PHARMACY BOARD OF SIERRA LEONE

GUIDELINES FOR MARKETING AUTHORISATION HOLDERS

REQUIREMENTS FOR QUALIFIED PERSONS FOR PHARMACOVIGILANCE (QPPV)

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1.0 INTRODUCTION

Pharmacy Board of Sierra Leone (PBSL) is mandated to ensure that manufacturer' representatives or marketing authorisation holders (MAH) have a functional pharmacovigilance systems 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.

2.0 GLOSSARY

In these guidelines, unless the context otherwise states:

Adverse Drugs Reaction (ADR)/Adverse Reaction

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 (or 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

means the Pharmacy Board of Sierra Leone (PBSL)

Consumer

Is defined as a person who is not a healthcare professional such as a patient, lawyer, friend, or relative of a patient.

Healthcare Professional

Healthcare professional is defined as a medically-qualified person such as a physician, pharmacist, dentist, nurse, coroner, or as otherwise specified by local regulations

Line listings

A line listing provides key information but not necessarily all the details customarily collected on individual cases. Reactions are classified by body system for the most serious-presenting sign or symptom. The headings usually included are:

- Country of occurrence
- Source (e.g. spontaneous, clinical trial, literature, regulatory authority)
- Age
- Gender
- Dose(s) of suspected medicine(s)
- Formulation and/or route of administration, batch number when applicable
- Duration of treatment (prior to event); time to onset
- Description of reaction (as reported)
- Patient outcome (e.g. fatal, resolved, etc.)
- Comment (if relevant)

In some instances, depending on the type or source, ADR reports may be presented as line listings. A line listing serves to help the Board to identify cases that it might wish to examine more completely by requesting full case reports.

Marketing authorization Holder

A person or company authorized by the Board to manufacture, import, receive as donation, distribute or sell a medicinal product in Sierra Leone.

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 on their behalf.

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 defines times during post-registration

Periodic Safety Update Report (PSURs)

A regular update of the world-wide safety experience of a medicinal product at defined times during post-registration period

Pharmacovigilance

The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.

Qualified Person for Pharmacovigilance (QPPV)

An individual named by the Marketing Authorization Holder (MAH) and approved by the Board as the person responsible for ensuring that the company MAH meets its legal obligation in accordance with PBSL PV regulatory obligations.

Risk Management Plan

A systematic approach and set of Pharmacovigilance 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 risk will be communicated to the Board and the general population.

Safety Concern

An important identified risk, important potential risk, or important missing information

3.0 THE ROLES AND RESPONSIBILITIES OF THE QUALIFIED PERSON FOR PHARMACOVIGILANCE (QPPV)

3.1 Qualifications of QPPV

3.1.1 The Qualified Person for Pharmacovigilance (QPPV) shall have a degree in pharmacy, medicine, nursing, pharmacology, chemistry, biochemistry, physiology, or any other science discipline deemed acceptable by the Board.

3.1.2 The QPPV should have received a formal training in pharmacovigilance recognized by the Board.

3.1.3. The QPPV should have knowledge of PBSL pharmacovigilance legislation and guidelines and other international standards for Pharmacovigilance such as ICH E2A-F

3.2 Responsibilities of QPPV

The QPPV should have oversight of the pharmacovigilance 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.

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

3.2.2 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 marketing authorization holder and to the medical representatives is collected, collated and assessed for onward submission to the Board.

3.2.3 Prepare the following documents for submission to the Board:

3.2.3.1. Adverse Drug Reaction reports/ individual case safety reports (ICSRs)

3.2.3.2. Periodic Safety Update Reports (PSURs) /Periodic Benefit-Risk Evaluation Report PBRER), when necessary

3.2.3.3. Company-sponsored pre-and post-registration study reports

3.2.3.4. Risk Management Plan (RMP)

3.2.3.5. Line listing

3.2.3.6. Summary report

3.2.4 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

3.2.5. Ensure safety monitoring oversight of the marketed products and any emerging safety concerns

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

3.3.7. 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 pharmacovigilance

3.3 Timelines for reporting (See appendix 1 for summary)

3.3.1 Reactions occurring in Sierra Leone

3.3.1.1. All serious, suspected adverse drug reactions, occurring in Sierra Leone with any medicine, must be reported by the applicant within 15 calendar days after first notification.

3.3.1.2. All non-serious, unexpected, suspected adverse drug reactions, occurring in Sierra Leone with any medicine, must be reported by the applicant within 15 calendar days after first notification. All non-serious, expected adverse reactions reports must be reported within 90 days after first notification.

3.1.2. Reactions occurring outside Sierra Leone

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

3.1.2.2. 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 three days of first knowledge.

See appendix 1 for summary

4.0. THE RESPONSIBILITIES OF THE MAH IN RELATION TO THE QPPV

The MAH should ensure that effective and efficient pharmacovigilance 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 Marketing Authorization Holder should always and uninterruptedly have at its disposal a fittingly Qualified Person Responsible for Pharmacovigilance domicile in Sierra Leone.

4.1. Responsibilities of the MAH

The MAH should:

4.1.1. Provide support to the QPPV in order for him/her to acquire comprehensive training in pharmacovigilance.

4.1.2. 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.

4.1.3. Ensure that full documentation is in place covering all procedures and activities of the QPPV.

4.1.4. 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.

4.1.5. 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).

4.1.6. Ensure that the QPPV has sufficient authority to:

4.1.6.1.1. Implement changes to the MAH PV systems, structure and processes so as to promote and improve compliance;

4.1.6.2. 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).

4.1.7. Notify the Board within fourteen (14) days when the QPPV ceases to be an employee of the MAH or when his/her roles and responsibilities changes

4.1.8. Have written a contract with the QPPV.

4.2. Information to be submitted to the Board by the MAH

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

4.2.1. Curriculum vitae including key information on the role of the QPPV

4.2.2 Contact details including but not limited to the name, telephone, and e-mail, postal and official working address

4.2.3 A detailed job description

4.2.4 Term of reference

4.2.5. Standard operating procedures (SOPs) for all PV activities

4.2.6 A list of tasks that have been delegated by the qualified person for Pharmacovigilance and to whom those tasks have been delegated.

5.0. SANCTIONS

The following regulatory sanctions shall be applied to the Manufacturer Representative or Marketing Authorization Holder in the case of non-compliance to the regulations in these guidelines:

5.1. The Board may issue a formal warning reminding Manufacturer representative or Marketing Authorization Holder of their Pharmacovigilance regulatory obligation.
5.2. The non-compliant Manufacturer Representative or Marketing Authorization Holder may be placed on high risk leading to additional monitoring and retraining.
5.3. The Board may consider making public a list of Manufacturer Representative or Marketing Authorization Holder found to be seriously or persistently non-compliant.
5.4. Urgent Safety Restriction
5.5. Variation of the Marketing Authorization
5.6. Suspension of the Marketing Authorization
5.7. Revocation of the Marketing Authorization

6.0. PENALTIES

Non-adherence to the requirements of these guidelines by Manufacturer representatives and Marketing Authorization Holder will result in the Board imposing penal sanctions.

7.0. REFERENCES

1. European Medicine Agency 2012. Guidelines on Good Pharmacovigilance Practices (GVP)-Module III-Pharmacovigilance Inspection (Rev1).

2. Food and Drug Authority Ghana 2013. Guidelines for conducting pharmacovigilance inspections.

3. Medicines Control Council of South African 2014. Reporting of post-marketing adverse drug reactions to human medicinal products in South Africa

8.0 APPENDIX 1: TABULATED SUMMARY OF REPORTING REQUIREMENTS

Post-Registration ADR Reports (registered medicinal products)

Type of ADR report	Time frame for reporting	Format for report
Local Serious (Expected and Unexpected)	15 days	PBSL ADR form#
Local non-serious (Expected and Unexpected)	Annually	PBSL Summary report format#
Foreign Serious (Spontaneous/Published/Study)	On request or relating to specific safety issue	As appropriate
Notification of change in nature, severity, frequency or risk factor	3 days	Detailed report (including publications)
New information impacting benefit-risk profile of product including international regulatory decisions	3 days	Detailed report (including publications)

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

8.0 APPENDIX 2: 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.

8.0. APPENDIX 3: 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).