	Title: Guideline Adverse Drug Reaction Reporting (ADR)	
Rev No: 00	**Doc No: PBSL/GL/058**	Version no. 02
Issue date: 25th 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

	Title: Guideline for Periodic Benefit-Risk Evaluation Reports (PBRERs)	
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Acknowledgement

The Pharmacy Board of Sierra Leone appreciates Paul Ehrlich Institute Germany for supporting and strengthening pharmacovigilance in Sierra Leone.

Executive summary

This Guideline outlines the requirements for reporting ADRs and other adverse events by healthcare professionals and consumers including product quality defects, therapeutic failures, medication error and drug abuse.

Abbreviations

ADR	Adverse drug reaction
AE	Adverse Event
AR	Adverse reactions
AEFI	Adverse Events Following Immunisation
AESI	Adverse event of special interest
GACVS	Global Advisory Committee on Vaccine Safety
HCP	Health care professional
ICSR	Individual case safety report

ICH	International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IND	Investigational new drug
ICP	Institutional Contract Person
IP	Internet Protocol
MAH	Marketing authorisation holders
MedDRA	Medical Dictionary for Regulatory Activities
PBRER	Periodic benefit risk evaluation report
NPC	National Pharmacovigilance Centre
PBSL	Pharmacy Board of Sierra Leone
PBRER	Periodic benefit-risk evaluation
PSUR	Periodic safety update report
QPPV	Qualified person responsible for Pharmacovigilance
RMP	Risk Management Plan
SAE	Serious adverse event
UMC	Uppsala Monitoring Centre
WHO	World Health Organisation

1.0 Introduction

This guideline was developed by PBSL in line with the Pharmacy and Drugs Act 2001 and other applicable legislations aligned with the legislation and the guidelines from the international organizations and standards developed by WHO, the European Union and other ICH documents with relevant information that include:

1. ICH E2A
2. Guideline on good pharmacovigilance practices (GVP) Module VI – Collection, management and submission of suspected adverse reactions to medicinal products (Rev 2)
3. EU Directive 2001/83/EC

Due to increased availability and use of medicinal products and vaccines, including medical devices, by the population for the management and control of diseases in Sierra Leone there is the need to monitor quality and safety of these products as part of a functioning pharmacovigilance (PV) system. Detecting and monitoring adverse reactions (ARs) of medicinal products and devices, also known as Adverse Drug Reactions (ADRs), and Adverse Events Following Immunisation (AEFIs) are one main part of securing health of the population. In accordance with Act, the Pharmacy Board of Sierra Leone, (hereafter referred to as PBSL), functions as the National Pharmacovigilance Centre (NPC). The regulation of a medicinal product and device in Sierra Leone is governed by the provisions and requirements of the Act by which PBSL was established as the regulatory body for medicinal products and devices. The PBSL is mandated to ensure that evidence of existing and new adverse events, interactions and information about pharmacovigilance of medicinal products and devices being monitored globally, are analysed and

acted upon.

In accordance with the Act and PBSL Reliance Policy, PBSL recognises regulatory decisions, reports including inspections and recommendations from other Medicines Regulatory Agencies and international bodies like the World Health Organisation (WHO) including the Global Advisory Committee on Vaccine Safety (GACVS). PBSL may rely on methods, tools, common processes, standards and templates developed for the safety monitoring by other national and international organisations and implement changes to the existing processes accordingly, if necessary.

This guideline for ADRs is intended for, guidance to all PV stakeholders in Sierra Leone, including but not limited to patients, healthcare professionals (HCPs), public health programmes, hospitals/clinics, marketing authorization holders (MAHs), manufacturers, distributors, importers and exporters of medicinal products and vaccines including medical devices. The guidance herein is also provided to help the PBSL in the continuous monitoring of the safety, efficacy, and benefit to risk balance of medicinal products granted marketing authorization (MA) in Sierra Leone. All stakeholders in PV in Sierra Leone are required to strictly adhere to this guideline. It describes who can report suspected cases of ADRs to the NPC, how to report and the content of the report. It explains what happens after reports are sent and underlines the benefits of a strong pharmacovigilance system. PBSL through the Drug Safety Monitoring Programme aims to ensure optimal safety of medicinal products and devices by detecting, assessing and preventing drug related adverse events/reactions.

The National Pharmacovigilance Centre will be grateful to receive your comments on experiences gained from the practical use of this guide, which

may help in developing it further. Please contact the NPC of PBSL with your comments at the address below or your nearest PBSL office nationwide.

National Pharmacovigilance Centre
Pharmacovigilance and Clinical Trials Department
Pharmacy Board of Sierra Leone
Central Medical Stores Compound,
Freetown, Sierra Leone.
Tel: +23225282886
Fax: (00 232 22) 224526
Email: info@pharmacyboard.gov.sl,
Web site: www.pharmacyboard.gov.sl

The effectiveness of safety monitoring of medicinal products including vaccines and medical devices in Sierra Leone by PBSL is directly dependent on the active participation of the whole population of Sierra Leone. The importance of healthcare professionals should be acknowledged. All healthcare providers (physicians, pharmacists, dentists and others) should report adverse reactions to PBSL as part of their professional responsibility, also in case of doubts about causality. Also, consumers should report suspected adverse reactions to their HCPs or directly to PBSL. HCPs, MAHs and manufacturers are key stakeholders in the detection and reporting of safety issues of medicinal products and devices marketed in Sierra Leone.

2.0 Objective

The objective of this guide is to promote early detection of drug safety problems, improve selection and rational use of drugs by HCPs and to reduce medicinal product-/ device-induced morbidity and mortality. Effective PV activity will enable Sierra Leone to develop a good record keeping habit and build a useful safety information database that will improve the quality of health care offered to the patient.

All reporters stand to benefit as follows:

- improvement on the quality of care offered to patients;
- reduction of medicinal product-related problems leading to better treatment outcomes;
- improved patient confidence in the professional's practice and consequently professional growth;
- improved knowledge, access to feedback information on drug related problems reported within the country and internationally;
- satisfaction for the fulfillment of moral and professional obligation.

Safety monitoring of medicinal products and devices by PBSL ensures continuity of safety for patients and the general public

3.0 Scope

This document provides guidance to all relevant stakeholders on reporting and requirements of reporting of ADRs of medicinal products including vaccines and medical devices in humans and animals. This guideline applies to all medicinal products and devices as defined in the Act and the Regulations

including but not limited to biologicals (e.g. vaccines, blood and blood components), herbal medicines and radiopharmaceutical products.

All adverse reactions resulting from the use of marketed medicinal products including vaccines and medical devices, as well as the abuse, misuse, overdose, interactions, medication error, lack of efficacy or substandard and falsified medical products are within the scope of this guideline.

This guideline also applies to all pre-registration clinical research phases (e.g. Phase IV clinical trials, auxiliary medicine or non-investigational medicinal products, etc) as well as post registration clinical research (non-interventional post-marketing safety or efficacy studies.)

4.0 Requirements and general principles of efficient ADR reporting

All healthcare professionals (HCPs)/workers, including doctors, dentists, pharmacists, pharmacy technicians, nurses, community health officers, traditional medicine practitioners and other health professional are requested to report all suspected adverse reactions. Consumers should report suspected adverse reactions to their HCPs or directly to PBSL. This should be done without regard to a possible alternative causality or existing lack of information. It applies to all medicinal products and medical devices including orthodox medicines, vaccines, biological products, X-ray contrast media, cosmetics, traditional and herbal remedies, household chemical agents, and nutritional agents. This includes all healthcare institutions such as primary, secondary and tertiary healthcare facilities, public health programmes as well as patients/consumers, MAH and manufacturers.

4.1 Events to report

The following should be reported to PBSL:

- adverse reactions (AR) resulting from non-prescription and prescription medicines;
- adverse reactions following immunisation;
- adverse reactions occurring in a recipient of blood or blood components;
- adverse reactions resulting from medicines used within the scope of their marketing authorisation during clinical research studies;
- overdose;
- misuse;
- abuse;
- medication errors such as**:**
    - omissions – any prescribed dose not given;
    - wrong dose dispensed or administered – too much or too little;
    - extra dose given;
    - given wrong medicinal product or device;
    - wrong dose interval;
    - wrong administration route – administration of a medicinal product by a different route or in a different form from that prescribed;
    - wrong time for administration;
    - not following warning advice when administering;
    - prescribed or administrated of a medicine to which the patient has a known allergy;
    - dispensed or administered medicinal product after the expiry date of the medicinal product;
    - un-prescribed medicine - dispense or administrate authorized medicinal product or device to a patient.
- drug interactions;

- suspected contamination;
- suspected counterfeit;
- product quality issues such as: suspected contamination, quality defects, poor packaging or labelling, questionable stability, defective component, expired batches;
- lack of therapeutic efficacy of certain medicines or vaccination failure following immunisation;
- suspected ADRs associated with drug withdrawals.
- reactions suspected of causing death, danger to life, admission to hospital, prolongation of hospitalization, birth defects;
- serious adverse reactions should be reported expedited as individual case safety reports (ICSR).

All suspected ADRs of clinical relevance should be reported even if the reporter doubts causality. All ADRs that occur in any healthcare institution and public health programme such as Malaria, HIV/AIDS, Leprosy/Tuberculosis, EPI, Neglected Tropical Diseases, Reproductive and Child Health, School Health Programme, Nutrition should be reported.

4.2 Timelines of Reporting

The AR should be reported as soon as possible after it occurs. The completed report should be sent through the appropriate channel to PBSL immediately, but not later than stipulated in this guideline. If possible, the decision to report

whilst the patient is still with the HCP should be undertaken, so that s/he can easily be questioned about the AR and all the details can be filled on the reporting form at once. HCPs should report all suspected serious adverse reactions (SARs) and serious AEFIs, whether expected or unexpected, associated with the use of any medicinal product/device or vaccine in Sierra Leone within **15 calendar days** of becoming aware of the SAR or AEFI. MAHs and representatives of MAHs should report SARs and serious AEFIs, whether expected or unexpected, associated with the use of any medicinal product or device including vaccines in Sierra Leone to PBSL immediately but not later than **15 calendar days** of becoming aware of the SAR or AEFI. Events that are not classifiable as SAR or AEFI but which may affect the benefit-risk balance of a medicine (emerging safety issue) should be reported in writing to PBSL immediately but not later than **3 calendar days (72 hours)** when becoming aware of them. In case all the information needed is not available at the time of reporting, the reporter should submit an initial report containing at least the minimum data required (identifiable source of information, identifiable patient, identifiable medicinal product/ device, an definable suspect reaction). A follow-up report containing more detailed information should be submitted not later than 15 calendar days. If any supplementary data is obtained later, e.g. if the same patient develops the reaction again, or if something happens which increases or verifies the suspicion or seems to exclude the reaction caused by the medicine, a follow-up report should be sent immediately. Non-serious adverse reactions should be reported as an ICSR to PBSL within **90 days**.

Table 1: Summary timelines of reporting

Type of Report	Time frame for reporting	Format
Occurred in Sierra Leone		
SARs and serious AEFIs (expected and unexpected) by healthcare professionals as ICSR	15 calendar days	AR Form
SARs and serious AEFIs (expected and unexpected) by MAHs as ICSR	15 calendar days	AR Form
Non serious ARs and AEFIs by all as ICSR	90 days	AR Form
Follow-up reports	15 calendar days	AR Form
Foreign reports including literature		
Foreign serious and unexpected ARs and AEFIs by MAHs as ICSR	15 calendar days	AR Form
All other foreign ARs and AEFIs	Periodically	PSUR/PBRER
Emerging Safety Issues		
New information that impact the benefit-risk profile of product including international regulatory decisions	72 hours (3 calendar days)	Detailed report
Action relating to product safety taken by a NMRA outside the country	3 working days	Detailed report

4.3 Reporting channels

For all reporters, there is the recommended possibility to use the PBSL web-based

online reporting system to report either ADRs, AEFIs or substandard and falsified medical (SF) products at https://www.pharmacyboard.gov.sl/ReportAdverseDrugReaction.php.

Suspected ADRs and AEFIs can be entered online into the app VigiMobile, which has been specifically developed by Uppsala Monitoring Centre (UMC) for national immunisation programmes as part of VigiFlow. All VigiMobile reports are sent directly to VigiFlow and PBSL will be alerted automatically.

Another option consists of submission of a hardcopy ADR reporting form. ADR forms are available at all tertiary, secondary and primary healthcare facilities at central and district levels, private hospitals, surgeries, clinics, pharmacies and drug stores nationwide. ADR forms can also be obtained by contacting the address provided below. The ADR reporting form is also available for download on PBSL´s website www.pharmacyboard.gov.sl. The completed reporting form can be submitted physically at the PBSL offices or via Whatsapp, email to info@pharmacyboard.gov.sl, facsimile, or posted to:

National Pharmacovigilance Centre
Pharmacovigilance and Clinical Trials Department
Pharmacy Board of Sierra Leone (PBSL)
Central Medical Stores Compound,
New England Ville,
Freetown, Sierra Leone
PMB 322
The National Pharmacovigilance Centre can be contacted on mobile: 025282886
.

Reporting can also be performed through the PBSL contact form which is available online on the website or by phone using 025282886, alternatively per mail (adresses mentioned above). . Should a reporting form not be available or cannot be completed for any reason within the required time frame for reporting, the initial report to NPC may be provided in writing or verbally by phone or voice message stating the minimum required information on the above-mentioned contact details.

Health facilities particularly all private and public secondary, tertiary hospitals and community health centres, should have an Institutional Contract Person (ICP) for PV. Private and public primary healthcare facilities providing immunization, HIV/AIDS, TB, and reproductive health services must have an ICP for PV. Other private and public health facilities, such as community health posts, maternal and child health posts, and clinics, are also encouraged to report adverse events. If the inability to fill out and submit ADR form exists, ICP can fill out and onward submission to PBSL. The role of the ICP includes coordinating adverse event reporting (ADRs or AEFIs) within their facilities and liaising with the NPC. The ICP can be any healthcare professional designated by the facility to perform PV activities with training and experience in PV. If the ICP designated by the facility lacks PV training, the NPC can provide training to enable the person to adequately perform this role.

4.4 Reporting information

Generally, it is recommended to use the ADR reporting form (Appendix 1) and to give as much details about the **patient, reaction, suspected medicinal product/ device** and the **sender** as possible. Attempts should be made to

obtain follow-up information on other listed items pertinent to the case. Follow-up information should be actively sought and submitted as it becomes available.

Minimum information for processing ADRs consists of:

- an identifiable **patient**;
- name of a **suspect medicinal product**;
- identifiable **reporting source**; and
- an **event or outcome** that can be identified as serious and unexpected and for which, in clinical investigation cases, there is a reasonable suspected causal relationship.

4.5 Expedited reporting

Expedited reporting is required for SAR associated with a suspected medicinal product.

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Key data elements for inclusion in expedited reports of serious adverse drug reactions are presented below.

The following information about the *patient* should be provided:

- patient initials or patient number (the patient's data protection should be regarded);
- date of birth and/or age;
- sex;
- weight;
- height;
- name of the health facility or vaccination centre (for AEFI reports);

- health data including medical history and medication(s);
- in case of pregnancy gestational age
- Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations.

The following information about the *reaction* should be provided:

- a detailed description of the reaction. In addition to a description of the reported signs and symptoms, whenever possible, attempts should be made to establish a specific diagnosis for the reaction;
- start date (and time) of onset of reaction and duration of reaction;
- outcome of the reaction. Information on recovery and any sequelae; what specific tests and/or treatment may have been required and their results; for a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction should be provided. Any autopsy or other post-mortem findings (including a coroner's report) should also be provided if available;
- the treatment provided for the reaction (if any);
- dechallenge and rechallenge information setting (e.g., hospital, out-patient clinic, home, nursing home).

The following information about the *suspected medicinal product/ device* should be provided:

- brand and generic name of the medicinal product/ device, expiry date, batch/lot number

(if known), name of the manufacturer, route of administration and daily dose.

If there is more than one suspected medicine, a separate sheet should be attached;

- dates of initation ending of therapy;
- dechallenge and rechallenge information, where available;
- indication or reason(s) for use of the medicinal product/device;
- concomitant medicinal products including herbal medicines and self-medication taken

within the last three months with dates of administration (if known). For concomitant

medicinal products (including non-prescription/OTC medicinal products) and non-

medicinal product therapies, provide the same information as for the suspected product;

- laboratory tests and results, if any;
- suspected or confirmed medication error, where available;
- suspected or confirmed poor quality/defect of the medicine or vaccine, where available.

The following information about the *reporter* should be provided:

- First name and last name and address;

- Job title and organization if the report is a healthcare professional or MAH/ manufacturer

  Representative;
- IP address, if available;
- Region (for AEFI reports);
- Contact details (phone number, e-mail).

The following information should be provided in case of an *administrative or sponsor/company*:

- details source of report: spontaneous, from a clinical investigation (provide details), from the literature (provide copy), other;
- date event report was first received by sponsor/manufacturer;
- country in which event occurred;
- type of report filed to authorities: initial or follow-up (first, second, etc.)
- name and address of sponsor/manufacturer/company
- name, address, telephone number, and FAX number of contact person in reporting company or institution
- identifying regulatory code or number for marketing authorisation dossier or clinical investigation process for the suspected product;
- sponsor/manufacturer's identification number for the case (this number must be the same for the initial and follow-up reports on the same case).
-

In clinical trial, reporting should occur within the timeframe and format specified by PBSL

Clinical Trial guideline.

4.6 Reporting in Special Situations

4.6.1 Overdose, abuse, misuse and medication error

If overdose, abuse, misuse or medication error is associated with a suspected serious adverse reaction, the adverse reaction should be submitted to PBSL as an ICSR.

The reports of overdose, abuse, misuse or medication error should be routinely followed-up by PBSL to ensure that information is as complete as possible with regard to the symptoms, suspected medicinal products/ devices, outcomes and context of occurrence (e.g. error in prescription, administration, dispensing, dosage, unauthorised indication or population, etc.).

4.6.2 Lack of efficacy or effectiveness

HCPs, MAHs, or their national representatives of MAHs and other stakeholders should notify PBSL when they are aware of lack of efficacy or vaccination failure.

In case the medicinal product/ device is used in critical conditions or for the treatment of life-threatening diseases or contraceptives, lack of therapeutic efficacy should be reported as ICSRs, unless the reporter has specifically stated that the outcome was due to disease progression and was not related to the medicinal product or device.

Clinical judgement should be used when considering if cases of lack of therapeutic-efficacy is qualified for submission or not.

For vaccines, cases of lack of prophylactic efficacy should always be submitted as ICSRs, in particular with the view to highlight potential signals of reduced immunogenicity in a sub-group of vaccines, waning immunity, or strain replacement.

4.6.3 Poor Quality/Defect of Medicinal products and devices and SF medical products

Poor medicine quality and defects of medical products/ devices including suspected SF medical products associated with a suspected adverse reaction should be reported. SF medical products should be reported using the web-based online reporting "Counterfeit Products" that is available on the official PBSL website under https://www.pharmacyboard.gov.sl/ReportCounterfeitDrugs.php.

If a product quality problem is associated with a suspected serious adverse reaction, the adverse reaction should be submitted to PBSL as an ICSR.

Specific responsibilities

Pharmaceutical companies and Marketing Authorisation Holders

Pharmaceutical companies and MAHs are responsible for the quality, safety and efficacy of medicinal products/ devices on the market. Responsibility includes monitoring to detect any adverse event. The mentioned above should:

- inform PBSL of any suspected serious adverse reaction that occurred in Sierra Leone
  and suspected unexpected serious adverse reactions that occurred in any other country as
  described above in sections.
- have in place a system for the collection and recording of all reports of suspected adverse reactions in Sierra Leone or in third countries which are brought to its attention, whether reported spontaneously by healthcare

professionals or consumers or occurring in the context of a post-authorisation study;

- not refuse to consider reports of suspected adverse reactions received electronically or by any other appropriate means from patients and healthcare professionals;
- establish procedures in order to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports;
- should also collect follow-up information on reports and submit the updates to PBSL;
- should establish mechanisms enabling the traceability and follow-up of adverse reaction reports while complying with the data protection legislation;
- should retain PV data and related documents as long as the product is authorised and for at least 25 years after the marketing authorisation has ceased to exist;

The MAH responsibilities also apply to reports related to medicinal products for which ownership cannot be excluded on the basis of one the following criteria: medicinal product name, active substance name, pharmaceutical form, batch number or route of administration. Exclusion based on the primary source country or country of origin of the adverse reaction is possible if the MAH can demonstrate that the suspected medicinal product has never been supplied or placed on the market in that territory or that the product is not a travel medicine (e.g. anti-malarial medicinal product).

The MAH shall ensure that any information on adverse reactions, suspected to be related to at least one of the active substances of its medicinal products authorised in Sierra Leone, is brought to its attention by any company outside Sierra Leone

belonging to the same mother company (or group of companies). The same applies to the MAH when having concluded a commercial agreement with a company outside Sierra Leone for one of its medicinal product authorised in Sierra Leone. The MAH should record those reports of suspected adverse reactions are accessible within Sierra Leone. The MAH should ensure that the reports and the source data or an image are easily accessible in order to be made available to PBSL upon request. The clock for the submission starts when a valid ICSR is first received by one of these companies outside Sierra Leone.

In addition to the requirements presented in this chapter, the definitions and general principles detailed in this guideline, together with the time frames and modalities presented should be applied by the MAH to all reports of suspected adverse reactions.

Role of Healthcare Professionals

Besides passive surveillance activities, HCPs are encouraged to be involved in active surveillance activities such as prescription event monitoring as PV is one of their key responsibilities. They are asked to report all adverse reactions they received directly to the pharmaceutical company, manufacturers or MAH. During contacts with patients, attempts should be made to obtain all information sufficient to ascertain the nature and seriousness of the event using the available ADR reporting tools like Vigimobile. Additional follow-up or medical confirmation might not be necessary for apparently non-serious and expected adverse reactions. On the other hand, if the event is serious/ or unexpected, reasonable additional efforts should be undertaken to contact the treating doctor or have the consumer provide the relevant medical documentation to allow for risk assessment and signal detection. Therefore, attention should be given to fill out the reporting form completely.

Pharmacy Board of Sierra Leone

- Shall establish a pharmacovigilance system for the collection and evaluation of information relevant to the risk-benefit balance of medicinal products authorised.
- Continually monitors the safety profile of the products available in Sierra Leone.
- Takes appropriate action where necessary.
- Monitors the compliance of Manufacturers and Marketing Authorisation Holders with their obligations with respect to pharmacovigilance.
- Ensures that Marketing Authorisation Holders implement, when appropriate, Risk Management Plans to effectively monitor and manage risks associated with the safety of their products
- Ensures that pharmacovigilance data are shared between stakeholders, health programmes and internationally.
- Collect and evaluate risk-benefit balance on medicinal products, monitor safety profile, take appropriate actions, monitor health care professional (HCP) and MAH.
- Have an established pharmacovigilance system for the collection and evaluation of information relevant to the risk-benefit balance of medicinal products.
- Constitute an Expert Committee on Drug Safety and Clinical Trials to carry out the safety assessment of medicinal products among others things such as providing scientific opinion for clinical trials monitoring by the Board and whose terms of reference shall be:
  - ✓ The committee shall review pharmacovigilance or medicine safety information and related data on all pharmaceuticals, biologicals and other regulated products on the Sierra Leone market;

- ✓ upon request, the expert committee will make recommendations to the Board regarding actions the Board may take to resolve issues or concerns related to post-approval product safety, quality and efficacy;
- ✓ the committee will also recommend to the Board appropriate product information labelling update; recall or withdrawal products as may be necessary;
- ✓ regularly review and advise the Board on the clinical trials structure in the country and make recommendations regarding its maintenance and enhancement;
- ✓ perform causality assessment and issue reports on adverse event in relation to clinical trials and also for adverse drug reaction reports from routine clinical care;
- ✓ make recommendations to the Board regarding actions the Board may take to resolve issues or concerns related to the conduct of clinical trials including the need to halt or suspend a clinical trial;
- ✓ recommend publication of case reports, as well as its risk or benefit assessments in medical and scientific journals with prior consent of the sponsor;
- ✓ recommend educational programmes and topics for pharmacovigilance and also for investigators aimed at enhancing reporting of adverse effect or event and improving compliance with Good Clinical Practice as recommended by the International Conference on Harmonization Guidelines and Helsinki Declaration;
- ✓ advise the Board periodically on the review of applications and guidelines for clinical trials, Good Clinical Practice and pharmacovigilance issued by the Board;
- ✓ recommend to the Board approval of clinical trials;

- ✓ evaluate final reports of clinical trials that have been approved by the Board;
- ✓ advise the Board on matters relating to Good Clinical and Laboratory Practice (GCLP) inspections; and
- ✓ perform any other functions that are supplementary to the attainment of the objectives of the Committee.

The membership of the Expert Committee should reflect areas of expertise and specialisation as the case maybe, such as:

1. General Medicine 2. Clinical Pharmacy 3. Clinical Pharmacology 4. Pharmacology/Toxicology 5. Epidemiology 6. Herbal Medicine 7. Pathology 8. Industrial Pharmacy/Quality Control/Quality Assurance 9. Biostatistics 10. Paediatrics/Child Health 11. Public Health

Role of Consumers and General Public

Patients/consumers should report any suspected ADR/AEFI to PBSL, pharmaceutical companies or MAHs. The patient/ consumer should be advised to seek medical attention from their healthcare provider. All consumer reports should however be documented as for any other type of report and should be taken into account when overall safety assessments are made.

Management of Adverse Reaction Reports by the PBSL

Regulators should be committed to acting promptly and responsibly to protect patients from potential harm by alerting, HCPs, manufacturers /MAHs about quality and potentials about medicinal products/ devices marketed in Sierra Leone, which should be graded according to the seriousness of their threat to the public's health. HCPs will in turn pass on this information to their patients

in cases where continuing to take the medicinal product or device poses a serious risk.

Any information related to the reporter and consumer or patient is kept strictly confidential. The information obtained from reporting is not to be used for commercial purposes. The information is only meant to improve PBSL´s understanding and use of medicinal products/ devices in Sierra Leone.

PBSL analyses the adverse reaction reports and takes appropriate regulatory action when necessary. PBSL should acknowledge receipt of serious ICSRs within 5 working days of receipt. The initial acknowledgement may be in the form of a telephone call or e-mail which may be followed by an official written acknowledgement letter. PBSL may perform additional investigations, if necessary. Attempts should be undertaken to obtain follow-up information on as many other listed items pertinent to the open cases as well follow-up information should be actively sought by PBSL.

The Board may provide feedback of evaluation of an ICSR to the reporter after the safety assessment of the submitted report, if it has an implication for further treatment of the patient or leads to regulatory actions. In order to assess the likelihood that the suspected adverse reaction is actually due to the medicinal product, the WHO- UMC and Naranjo have provided a list of causality assessment criteria for deciding the association of the medicine towards the adverse event (Appendix 2).

PBSL enters ICSRs on marketed medicinal products/ devices into the WHO provided web-based individual case safety report (ICSR) management system, VigiFlow. Details and analyses of the reports are stored confidentially in the UMC-WHO Global Database.

The outcome of the report, together with any important or relevant information relating to the reaction you have reported, will be communicated to the sender as appropriate.

PBSL maintains all ICSRs and related documentation in respective files for at least 25 years.

Consequences of Adverse Drug Reaction Reporting

The information obtained from reporting are used to promote the safe use of medicinal products/ devices on a local, national and international level. The reported case will be entered into the national ADR database and analyzed by expert reviewers. A well-completed ADR reporting form could result in one or more of the followings:

- additional investigations into the use of the medicinal product/ devices in Sierra Leone;
- educational initiatives to improve the safe use of the medication;
- appropriate package insert changes to include the potential for the reaction reported by Sierra Leonean health professional and workers;
- changes in the scheduling or manufacture of the medicinal product/ device to increase safety;
- other regulatory and health promotion interventions as the situation may warrant including change in supply status or withdrawal.

Therefore, the purpose of ADR reporting is to reduce the risk associated with prescribing and administration of medicinal products/ devices and to ultimately improve patient care, safety and treatment outcome.

Adverse drug reaction reporting flow

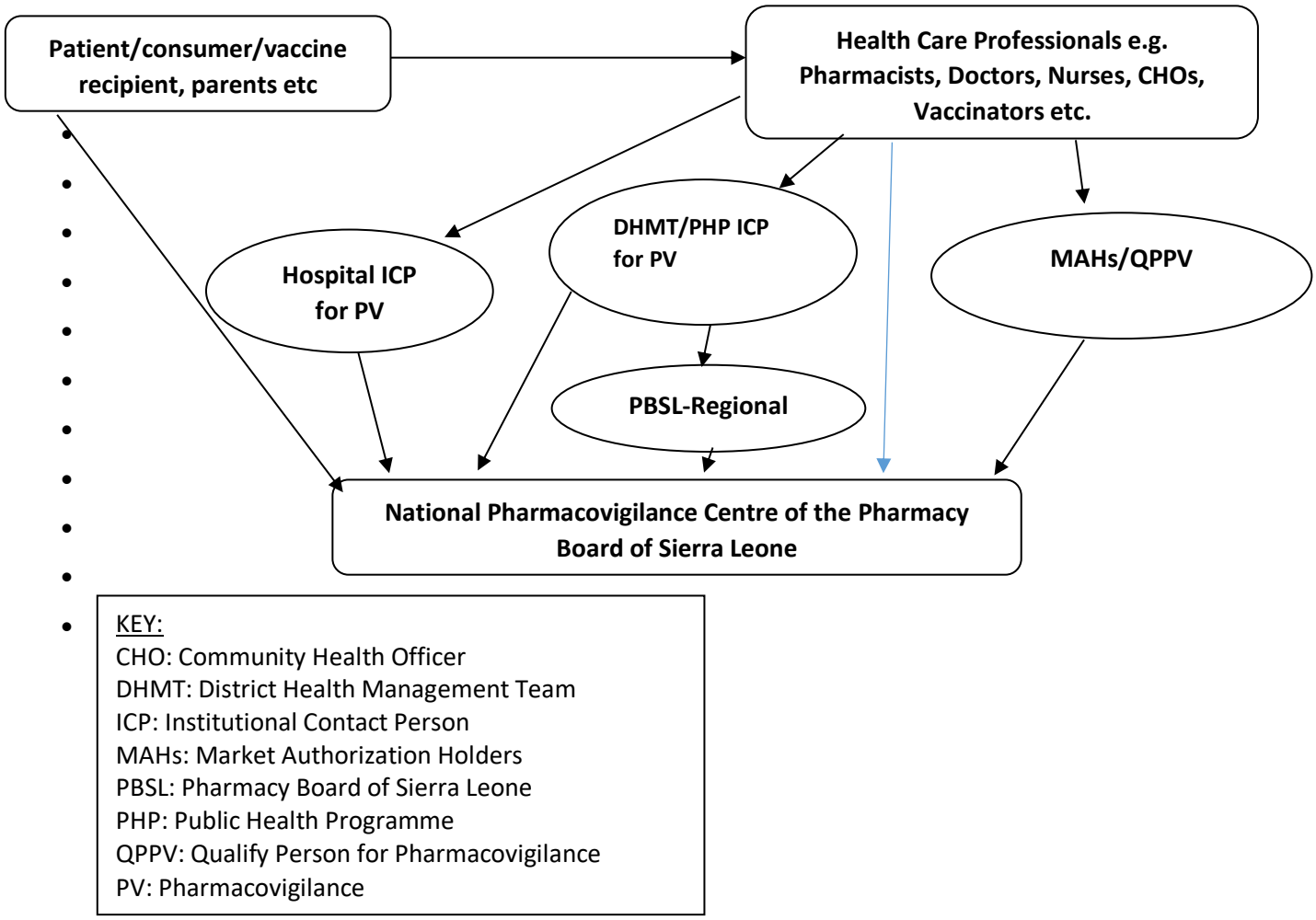


Figure 1: Adverse drug event reporting information flow

*5.0***Glossary**

A drug or medicinal product

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.

Abuse

The persistent or sporadic, intentional excessive use of a medicinal product, which is accompanied by harmful physical or psychological effects.

Active Substance

Any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis.

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 the prophylaxis, diagnosis of disease, or for the modification of physiological function.

Adverse Event

Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign
(including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

Adverse Event Following Immunisation (AEFI)

Any untoward medical occurrence which follows immunisation and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

Adverse event of special interest (AESI)

An adverse event of special interest (serious or non-serious) is one of scientific and medical concern specific to the sponsor's product or programme, for which ongoing monitoring and rapid communication by the investigator to the sponsor can be appropriate. Such an event might warrant further investigation in order to characterise and understand it. Depending on the nature of the event, rapid communication by the trial sponsor to other parties (e.g., regulators) might also be warranted.

Adverse Drug Reaction (ADR) Case Report

A case report in pharmacovigilance is a notification related to a patient who has experienced an adverse medical event or laboratory test abnormality suspected to be induced by a medicine.

It is important to stress that healthcare workers should send reports of ADRs even if they do not have all the information required.

Board

The Pharmacy Board of Sierra Leone

Consumer

For the purpose of reporting cases of suspected adverse reactions, a person who is not a healthcare professional such as a patient, lawyer, friend or relative of a patient or carer.

Expedited Reporting

Is the immediate reporting and in not more than 7 calendar days, of a serious adverse reaction to the Board.

Healthcare professional

A person who is a medically qualified person such as a physician, dentist, pharmacist, nurse or community health officer.

Individual case safety report (ICSR); synonym: Adverse (drug) reaction report

Format and content for the reporting of one or several suspected adverse reactions to a medicinal product or device that occur in a single patient at a specific point of time.

Marketing Authorisation Holder

An organisation that has been issued licence by the competent authority to market a medicinal product, medical equipment, or cosmetics within Sierra Leone or any other country and may or may not be the manufacturer of the particular product.

Medication Error

Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient or consumer.

New Drug

A chemical or biologically active pharmaceutical ingredient that has not previously been issued with a marketing authorization as an ingredient in any pharmaceutical product in Sierra Leone.

Misuse

Situations where the medicinal product is intentionally and inappropriately used not in accordance with the authorized product information.

Off-label use

Situations where the medicinal product is intentionally used for a medical purpose not in accordance with the authorized product information.

Overdose

Administration of a quantity of a medicinal product given per administration or cumulatively, which is above the maximum recommended dose according to the authorized product information.

Periodic Benefit Risk Evaluation Report (PBRER)

An update of the world-wide marketing experience of a product at defined times with focus on formal evaluation of benefit in special population at defined times during post-registration period.

Periodic Safety Update Report (PSUR)

A regular update of the world-wide safety experience of a 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 medicine related problem.

Qualified Person for Pharmacovigilance (QPPV)

An individual named by a Marketing Authorization Holder (MAH) and approved by the Board as the person responsible for ensuring that the company (the MAH) meets its legal obligations in the for monitoring of the safety of the product marketed in Sierra Leone.

Risk Management Plan

A systematic approach and set of pharmacovigilance activities and interventions designed to identify, characterize, prevent or minimize risks relating to medical products, and the assessment of effectiveness of those interventions and how these risks will be communicated to the Board and the general population.

Serious Adverse Event or Reaction*:*

A serious adverse event or reaction is any untoward medical occurrence that at any dose: experience is an adverse drug experience that results in

- death;
- 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);
- inpatient hospitalization or prolongation of existing hospitalization;
- a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; or
- a congenital anomaly or birth defect.

Side Effect

Any unintended effect of a pharmaceutical product occurring at doses normally used in human, which is related to the pharmaceutical properties of the drug.
Such effects may or may not be beneficial. Side effects are related to the known properties of the drug and can often be predicted. It must be stressed that in pharmacovigilance, we are interested in all drug related reactions, this includes side effects and suspected adverse drug reactions. Healthcare professionals must therefore report all drug related problems to the NPC.

Signal

A Signal refers to "Reported information on a possible causal relationship between an adverse event and a drug; the relationship being known or incompletely documented previously. "Usually more than a single report is required to generate

a signal depending upon the seriousness of the event and the quality of the information.

Spontaneous Report or Spontaneous Notification

An unsolicited communication to a company, regulatory authority or other organization that describes an ADR in a patient given one or more medical products and which does not derive from a study or any organized data collection scheme.

Unexpected adverse reaction

An adverse reaction, the nature or severity of which is not consistent with domestic labeling or market authorization, or expected from the characteristic of the drug

7.0 APPENDIX

Appendix 1: Suspected Adverse Reaction Reporting Form (PBSL-XX)

APPENDIX 1: ADR/AEFI REPROTING FORM

***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*	***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 : _ _ /_ _ /_ _

PREGNACY STATUS: 1st trimester 2nd trimester 3rd trimester	

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):** Severe local reaction *>3 days beyond nearest joint* Seizures (*febrile,afebrile)* Absc ess Sepsi s Encephalopathy Toxic shock syndrome Thrombocytop enia Anaphylaxis Fever ≥38°C Other (specify).....	⁎Date ADR/ AEFI started **:** _ _ /_ _/_ _ Time _____: Describe AEFI/ADR (Signs & Symptoms):
***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	

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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

Compulsory field

(e.g. Relevant history, previous exposure, Allergies, Baseline test results/Laboratory data)

Appendix 2: Causality assessment methods

Naranjo

Naranjo Adverse Drug Reaction Probability Scale				
Question	Yes	No	Do Not Know	Score
1. Are there previous conclusive reports on this reaction?	+1	0	0	
2. Did the adverse event appear after the suspected drug was administered?	+2	-1	0	
3. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?	+1	0	0	
4. Did the adverse event reappear when the drug was re-administered?	+2	-1	0	
5. Are there alternative causes (other than the drug) that could on their own have caused the reaction?	-1	+2	0	
6. Did the reaction reappear when a placebo was given?	-1	+1	0	
7. Was the drug detected in blood (or other fluids) in concentrations known to be toxic?	+1	0	0	

8. Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	
9. Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	+1	0	0	
10. Was the adverse event confirmed by any objective evidence?	+1	0	0	
			Total score:	

Total Score	Interpretation of Scores
≥9	Definite. The reaction (1) followed a reasonable temporal sequence after a drug or in which a toxic drug level had been established in body fluids or tissues, (2) followed a recognized response to the suspected drug, and (3) was confirmed by improvement on withdrawing the drug and reappeared on reexposure.
5 to 8	Probable. The reaction (1) followed a reasonable temporal sequence after a drug, (2) followed a recognized response to the suspected drug, (3) was confirmed by withdrawal but not by exposure to the drug, and (4) could not be reasonably explained by the known characteristics of the patient's clinical state.
1 to 4	Possible. The reaction (1) followed a temporal sequence after a drug, (2) possibly followed a recognized pattern to the suspected drug, and (3) could be explained by characteristics of the patient's disease.
≤0	Doubtful. The reaction was likely related to factors other than a drug.

WHO-UMC

Causality term	Assessment criteria*
Certain	• Event or laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognised pharmacological phenomenon) • Rechallenge satisfactory, if necessary
Probable / Likely	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Conditional/ Unclassified	• Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination

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Unassessable/ Unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because information is insufficient or contradictory • Data cannot be supplemented or verified

*All points should be reasonably complied with

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