Drug Safety Monitoring Programme
Pharmacy Board of Sierra Leone
Ministry of Health And Sanitation

Suspected Adverse Drug Reaction Reporting Form

1. Patient Details
   - Last Name : Sex: 
   - Other Name (s) : Age (Years): 
   - Address : 
   - Inpatient/Outpatient Number : Weight (kg): 
   - Hospital/Treatment Centre: 

2. Suspected Drugs/Products
   - Brand Name: 
   - Strength 
   - Generic Name: 
   - Batch No (if any) 
   - Man. Date 
   - Expiry Date 

3. Name and Address of Manufacturer
   - Therapeutic indication (Reason for Use) 
   - Daily dose 
   - Route 
   - Date started 
   - Date stopped 

4. Drugs taken Concomitantly
   - All concomitant drugs including herbal preparations 
   - Brand or Generic Name 
   - Daily dosage 
   - Route 
   - Date started 
   - Date stopped 
   - Reasons for use 

COMMENTS: (e.g. Relevant history, Allergies, Previous exposure, Baseline test results/laboratory data).
Add separate sheet if necessary.

5. Source of Drug
   - Prescribed? Yes [ ] No [ ] 
   - Obtained over the counter? [ ] Yes [ ] No [ ] 
   - Hospital Pharmacy/Health Center [ ] Community Pharmacy/Drug Store [ ] Patent Medicine Shop [ ] Herbalist/Traditional Healer [ ] Relative/Friend/street vendor [ ] Other (Specify) [ ]

6. Details of reaction experienced by the patient
   - (Please Describe) (Use separate sheet if necessary)

   Date / time reaction started: Date / Time reaction stopped: 
   - Was patient admitted: Yes [ ] No [ ] 
   - Duration of admission (hours) [ ]
7. Adverse Reaction Outcome

- Death
- Life threatening
- Disability
- Hospitalization
- Congenital anomaly
- Other

Event reappeared on rechallenge: Yes □ No □
Rechallenge not done: Yes □ No □
Treatment of Reaction:

Recovery:
- Yes □ No □
- Recovered With sequelae Yes □ No □
- Reaction Continuing Yes □ No □

8. Product Quality Complaints

- Brand or Generic Name
- Batch No.
- Dosage form & Strength
- Mfg. date
- Expiry Date
- Pack Size
- Type of Container

9. Causality Assessment

- Certain □
- Probably/Likely □
- Possible □
- Unlikely □ Unclassified □

10. Health Care Professional/Reporter Detail

- Doctor □
- Pharmacist □
- Pharm. Tech □
- Nurse □
- CHO □
- Other □ (Specify)

Name:
Address:
Email:
Fax
Telephone:
Mobile:
Date:
Signature:

For all questions relating to actual or suspected Adverse Drug Reactions, please call The Pharmacy Board, Drug Information And Pharmacovigilance Unit during working hours on 225853 / 228497 or email us on infoibr_phbsl@yahoo.com. Please return this form to The Pharmacy Board of Sierra Leone 64 Slaka Street Freetown PMB 322. Fax: 224528, OR to any of the Regional Offices in BO, Mobile: 076-680-321, KENEMA, Mobile: 076-660-965, KONO, Mobile: 076-713-946, MAKENI, Mobile: 076-687-227 OR KAILAHUN, Mobile: 076-685-690

For further information please visit our website at www.pharmbsl.org

(Please note this report does not constitute an admission that the reporting medical professional or the suspected product caused or contributed to the event)

ADVICE ABOUT VOLUNTARY REPORTING

Report adverse experiences with:
- Medications (Drugs and Biologicals)
- Medical devices (including in-vitro diagnostics)
- Traditional and herbal remedies
- Cosmetics.
- Nutritional Agents

Report Product Quality Problems such as:
- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging or labelling
- Therapeutic failure

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

Confidentiality: Identities of the reporter and patient will remain strictly confidential.

Your support of the Drug Safety Monitoring Programme is much appreciated. Information provided by you will contribute to the improvement of drug therapy in Sierra Leone.