchical relationships of managerial and supervisory staff;
- instructions on critical processes in the PV system master file (PSMF);
- their record management system in the PV system master file (PSMF).

It is recommended that the documentation of the quality system additionally include the organisational structures and assignments of tasks, responsibilities and authorities to all personnel directly involved in PV tasks.

4.9.5 Critical pharmacovigilance processes and business continuity

The following PV processes should be considered as critical:

- continuous safety profile monitoring and benefit-risk evaluation of authorised medicinal products;
- establishing, assessing and implementing risk management systems and evaluating the effectiveness of risk minimisation;

- collection, processing, management, quality control, follow-up for missing information, coding, classification, duplicate detection, evaluation and timely electronic transmission of individual case safety reports (ICSRs) from any source;
- signal management;
- scheduling, preparation (including data evaluation and quality control), submission and assessment of periodic safety update reports;
- meeting commitments and responding to requests from the Board, including provision of correct and complete information;
- interaction between the PV and product quality defect systems;
- communication about safety concerns between MAHs and the Board, in particular notifying changes to the risk-benefit balance of medicinal products;
- communicating information to patients and healthcare professionals about changes to the risk benefit balance of products for the aim of safe and effective use of medicinal products;
- keeping product information up-to-date with the current scientific knowledge, including the conclusions of the assessment and recommendations from the Board;
- implementation of variations to marketing authorisations for safety reasons according to the urgency required.

4.9.5 Business continuity plans

Business continuity plans should be established in a risk-based manner and should include:

- provisions for events that could severely impact on the organisation's staff and infrastructure in general or on the structures and processes for PV in particular; and
- back-up systems for urgent exchange of information within an organisation, amongst organisations sharing PV tasks as well as between MAHs and the Board.

4.10 Monitoring of the performance and effectiveness of the pharmacovigilance system and its quality system

Processes to monitor the performance and effectiveness of a PV system and its quality system should include:

- reviews of the systems by those responsible for management;
- audits;
- compliance monitoring;
- inspections;
- evaluating the effectiveness of actions taken with medicinal products for the purpose of minimising risks and supporting their safe and effective use in patients.

The organisation may use performance indicators to continuously monitor the good performance of PV activities in relation to the quality requirements. The requirements for the quality system itself are laid out in this Module and its effectiveness should be monitored by managerial staff, who should review the documentation of the quality system (see section 2.5) at regular intervals, with the frequency and the extent of the reviews to be determined in a risk-based manner. Pre-defined programmes for the review of the system should therefore be in place. Reviews of the quality system should include the review of standard operating procedures and work instructions, deviations from the established quality system, audit and inspections reports as well as the use of the indicators referred to above.

Risk-based audits of the quality system shall be performed at regular intervals to ensure that it complies with the requirements for the quality system, the human resource management, the compliance management, the record management and the data retention and to ensure its effectiveness. Audits of the quality system should include audit of the PV system which is the subject of the quality system. In relation to the PV system of a MAH, a report shall be drawn up on the results for each quality audit and any follow-up audits be sent to the management responsible for the matters audited. The report should include the results of audits of organisations or persons the MAH has delegated tasks to, as these are part of the MAH‘s PV system.

As a consequence of the monitoring of the performance and effectiveness of a PV system and its quality system (including the use of audits), corrective and preventive measures should be implemented when deemed necessary. In particular as a consequence of audits, corrective action(s), including a follow-up audit of deficiencies, shall be taken where necessary.

Section 2: Pharmacovigilance System Master File

1. Introduction

The Pharmacovigilance System Master File (PSMF) shall be located either at the site in the Sierra Leone where the main PV activities of the MAH are performed or at the site in the Sierra Leone where the qualified person responsible for PV operates. It is a requirement of the marketing authorisation application that summary information about the PV system is submitted to the Board. This Module provides detailed guidance regarding the requirements for the PSMF, including its maintenance, content and associated submissions to the Board.

2. Objective

To describe the PV system and support/document its compliance with the requirements and to also contribute to the appropriate planning and conduct of audits by the applicant or marketing authorisations holder(s), the fulfilment of supervisory responsibilities of the QPPV, and of inspections or other verification of compliance by the Board.

3. Scope

This guidance concerns the requirements for the PSMF and is applicable for any medicinal product authorised for use in the Sierra Leone, irrespective of the marketing authorisation procedure. The required content and management of the PSMF applies irrespective of the organisational structure of a MAH, including any subcontracting or delegation of activities, or their location. The content of the PSMF should reflect global availability of safety information for medicinal products authorised in the Sierra Leone, presenting information on the PV system applied at global, regional and local levels.

4. Requirements

4.1. Summary of the applicant's pharmacovigilance system

MAHs are required to submit a summary of their PV system, which shall be included in the marketing authorisation application for new applications and renewals and shall include the following elements in module 1.8.1 of the common technical document (CTD) dossier:

- proof that the applicant has at his disposal a qualified person responsible for PV;
- the contact details of the qualified person;
- a statement signed by the applicant to the effect that the applicant has the necessary means to fulfil the required tasks and responsibilities
- a reference to the location where the PSMF for the medicinal product is kept.

4.2 Location, registration and maintenance

The PSMF shall be located within Sierra Leone, either at the site where the main PV activities are performed or at the site where the qualified person responsible for PV operates, irrespective of the format (paper-based or electronic format file). At the time of marketing authorisation application, the applicant should submit the PSMF reference number.

MAHs shall continue to ensure that their PSMF are up-to-date, including the information about the qualified person responsible for pharmacovigilance (QPPV), name and contact details (telephone and fax numbers, postal address and email addresses) For specific details on content and structure of the PSMF, see section 4.5 below. Upon a change in the QPPV or location of the PMSF information, PSMF shall be updated by the MAH immediately and no later than 30 working days, and to allow continuous supervision by the Board. The PBSL must also be notified of such changes.

The required location information for the PSMF is a physical office address of the MAH. Where the PSMF is held in electronic form, the location stated must be a site where the data stored can be directly accessed, and this is sufficient in terms of a practical electronic location.

4.3 Transfers of responsibilities for the pharmacovigilance system master file

The PV system may change with time. Transfer or delegation of responsibilities and activities concerning the master file should be documented and managed to ensure that

the MAH fulfils their responsibilities. Since a specific QPPV has responsibility for the PV system, changes to the PSMF should also be notified to the QPPV in order to support their authority to make improvements to the system. The types of changes that should be routinely and promptly notified to the QPPV are:

- Updates to the PSMF or its location that are notified to the Board;
- The addition of corrective and/or preventative actions to the PSMF (e.g. following audits and inspections). The QPPV should also be able to access information about deviations from the processes defined in the quality management system for PV;
- Changes to content that fulfil the criteria for appropriate oversight of the PV system (in terms of capacity, functioning and compliance);
- Changes in arrangements for the provision of the PSMF to the Board;
- Transfer of significant services for PV to a third party (e.g. outsourcing of PSUR production);
- Inclusion of products into the PV system for which the QPPV is responsible;
- Changes for existing products which may require a change or increased workload in relation to PV activity e.g. new indications, studies or the addition of territories.

Any recipient QPPV should explicitly accept the responsibility for a PV system in writing. The QPPV should be in a position to ensure and to verify that the information contained in the PSMF is an accurate and up to date reflection of the PV system under his/her responsibility.

4.4 The representation of pharmacovigilance systems

The PSMF, shall describe the PV system for one or more medicinal products of the MAH. For different categories of medicinal products, the MAH may, if appropriate, apply separate PV systems. Each such system shall be described in a separate PSMF. Those files shall cumulatively cover all medicinal products of the MAH for which a marketing authorisation has been issued or an authorisation has been granted.

- It is anticipated that there will be circumstances where a single MAH or local agent may establish more than one PV system e.g. specific systems for particular types of

products, manufacturers (vaccines, consumer health, etc.), or that the PV system may include products from more than one MAH or local agents. In either case, a single and specific PSMF shall be in place to describe each system.

- A single QPPV shall be appointed to be responsible for the establishment and maintenance of the PV system described in the PSMF.
- Where a PV system is shared by several MAHs each MAH is responsible ensuring that a PSMF exists to describe the PV system applicable for his products. For a particular product(s) the MAH may delegate through written agreement (e.g. to a licensing partner or contractor) part or all of the PV activity for which the MAH is responsible. In this case the PSMF of the MAH may cross refer to all or part of the PSMF managed by the system of the party to whom the activity has been delegated subject to agreement on access to that system's information for the MAH and the authorities. The MAH should be able to assure the content of the referenced file(s) in relation to the PV system applicable to their product(s). Activities for maintaining the PSMF in a current and accessible state can be delegated.
- Where applicable, a list of all PSMFs held by the same MAH shall be provided in the annex; this includes their location(s), details of the responsible QPPV(s) and the relevant product(s).
- When delegating any activities concerning the PV system and its master file, the MAH retains ultimate responsibility for the PV system, submission of information about the PSMF location, maintenance of the PSMF and its provision to the Board upon request. Detailed written agreements describing the roles and responsibilities for PSMF content, submissions and management, as well as to govern the conduct of PV should be in place.
- When a PV system is shared, it is advised that the partners agree on how to mutually maintain the relevant sections within their own PSMFs. Accessibility of the PSMF to all the applicable MAH(s), and its provision to the Board should be defined in written agreements. It is vital that MAH(s) can gain assurance that the PV system used for its products is appropriate and compliant.

4.5 Content and structure of the pharmacovigilance system master file

The PSMF shall describe the PV system. The contents of the PSMF should reflect the global availability of safety information for medicinal products authorised in Sierra Leone. The main principle for the structure of the content of the PSMF is that the primary topic sections contain information that is fundamental to the description of PV system. Detailed information is required to fully describe the system, and, since this may change frequently, it should be referred to and contained in the Annexes. It is accepted that, where no marketing authorisation (and master file) previously existed in Sierra Leone, there may be information that cannot be initially provided, for example, compliance information, however, descriptions of what will be implemented should be provided instead.

Cover page	The name of the MAH or Local Representative. The date of preparation and last update (version) and reference number.
Section 1: Administrative Information	A signed statement that the Local Representative or the MAH (MAH) has the necessary means to fulfill the tasks and responsibilities as stated in PBSL Guide for Safety Monitoring of Medicines in Sierra Leone.
Section 2- Qualified person responsible for pharmacovigilance (QPPV)	• a description of the responsibilities and job description guaranteeing that the qualified person has sufficient authority over the PV system in order to promote, maintain and improve compliance; • curriculum vitae with the key information on the role of the QPPV, including proof of registration and certification as a QPPV in Sierra Leone; • contact details; • a signed contract between the Local Representative or the MAH and the QPPV • details of back-up arrangements to apply in the absence of the

	QPPV; and • a list of tasks that have been delegated by the QPPV shall also be included in the Annexes. This should outline the activities that are delegated and to whom, and include the access to a medically qualified person if applicable. • The details provided in relation to the QPPV should also include: ✓ the description of the QPPV qualifications, experience and registrations relevant to PV (including registration and certification as a QPPV in Sierra Leone). ✓ The contact details supplied should include name, postal address, telephone, fax and e-mail and represent the usual working address of the QPPV, which may therefore be different to a MAH address. ✓ If the QPPV is employed by a third party, even if the usual working address is an office of the MAH, this should be indicated and the name of the company the QPPV works for provided.
Section 3- Organisational structure of the marketing authorisation holder	A description of the organisational structure of the MAH relevant to the PV system must be provided. The description should provide a clear overview of the company(ies) involved, the main PV departments and the relationship(s) between organisations and operational units relevant to the fulfilment of PV obligations. This should include third parties. Specifically, the PSMF shall describe: • The organisational structure of the MAH(s) or local agent, showing the position of the QPPV in the organisation. • The site(s) where the PV functions are undertaken covering individual case safety report collection, evaluation, safety database

	case entry, periodic safety update report production, signal detection and analysis, risk management plan management, pre- and post-authorisation study management, and management of safety variations to product particulars. • Diagrams showing the organizational charts will be helpful and preferred. • Any PV related activities performed by third parties • Description of co-marketing agreements and contracts of PV activities, if any. • List of product(s) for which the QPPV is responsible
Section 4-Sources of safety data	• Flow diagrams and Inflow of adverse reaction reports and safety information and description of the stages involved in the processing of ICSRs including the timelines for submission to the Board should be provided. • Outflow of safety data to regulatory authorities including the Board should also be indicated. • For the purposes of inspection and audit of the PV system, sources of safety data, including but not limited to spontaneous reports, sources include data arising from study sources, including any studies, registries, surveillance or support programmes sponsored by the MAH through which ICSRs could be reported. MAHs should be able to produce and make available a list of such sources to support inspection, audit and QPPV oversight.
Section 5-Computerised systems and databases	• The location, functionality and operational responsibility for computerised systems and databases used to receive, collate, record and report safety information and an assessment of their fitness for purpose shall be described in the PSMF.

	• The validation status of key aspects of computerised system functionality should also be described; ✓ the change control, ✓ nature of testing, ✓ back-up procedures and ✓ electronic data repositories vital to PV compliance should be included in summary, and ✓ the nature of the documentation available described. • For paper-based systems (where an electronic system may only be used for expedited submission of ICSRs), the management of the data, and mechanisms used to assure the integrity and accessibility of the safety data, and in particular the collation of information about adverse drug reactions, should be described.
Section 6- Pharmacovigilance processes	An essential element of any PV system is that there are clear written procedures in place. A description of the procedural documentation available that are aligned with national law, regulation and guidelines on PV and in compliance with international standards, guidelines and recommendations (e.g. EU GVP), the nature of the data held (e.g. the type of case data retained for ICSRs) and an indication of how records are held (e.g. safety database, paper file at site of receipt) should be provided in the PSMF. Details of all the current standard operating procedures relating to PV which are expected includes but not limited to the following; 1. Archiving and retrieval 2. Corrective and Preventive Action (CAPA) processes for PV 3. Causality assessment, if applicable 4. Coding of Individual Case Safety Reports (ICSRs), if applicable

	5. Communication of safety concerns to patients/consumers, healthcare professionals and the Board 6. Complaint handling 7. Deviation Documentation 8. Escalation of safety issues 9. Handling of Counterfeits 10. Internal audits 11. Literature searches (scientific and lay media) 12. Management of PV inspections 13. Manual handling of ICSRs, if applicable 14. ICSR collection, collation, follow up, assessment and reporting 15. Scheduling, production and submission of regulatory documents (e.g. PSURs/PBRERs, RMPs), if applicable 16. Signal generation 17. SOP for developing and maintaining SOPs 18. Training 19. Implementation of safety variations to the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL), if applicable 20. Risk management system(s) and monitoring of the outcome of risk minimisation measures The list, which may be located in the Annexes, should comprise the procedural document reference number, title, effective date and document type (for all standard operating procedures, work instructions, manuals etc.). Procedures belonging to service providers and other third parties should be clearly identified.
Section 7- Pharmacovigilance system	The PSMF should contain evidence of the ongoing monitoring of performance of the PV system including compliance of the main outputs of PV. The PSMF should include a description of the monitoring

performance	methods applied and contain as a minimum: • An explanation of how the correct reporting of ICSRs is assessed. In the annex, figures/graphs should be provided to show the timeliness of 15-day and 90-day reporting over the past year; • A description of any metrics used to monitor the quality of submissions and performance of PV. This should include information provided by competent authorities like the Board regarding the quality of ICSR reporting, PSURs or other submissions; • An overview of the timeliness of PSUR reporting to the Board (the annex should reflect the latest figures used by the MAH to assess compliance); • An overview of the methods used to ensure timeliness of safety variation submissions compared to internal and the Board's deadlines, including the tracking of required safety variations that have been identified but not yet been submitted; • Where applicable, an overview of adherence to risk management plan commitments, or other obligations or conditions of marketing authorisation(s) relevant to PV. Targets for the performance of the PV system shall be described and explained and a list of performance indicators must be provided.
Section 8-quality system	A description of the quality management system should be provided, in terms of the structure of the organisation and the application of the quality to PV. This shall include: **<u>Document and Record Control</u>** A description of the archiving arrangements for electronic and/or hardcopy versions of the PSMF should be provided, as well as an overview of the procedures applied to other quality system and PV

records and documents.

Procedural documents

- A general description of the types of documents used in PV (standards, operating procedures, work instructions etc), the applicability of the various documents at global, regional or local level within the organisation, and the controls that are applied to their accessibility, implementation and maintenance.
- A list of specific procedures and processes related to the PV activities and interfaces with other functions, with details of how the procedures can be accessed must be provided.

Training

- A description of the resource management for the performance of PV activities: – the organisational chart giving the number of people (full time equivalents) involved in PV activities, which may be provided in the section describing the organisational structure
- A summary description of the training concept, including a reference to the location training files. Staff should be appropriately trained for performing PV related activities and this includes not only staff within PV departments but also any individual that may receive safety reports.
- Evidence of training should be available (certificate, attendance list, training materials etc)

Auditing

- Information about quality assurance auditing of the PV system should be included in the PSMF. A description of the approach used to plan audits of the PV system and the reporting mechanism and timelines should be provided, with a current list of the scheduled and completed audits concerning the PV system maintained in the

	annex of the PSMF This list should describe the date(s) (of conduct and of report), scope and completion status of audits of third parties including Local Distributors. • The PSMF shall also contain a note associated with any audit where significant findings are raised. This means that the presence of findings that fulfil the criteria for major or critical findings must be indicated. The audit report must be documented within the quality system; in the PSMF it is sufficient to provide a brief description of the corrective and/or preventative action(s) associated with the significant finding, the date it was identified and the anticipated resolution date(s), with cross reference to the audit report and the documented corrective and preventative action plan(s). In case corrective and preventative action plan(s) have not yet been agreed for a particular audit or finding, the PSMF should include the note required and stating that "corrective and preventative action plan(s) are to be agreed". In the annex, in the list of audits conducted, those associated with unresolved notes in the PSMF, should be identified. The note and associated corrective and preventative action(s), shall be documented in the PSMF until the corrective and/or preventative action(s) have been fully implemented, that is, the note is only removed once corrective action and/or sufficient improvement can be demonstrated or has been independently verified • The addition, amendment or removal of the notes must therefore be recorded in the logbook. As a means of managing the PV system, and providing a basis for audit or inspection, the PSMF should also describe the process for recording, managing and resolving deviations from the quality system. The master file shall also document deviations from PV procedures, their impact and

	management until resolved. This may be documented in the form of a list referencing a deviation report, and its date and procedure concerned.
Section 9-Annex to the PSMF	An annex to the PSMF shall contain the following documents: • A list of medicinal products covered by the PSMF including the name of the medicinal product, the international non-proprietary name of the active substance(s); • For marketing authorisations that are included in a different PV system, for example, because the MAH has more than one PV system or third-party agreements exist to delegate the system, reference to the additional PSMF(s) should also be provided as a separate list in the Annexes, such that, for a MAH, the entire product portfolio can be related to the set of PSMFs. • Where PV systems are shared, all products that utilise the PV system should be included, so that the entire list of products covered by the file is available. The products lists may be presented separately, organised per MAH. Alternatively, a single list may be used, which is supplemented with the name of the MAH(s) for each product, or a separate note can be included to describe the product(s) and the MAH(s) covered; • A list of written policies and procedures for the purpose of complying with the Board's PV requirements • A list of contractual agreements covering delegated; • A list of tasks that have been delegated by the QPPV; • A list of all completed audits, for a period of five years, and a list of audit schedules; • Where applicable, a list of performance indicators; • Where applicable, a list of other PSMFs held by the same MAH or local agents; This list should include the PSMF number(s), and the

	name of MAH of the QPPV responsible for the PV system used. If the PV system is managed by another party that is not a MAH, the name of the service provider should also be included. • Updated training materials and records of the training should be provided including assessment of the effectiveness of the training programmes • PV agreement between the MAH/Local Representative and the Local Distributor(s) • A logbook. Other change control documentation should be included as appropriate. Documented changes shall include at least the date, person responsible for the change and the nature of the change. • That list of any PASS OR PAES studies that are being performed by the MAH in SL or in other territories on the same products marketed in SL, should be provided. • Also any unresolved or open CAPA issues should be described as an annex. • Also an annex of the review schedules of the procedures/system should be included. • Safety data surveillance schedule should be provided.

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Section 3: Requirement for Qualified Person responsible for Pharmacovigilance (QPPV)

1. Introduction

Pharmacy Board of Sierra Leone (PBSL) is mandated to ensure that manufacturer' representatives or marketing authorisation holders (MAH) have a functional PV system in place so that they can assume responsibility and liability for their products on the market and to ensure that appropriate actions are taken when necessary. The manufacturer representative or MAH should ensure that all information that is important to the benefit-risk ratio of a product is reported promptly to PBSL in accordance with PBSL's PV regulatory obligations as stipulated in the Law and guidelines.

2. Objective

To provide a guide for MAHs in selecting a QPPV.

3. Scope

This guideline covers the roles and responsibilities of the QPPV and MAH

4. Requirements

4.1 Qualifications of QPPV

a) The QPPV shall have a degree in pharmacy, medicine, or any other science discipline deemed acceptable by the Board.
b) The Board may also accept a person with a relevant scientific discipline with at least two years minimum experience with specific job function in the area of PV for designation as the QPPV.
c) The QPPV should have received a formal training in PV recognized by the Board.
d) The QPPV should have knowledge of PBSL PV legislation and guidelines and other international standards for PV such as ICH E2A-F
e) An applicant will be designated QPPV if s/he fulfils the above (a-d) with a completed application form (Appendix 4).

4.2 Back-up QPPV

a) The Back-up QPPV shall meet all the requirements of a QPPV and must perform the role for a minimum of 30 working days. The Back-up QPPV shall however receive training in PV appropriate for his/her roles.

b) In addition to the above the QPPV and the Back-up QPPV should have knowledge on applicable Sierra Leone safety monitoring legislation and guidelines and international standards for PV and also demonstrate (e.g. through qualifications and training) that he/she has knowledge of the key PV activities performed as part of the MAH's PV system and how to implement them.

4.3 Re-Designation of QPPV

a) The QPPV shall be eligible for the performance of the responsibilities assigned for a period of three (3) years after successfully completing the training programme described in Section 5.1.1.3.

b) The Board shall re-designate the QPPV for another three years upon application (Refer Appendix 5) and evidence of the underlisted conditions.

c) No pending Corrective Action Plan (CAP) after a GVP inspection.

d) Good standing in the professional body/association the QPPV belongs to (e.g. Sierra Leone Medical and Dental Council, Pharmaceutical Society of Sierra Leone etc).

e) Participation in at least one PV conference OR training programme relevant to patient safety OR passing a written exam related to the QPPV roles administered by the Board.

4.4 Responsibilities of QPPV

a) The QPPV should have oversight of the PV system in relation to structure and proper functioning and be in a position to ensure that all responsibilities are performed well and to ensure in particular the following system components and processes, either directly or through supervision. The QPPV should reside in Sierra Leone.

b) The QPPV should act as a point of contact for the MAH on all matters relating to PV and safety of marketed products including PV inspections. He or she should be available during PV inspections.

c) Establishment and maintenance of a system which ensures that information about all suspected adverse drug reactions/ events which are reported to the personnel of the MAH and to the medical representatives is collected, collated and assessed for onward submission to the Board.

d) The QPPV should have access to the PSMF and be in a position of authority to ensure and to verify that the information contained in the PSMF is an accurate and up-to-date reflection of the PV system under the QPPV's responsibility. All PSMFs submitted shall be accompanied by a declaration to be signed by the QPPV (Refer Appendix 6). The declaration should indicate that the QPPV has read the RMP and will ensure implementation of all activities outlined in the RMP.

e) Providing input into the preparation of regulatory action in response to emerging safety concerns (e.g. variations, urgent safety restrictions, and communication to patients and healthcare professionals);

f) Prepare the following documents for submission to the Board:

   i. Adverse Drug Reaction reports/ individual case safety reports (ICSRs)
   ii. Periodic Safety Update Reports (PSURs)/Periodic Benefit-Risk Evaluation Report PBRER), when necessary
   iii. Company-sponsored pre-and post-registration safety and efficacy study reports
   iv. Risk Management Plan (RMP). All RMPs submitted shall be accompanied by a declaration to be signed by the QPPV (Refer Appendix 7). The declaration should indicate that the QPPV has read the RMP and will ensure implementation of all activities outline in the RMP.
   v. Line listing
   vi. Summary report

g) Ensure that any request from the Board for additional information deemed necessary for the evaluation of the risk–benefit afforded by a marketed product, is provided to PBSL promptly and fully. Inclusive of information on sales volume or prescriptions of the medicines concerned

h) Ensure safety monitoring oversight of the marketed products and any emerging safety concerns

i) Notify the Board within fourteen (14) days from the date he/she ceases to be QPPV for the MAH.

j) Act as a contact point for the Board on a 24-hr basis.

The oversight by the QPPV referred to above should cover the functioning of the MAH PV system in all relevant aspects, including quality control and assurance procedures, SOPs, database operations, contractual agreements, compliance data (e.g. with respect to the quality, completeness and timeliness for expedited reporting and submission of PSURs), audit reports and training of personnel in relation to PV

4.5 Timelines for reporting (See appendix 8 for summary)

a) Local Representative or MAH shall submit all relevant information available at the time of initial notification of an adverse drug reaction report. Details including but not limited to post-mortem reports, relevant laboratory data may be attached when necessary. The original words/description (verbatim) used by the initial reporter to describe the adverse reaction should be provided. The medicine (or trade) name must be provided as reported by the initial reporter. Additional information, not available at the time of initial report, should be provided in the form of follow-up reports. The Local Representative or MAH is required to submit the name or initials, address and telephone number and qualification of the initial reporter on the adverse drug reaction report form.

b) **Serious adverse reaction reports** received by the Local Representative or the MAH shall be submitted to the Board within 15 calendar days. In case all the information needed is not available within 15 days, the Local Representative or MAH shall submit

an initial report containing at least the minimum data elements required (i.e. patient details, suspected product details, reaction details and the reporter details) in order to meet the expedited reporting time frames. A follow-up report containing more detailed information should be submitted later as soon as this becomes available.

c) All non-serious suspected adverse drug reactions, occurring in Sierra Leone with any medicine, must be reported by the applicant within 90 calendar days on first notification.

d) Local Representative or MAH is required to **search widely referenced databases (e.g. google scholar, Pubmed)** on weekly basis and submit any case originating from Sierra Leone on registered products to the Board. Local Representatives or MAHs are also required to search local scientific and medical journals not included in widely referenced databases on scheduled basis depending on the periodicity of such journals and submit any publication identified as coming from Sierra Leone on marketed products to the Board. Publications should be accompanied by a copy of the article. If the article describes identifiable patients, adverse reaction report(s) should be completed for each patient and the publication authors considered as the primary source.

e) **Reports from lay press** should be handled as spontaneous report; every attempt should be made to collect minimum information that constitutes a valid ICSR. The same timelines apply as for spontaneous reports.

f) **Internet or Digital media under the management of MAH** shall be screened regularly for adverse reaction reports and report to the Board within the specified timelines. Reports from noncompany sponsored internet sites or social media (e.g. Facebook, WhatsApp, Twitter, TikTok, Instagram etc) should be assessed to determine whether minimum reporting criteria are met and these should also be treated as spontaneous reports.

g) All safety information that becomes available to the Local Representative or MAH as a result of follow-up activities should also be reported within 7 calendar days.

h) All Suspected Unexpected Serious Adverse Reactions (SUSARs) occurring in all **post authorization safety studies in Sierra Leone of which the Local Representative or MAH is aware** and includes the design and conduct of company-sponsored Post Marketing Surveillance (PMS) Studies (i.e Phase IV clinical trials) should be reported within 15 days. However, if the **post-authorization safety study is conducted by an investigator** independent of the Local Representative or MAH (e.g. "investigator –initiated post authorization safety study"), the responsibility for reporting adverse reactions to the Board shall rest with the investigator and not the Local Representative or MAH.

i) Significant safety issues identified by the Local Representative or MAH as a result of ongoing review and analysis of all information (including foreign ADR reports) that is pertinent to the safety **or benefit-risk assessment of the product or action taken by a foreign regulatory agency**, including the basis for such actions shall be reported to the Authority within 7 days.

j) **Foreign regulatory agency decisions** to be communicated to the Board include:

k) Any matter relating to the safety of the product, withdrawal or suspension of availability of the product, the addition of a contraindication or the modification for safety reasons of an existing contraindication, warning or precaution statement in the approved product information.

l) Foreign individual case safety reports should not be submitted to the Board on a routine basis, but should be reported in the context of a specific safety issue or on specific request by the Board.

m) The applicant should advise the Board of any action relating to safety that has been taken by a foreign agency, including the basis for such action, within seven days of first knowledge.

n) MAHs of both innovator and generic drugs are required to submit **PSUR/PBRER** to the Board at the time of renewal of the registration of the drug**. Refer to PBSL PSUR/PBRER Guideline for more details**.

4.6 The Responsibilities of the MAH in relation to the QPPV

The MAH should ensure that effective and efficient PV systems are in place so as to assure responsibility of its products being marketed in Sierra Leone and to take appropriate action when necessary. The MAH should always and uninterruptedly have at its disposal a fittingly QPPV domicile in Sierra Leone.

The MAH should:

a) Have written a contract with the QPPV
b) Provide support to the QPPV in order for him/her to acquire comprehensive training in PV.
c) Ensure that there are effective and efficient processes, resources, communication mechanisms and access to all source of relevant information in place so that QPPV will be able to fulfil his/her responsibilities and tasks.
d) Ensure that full documentation is in place covering all procedures and activities of the QPPV.
e) MAH should ensure the implementation of appropriate mechanisms for the QPPV to be kept informed of emerging safety concerns and any other information with respect to the risk-benefit ratio. This should include information from on-going or completed clinical trials and other studies that may be important to the products marketed in Sierra Leone by the MAH.
f) Assess risks with potential impact on the PV system and plan for contingency, including back-up procedures (e.g. in case of absence of personnel, adverse drug reaction database failure, failure of other hardware or software with impact on electronic reporting and data capture and analysis).
g) Ensure that the QPPV has sufficient authority to:
    i. Implement changes to the MAH PV systems, structure and processes so as to promote and improve compliance;
    ii. Provide input into the RMP and the preparation of regulatory action in response to emerging safety issues or concerns (e.g. variations, urgent safety restrictions, and, as appropriate, communication to patient and healthcare professionals).

iii. .

4.7 Information to be submitted to the Board by the MAH

The MAH shall submit the following information to the Board relating to the QPPV.

a) Curriculum vitae including key information on the role of the QPPV
b) Contact details including but not limited to the name, telephone, and e-mail, postal and official working address
c) A detailed job description
d) Terms of reference
e) Standard operating procedures (SOPs) for all PV activities
f) A list of tasks that have been delegated by the QPPV and to whom those tasks have been delegated.

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 authorization holder (MAH)	A person or company authorized by the Board to manufacture, import, 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 responsible for pharmacovigilance (QPPV)	An individual named by the MAH and approved by the Board as the 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 (v) 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**).**
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.

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

ISO International Organization for Standardization

MA Marketing Authorisation

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

QA 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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9. European Medicine Agency 2017. Guidelines on Good Pharmacovigilance Practices (GVP)-Module III- Post authorisation safety studies (Rev3).

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12. *Guidelines for Reporting Adverse Reaction*. Food and Drug Administration, Sierra Leone,2016.
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6.1 Legislations and guidelines used to develop this guideline:

- Regulation 726/2004 European Commission (EC) as amended
- Directive 2001/83 EC as amended
- COMMISSION IMPLEMENTING REGULATION (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council

- General principles of the ISO 9000 Standards on good quality management practices, specifically the ISO 9001:2015, standards on quality management systems, issued by the International Organization for Standardization (ISO)
- European Medicines Agency (EMA) Guideline on good pharmacovigilance practices (GVP) Module I – Pharmacovigilance systems and their quality systems.
- European Medicines Agency (EMA) Guideline on good pharmacovigilance practices: Module II – Pharmacovigilance system master file (Rev. 2)
- WHO Expert Committee on Specifications for Pharmaceutical Preparations Fifty-fourth report: Annex 13 WHO guideline on the implementation of quality management systems for national regulatory authorities https://iris.who.int/bitstream/handle/10665/341942/9789240022379-eng.pdf?sequence=1
- ICH guideline Q10 on Pharmaceutical quality system

7.0 Annex

APPENDIX 1: ADR/AEFI REPROTING FORM

REPORTING FORM FOR ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI) & ADVERSE DRUG REACTION (ADR)

***Patient Initials*:** ☐ ☐ ***Patient's full Address*:** Sex M ☐☐ ☐ F ☐☐ ☐ ☐☐☐ ☐ Identification Number: Telephone: District: ***Date of birth* :** _ _ /_ _ /_ _ *OR Age at onset: Years* *Months Days* *OR Age Group at onset: <1 Year 1 to 5 Years >5 Years* *PREGNACY STATUS: 1st trimester 2nd trimester 3rd trimester*	***Reporter's Name*:** Institution: Designation & Department: **Health facility (place or vaccination centre) name & address:** Telephone & E-mail: Date patient notified event to health system: _ _ /_ _ /_ _ Today's date : _ _ /_ _ /_ _

PRODUCT DETAILS (DRUG,VACCINE, MEDICAL DEVICE)									
Brand & generic Name of product(vaccine, drug, medical device etc)	***Date of administration of vaccine or drug***	***Time of administration of vaccine or drug***	**Dose (1st, 2nd, etc.)**	***Batch /Lot number***	**Expiry date**	**Strength and dose of drug(e.g od, bd,tid, etc)**	***Route of administration of drug/vaccine***	**Therapeutic indication of the drug or vaccine**	Name of manufacturer of product if applicable

Diluent if applicable- name, batch/lot number, expiry date, date and time of reconstitution……

***Adverse event(s):**	⁎Date ADR/ AEFI started **:** _ _ /_ _/_ _
Severe local reaction *>3 days beyond nearest joint*	Time _____:
Seizures (*febrile,afebrile)*	Describe AEFI/ADR (Signs & Symptoms):
Absc	

ess Sepsis Encephalopathy Toxic shock syndrome Thrombocytopenia Anaphylaxis Fever ≥38°C Other (specify)..... ☐ ☐ ☐	

***Serious: Yes / No;** ☐ If Yes Death Life threatening ☐ ☐ ☐
Persistent or significant disability Hospitalization ☐ ☐
Congenital anomaly Other important medical event (specify).....

***Outcome:** ☐ Recovering ☐ Recovered ☐ Recovered with sequelae ☐ ☐ ☐
Not Recovered Unknown ☐ ☐

Died If Died, date of death : _ _ /_ _ /_ _ ☐ ☐ Autopsy done: Yes No Unknown

Past medical history (including history of similar reaction or other allergies), concomitant medication and other relevant information (e.g. other cases). *Use additional sheets if needed:*

First Decision making level to complete:

Investigation needed: Yes ☐ No ☐	If Yes, date investigation planned : _ _ /_ _ /_ _

National level to complete:

Date report received at National level _ _ /_ _ /_ _	AEFI/ADR worldwide unique ID **:**
Comments:	

PRODUCT QUALITY DEFECT/ THERAPEUTIC INEFFECTIVENESS (Fill if applicable)

Brand or Generic Name	Batch No	Dosage Form & Strength	Mfg. Date	Expiry Date	Type of Container

Additional Comments

(eg Relevant history, previous exposure, Allergies, Baseline test results/Laboratory data)

- COMPULSORY FIELDS

THIS FORM SHOULD BE COLLECTED BY INSTITUTIONAL CONTACT PERSONS FOR PHARMACOVIGILANCE OR AEFI FOCAL PERSONS FOR THE EXPANDED PROGRAM ON IMMUNIZAION FOR ONWARD SUBMISSION TO PHARMACY BOARD OF SIERRA LEONE

Appendix 2: Template Contract for QPPV

The Registrar

Pharmacy Board of Sierra Leone

Central Medical Stores Compound

New England Ville

Freetown

Dear Sir,

CONTRACT FOR QUALIFIED PERSON FOR PHARMACOVIGILANCE (QPPV)

This contract is effective as of [effective date], [name of MAH], a company incorporated in accordance with the laws of [Country of MAH], located at [full address of MAH], (hereinafter referred to as ["short name of MAH if applicable] hereby empowers

[Full Name of QPPV], in his/her function as QPPV of [name of MAH] in the Republic of Sierra Leone, located at [full address of MAH or Local Representative in Sierra Leone] (hereinafter referred to as the "Local Representative") to:

1. Act as a single point of contact for the Pharmacy Board of Sierra Leone (PBSL), on all matters relating to pharmacovigilance and safety of marketed products including pharmacovigilance inspections.

2. Establish and maintain a system which ensures that information about all suspected adverse drug reactions/events which are reported to the personnel of the Marketing Authorization Holder, including medical representatives is collected, collated, processed and evaluated and forwarded to the Pharmacy Board of Sierra Leone in line with the timelines stipulated in the PBSL Guidelines.

3. Serve as a point of contact and be available during pharmacovigilance inspections.

4. Prepare regulatory documents relating to the safety of marketed products as per PBSL "a guide for safety monitoring of medicines in Sierra Leone"

5. This Contract shall be effective as of [the Effective Date] and shall, automatically and without separate notification to third parties, terminate on the earliest of the following occasions:

i. [Contract End Date] unless extended by [MAH] in writing;

ii. Termination of the contract between the [MAH] and the QPPV by either party. This Contract shall in all aspects be subject to, and interpreted in accordance with the laws of Sierra Leone.

MAH	QPPV
Signature:……..	Signature:……..
Name: ……	Name ……...
Title: ……	Title……...
Date: ……...	Date……

APPENDIX 3: CONTACT INFORMATION OF PBSL OFFICES

PBSL HEAD OFFICE

Postal address

The Registrar

Pharmacy Board of Sierra Leone

Central Medical Stores

New England Ville

Freetown

PMB 322

Tel :(0023222) 025-282826

Email: registrar@pharmacyboard gov.sl

Website:pharmacyboard.gov.sl

Kono Regional Office

57, Masinqbi road

Koidu city

Email: konooffice@pharmacyboard.gov.sl

Tel: 025-388748

Lungi 0ffice

Freetown International Airport

Lungi

Email: pbsllungi@gmail.com

Tel: 077-527220

Bo Regional Office

Bo-Kenema Highway

Nyagolihun junction

Email**:** booffice@pharmacyboard.gov.sl

Tel: +232-76466786

Kenema Regional office

9 Humonya Avenue

Tel: 025582886

Email: registrar@pharmacyboard.gov.sl

Makeni Regional Office

87 Aluzin highway

Makeni

Tel: +23278855471

APPENDIX 4

APPLICATION FORM FOR QUALIFIED PERSON RESPONSIBLE FOR PHARMACOVIGILANCE

NAME

GENDER

MOBILE

WORK PHONE

EMAIL

MARKETTING AUTHORIZATION HOLDERS DETAILS

NAME: ADDRESS: TELEPHONE NUMBER: EMAIL:

QUALIFICATION

SIGNATURE

DATE.....

APPENDIX 5: APPLICATION FORM FOR RE-DESIGNATION AS A QPPV

Addressed to: THE REGISTRAR

PHARMACY BOARD OF
SIERRA LEONE

CENTRAL MEDICAL STORE
NEW ENGLAND VILLE ,
FREETOWN

A. Particulars of the QPPV:

1. Name

……...

2. Postal Address

……...

3. Tel

……...

4. Fax ……...

5. Educational Qualification / Profession ……...

6. Qualified Person for ……... Pharmacovigilance (QPPV) Certificate Number

7. Date of Formal Designation as a QPPV ……..

8. Date of Expiration of ……... designation as a QPPV

B. Employment History as a Qualified Person for Pharmacovigilance

No.	Name of Local Representative	Name of Marketing Authorization Holder	Period
			(dd/mm/yyyy-dd/mm/yyy

2025

C. Continuing Professional Development Undertaken within the last three years

No.	Name of Training Programme	Institution	Period (dd/mm/yyyy-dd/mm/yyyy)	Certificate Awarded (attach copie

Declaration

I/We, the undersigned, hereby declare that all information contained herein is correct and true. Name of QPPV:……

Signature :……..

Date :…….

If QPPV is designated to a company

Name of Director of LR/MAH Representative ……..

Signature :…….

Date :…….

Official Stamp:

APPENDIX 6: QPPV DECLARATION FOR PHARMACOVIGILANCE SITE MASTER FILE(PSMF)

DECLARATION

1. I, the undersigned certify that all the information in PSMF and accompanying documentation is correct, complete and true to the best of my knowledge.

2. I further confirm that the information on all PSMF activities will be available for verification during Good Pharmacovigilance Practice (GVP) inspection.

3. I also agree that, I the Qualified Person for Pharmacovigilance in collaboration with the Marketing Authorization Holder (MAH) will implement all activities contained in the PSMF for this product in accordance with the PBSL requirements.

4. I also agree that I am obliged to follow all the requirements of the PHARMACY and DRUGS ACT 2001 and all applicable guidelines in ensuring the safety of marketed products.

……..

Name

Date: …….

APPENDIX 7: QPPV DECLARATION FOR RISK MANAGEMENT PLAN

DECLARATION

1. I, the undersigned certify that all the information in Risk Management Plan and accompanying documentation is correct, complete and true to the best of my knowledge.

2. I further confirm that the information on all Risk Management activities will be available for verification during Good Pharmacovigilance Practice (GVP) inspection.

3. I also agree that, I the Qualified Person for Pharmacovigilance in collaboration with the Marketing Authorization Holder (MAH) will implement all activities contained in the Risk Management and Pharmacovigilance plans for this product in accordance with the PBSL requirements.

4. I also agree that I am obliged to follow all the requirements of the PHARMACY and DRUGS ACT 2001 and all applicable guidelines in ensuring the safety of marketed products.

……..

Name

Date: …….

APPENDIX 8 : TABULATED SUMMARY OF REPORTING REQUIREMENTS

Post-Registration ADR Reports (registered medicinal products)

Type of ADR report	Time frame for reporting	Format for report
Local reports: Serious (Expected and Unexpected)	7 days	PBSL ADR form#
Non-serious (Expected and Unexpected)	28days	PBSL Summary report format#
Foreign reports: Foreign regulatory decisions that affect the safety or use of the	7 days	Detailed report

product		
Notification of change in nature, severity, frequency or risk factor	28 days	Detailed report
New information impacting benefit-risk profile of product including international regulatory decisions	7 days	Detailed report
Literature reports that affect the safety of the product	7 days	Detailed report (including publication)

Applicant"s in-house ADR report form or PBSL ADR report form or format.

APPENDIX 9: SUMMARY REPORT

Every applicant shall submit to the PBSL all ADR reports which occurred in Sierra Leone received during the specified reporting period on an annual basis as a summary report (SR). The Board may also request a SR for any other time period if deemed necessary.

Format of the SR: Each applicant should submit a single report which covers all medicines for which it received ADR reports. The format used should include for each medicine (Appendix 3):

(i) the local usage of each formulation for the review period (e.g. sales data or patient exposure).

(ii) a concise critical analysis of the reported ADRs for each medicine. The critical analysis should - identify any new ADRs and risk factors associated with the medicine - indicate any changes in the reporting rates of ADRs in a comparable period using estimated exposure (local) of the medicine, and with reference to international and cumulative data - address any new safety issue related to drug interactions, overdose, drug abuse or misuse, use in pregnancy, use in special patient groups or effects of long-term treatment

(iii) any actions taken or to be taken, including actions taken by any other regulatory authority or marketing authorisation holder

(iv) in a conclusion a simple risk-benefit statement for ongoing use and monitoring of the medicine.

(v) a line listing which includes the source, patient gender and age, formulation (including strength), daily dose, treatment dates and duration or time to onset, adverse reaction(s), seriousness, outcome and comment (including medical history and concomitant medicines). Reports received from a consumer should be clearly identified.

Depending on the medicine or circumstances, it may be useful or practical to have more than one line listing, such as dosage forms or indications, if such differentiation facilitates presentation and interpretation of data. It may also be useful to have separate tabulations for serious reactions and for non-serious reactions, for expected and unexpected reactions, or any other breakdown as may be useful for interpretation of the data. When the number of cases is very small, or the information is inadequate for any of the tabulations, a narrative description rather than a formal table would be considered suitable.

Time frame for submission of SR: Each applicant will specify the 12-month period which it will use for the SR. The 12-month period and the data lock-point selected by an applicant should be communicated to the PBSL.

ADR reports to be included: All domestic (Sierra Leone) spontaneous reports (serious and nonserious) received by the applicant during the specified 12-month period, all published reports of suspected ADRs, all domestic lack of efficacy reports, and all reports from post-marketing studies (published and unpublished).

If an applicant has received no reports during the time period, it must communicate this to the PBSL.

APPENDIX 10: TEMPLATE FOR SUMMARY REPORT

Each applicant should submit a single summary report (SR) which covers all medicines for which it received ADR reports. If an applicant has received no reports during the time period, it must communicate this to the PBSL.

The format of the SR used should include for each medicine:

1. Review period

Specify the dates for the 12-month period applicable to the data presented. If periods differ for different medicines, this needs to be specified. It should be kept in mind that the data must be presented annually.

2. Local usage of each formulation for the review period

This may be sales data or patient exposure.

3. Critical (concise) analysis of the reported ADRs for each medicine

3.1 New ADRs identified Indicate whether any new ADRs have been identified and whether such are serious or nonserious

3.2 New risk factors identified

3.3 Changes in reporting rate Any changes in reporting rate(s) of ADRs reported in a comparable period, using estimated exposure (local) of the medicine, and with reference to international and cumulative data

3.4 Other new safety issues This includes any new safety issue related to drug interactions, overdose, drug abuse or misuse, use in pregnancy, use in special patient groups or effects of long-term treatment, if not included in any of the above points

3.5 Actions taken or to be taken This includes actions taken or to be taken by any other regulatory authority or marketing authorisation holder (includes the local applicant)

4. Conclusion

A simple risk-benefit statement for ongoing use and monitoring of the medicine is required.

5. Line-listing

The line listing should include the source, patient gender and age, formulation (including strength), daily dose, treatment dates and duration or time to onset, adverse reaction(s), seriousness, outcome and comment (including medical history and concomitant medicines). Reports received from a consumer should be clearly identified.

Depending on the medicine or circumstances, it may be useful or practical to have more than one line-listing, such as dosage forms or indications, if such differentiation facilitates presentation and interpretation of data. It may also be useful to have separate tabulations for serious reactions and for non-serious reactions, for expected and unexpected reactions, or any other breakdown as may be useful for interpretation of the data. When the number of cases is very small, or the information is inadequate for any of the tabulations, a narrative description rather than a formal table would be considered suitable.

The line-listing should include all domestic (Sierra Leone) spontaneous reports (serious and nonserious) received by the applicant during the specified 12-month period, all published reports of suspected ADRs, all domestic lack of efficacy reports, and all reports from post-marketing studies (published and unpublished).

Appendix 11- Timelines for submission of PSUR/PBRER to the Board

For New Chemical Entities (NCEs) PSURs/PBRERs should be submitted as stated below unless otherwise requested by the Board

1. 6 monthly for the first two years
2. At the time of renewal of the registration of the drug.
3. Immediately upon request by the Board.

For all other products, the most recent PSUR/PBRER should be submitted at the time of renewal of the registration of the drug. PSURs and PBRERs should be harmonized with the International Birth Date of the Product. Generally, each PSUR and PBRER should cover the period of time since the last PSUR/PBRER and should be submitted within 60 days after the Data Lock Point. For medicinal products with marketing authorization in different countries, the MAH may synchronize the Local Birth Date (LBD) with the International Birth Date (IBD). The Board will accept a single harmonized IBD and Data Lock Point (DLP) for each product in order to reduce the burden of work in preparing PSURs/PBRERs for different regulatory authorities. In situations where an MAH is preparing PSURs/PBRERs on annual basis or longer period for different regulatory authorities based on the IBD and the Board requires a six-month cycle based on the LBD, the most recent PSUR/PBRER with a longer time frame will be acceptable to the Board. The Board may also request for Ad hoc PSUR/ PBRERs i.e., reports outside the specified reporting requirements when there are new risks, when risks have

changed, when efficacy/effectiveness has changed, or when there are changes to the benefit-risk profile of a medicinal product.

APPENDIX 14

LIST OF STAKEHOLDERS INVOLVED IN COORDINATION AND COMMUNICATION OF VIGILANCE ACTIVITIES

1. Healthcare providers
2. PUBLIC HEALTH PROGRAMS
3. Media(print and electronic)
4. Manufacturers/MAH/LOCAL REPRESENTATIVES
5. PUBLIC /CIVIL SOCIETY
6. PARTNERS SUCH AS WHO,UNICEF,UNFPA etc
7. Academic institutions
8. Research institutions
9. Primary, secondary and tertiary hospitals

Prepared by	Reviewed by	Approved by
Signature	Signature	Signature
Head, Pharmacovigilance & Clinical trials	Head, Quality Assurance	Registrar
Name: Dr. Onome Abiri	Name	Name