**Drug Safety Monitoring Programme**  **Pharmacy Board of Sierra Leone**

**Ministry of Health and Sanitation**

☐ Adverse Drug Reaction
☐ Products Quality Defect
☐ Medication Error

☐ Initial Report
☐ Follow-up Report

# Suspected Adverse Drug Reaction/ Medication Error Reporting Form

## *1.PATIENT DETAILS*

*.Patient's name: Address:

*.Sex: *.Age(months/years): Weight: (kg) Height:(cm)

Health Facility: Inpatient/Outpatient No:

Pregnancy Status: ☐ 1st Trimester ☐ 2nd Trimester ☐ 3rd Trimester

## *2.SUSPECTED DRUG(S)/PRODUCT(S) DETAILS*

Brand Name: *.Generic Name: Batch No. Man. Date: Expiry date

*.Strength: *.Dose: *.Start date: End date:

Therapeutic indication: Route of administration:

Name and Address of Manufacturer:

Source of Drugs: Prescribed? ☐ Yes ☐ No Obtained over the counter? ☐ Yes ☐ No

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

***Drugs taken concomitantly /in the last 3 months prior to the reaction (include OTCs and herbals). use rear side of this form/separate sheet for additional drugs***

| Brand or Generic Name | Daily dose | Route of Administration | Date started | Date Stopped | Therapeutic indication |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |

## *3. DETAILS OF ADVERSE EVENTS/MEDICATION ERROR (use separate sheet if necessary)*

*.Description of reaction/ medication error:

| *.Date/time reaction/incident started | Date/time reaction/incident stopped | Event reappeared on Rechallenge ☐ Yes ☐ No<br>Rechallenge not done ☐ Yes ☐ No<br>**Treatment of Reaction**:…… |
|---|---|---|

**SEVERITY OF REACTION/ MEDICATION ERROR**
- ☐ Mild
- ☐ Moderate
- ☐ Severe

**ACTION TAKEN**
- ☐ Drug withdrawn
- ☐ Dose Increased
- ☐ Dose Reduced
- ☐ Dose not changed
- ☐ Unknown

**OUTCOME OF REACTION**
- ☐ Recovering/Resolving.
- ☐ Recovered/resolved
- ☐ Recovered with sequelae
- ☐ Not recovered

**CAUSALITY OF REACTION**
- ☐ Certain
- ☐ Probable/Likely
- ☐ Possible/Unlikely
- ☐ Conditional/unclassified
- ☐ Unassessable/Unclassifiable

**If reaction/error is serious, did it lead to:**
☐ Death ☐ Disability ☐ Life –threatening ☐ Hospitalization ☐ Congenital abnormality ☐ Other (specfiy)

If patient was hospitalized what is the duration of admission (hours/days):……

## *4. DETAILS OF MEDICATION ERROR (Fill if applicable)*

**Stage of Medication Error in the Medication use System (tick all that apply)**
☐ Prescribing ☐ Transcription ☐ Dispensing ☐ Administration ☐ Monitoring ☐ Other (specify)

**Type of Medication Error (tick all that apply)**

- ☐ Wrong patient
- ☐ Wrong dose or strength
- ☐ Wrong rate (too fast/too slow)
- ☐ Wrong route of administration
- ☐ Wrong method of administration
- ☐ Poor quality or counterfeit medicine
- ☐ Wrong medicine
- ☐ Wrong quantity
- ☐ Wrong dosage form/formulation
- ☐ Wrong preparation method
- ☐ Wrong time of dose administration
- ☐ Monitoring error clinical or laboratory
- ☐ Contraindication including known allergy
- ☐ Wrong duration
- ☐ Expired medicine
- ☐ Dose omitted or delayed
- ☐ Wrong frequency
- ☐ Other (specify)

**Staff or health care professional who made the error**

☐ Physician ☐ Pharmacist ☐ Nurse ☐ Dentist ☐ CHO ☐ Patient/caregiver ☐ Unknown

☐ Other (please specify)……

## *5. PRODUCT QUALITY DEFECT/ THERAPEUTIC INEFFECTIVENESS (Fill if applicable)*

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

## *6. *.REPORTER DETAILS*

☐ Doctor ☐ Pharmacist ☐ Nurse ☐ Pharm. Tech ☐ CHO ☐ Other (specify):……

| | |
|---|---|
| Name: | Telephone/Mobile: |
| Address: | Signature: |
| Email: | Date: |

For all questions relating to actual or suspected Adverse Drug Reactions, Medication Error or Products Quality Defect, please call the Pharmacy Board, National Pharmacovigilance Centre during working hours on 099-117117 or email us on drugsafety@pharmacyboard.gov.sl. Please return this form to the Pharmacy Board of Sierra Leone, Central Medical Stores Compound, New England Ville, Freetown. PMB 322, or to any of the regional offices in Bo, Mobile 078-534-757, Kenema, mobile 076-692-437, Kono, mobile 076-741-040, Makeni, mobile 076-692-576, or Lungi, mobile 076-338-468/076856-231.
For further information please visit our website at www.pharmacyboard.gov.sl
(Please note this report does not constitute an admission that the reporting medical professional or the suspected products caused or contributed to the event).

## ADVICE ON VOLUNTARY REPORTING

**Report adverse experience with:**
Medications (Drug and biologicals)
Medical devices
Traditional and herbal remedies
Cosmetics
Nutritional Agents

**Reports medication errors such as:**
Wrong dose, strength or frequency
Wrong medicine
Wrong route of administration
Wrong dosage form
Wrong time of dose administration

**Report product quality problems such as:**
Suspected contamination
Questionable stability
Defective components
Poor packaging or labeling
Therapeutic failure

**Report even if:** You're not certain the product caused the event or you don't have all the details

**Criteria for Assessment of Severity of an ADR**

| | |
|---|---|
| **Mild** | • The ADR requires no change in treatment with the suspected drug<br>• The ADR requires that the suspected drug be withheld, discontinued or otherwise changed. No antidote or other treatment is required<br>• No increase in length of stay/hospitalization |
| **Moderate** | • The ADR requires that the suspected drug be withheld, discontinued or otherwise changed, and/or an antidotes or other treatment is required<br>• Increases length of stay by at least one day<br>• The ADR is the reason for admission |
| **Severe** | • The ADR requires intensive medical care<br>• The ADR causes permanent harm to the patient<br>• The ADR either directly or indirectly leads to the death of the patient |

Your support of the Drug Safety programme is much appreciated. Information provided by you will contribute to the improvement of drugs therapy in Sierra Leone.
**Confidentiality**: Identities of the reporter and patient will remain strictly confidential

**Note: Fields marked (*.) are mandatory**