



Suspected Adverse Event Reporting Form

Identities of reporter, patient, institution, and product trade name(s) will remain confidential



ADR report number _____ (For office use only)
Date received _____

A. PATIENT AND HOSPITAL INFORMATION

Name of health facility (if applicable) _____

Patient name _____ Registration # _____

Patient address

Contact number _____

Age _____ Weight (kg) _____ Height (cm) _____ Gender Male Female

Pregnant Yes No Unknown Not applicable

B. SUSPECTED ADVERSE EVENT INFORMATION

Type of event <input type="checkbox"/> Adverse drug reaction <input type="checkbox"/> Product quality problem <input type="checkbox"/> Medication error	Suspected product Brand name _____ Generic name _____ Indication _____ Start Date _____ End Date _____ Dose [strength, unit] _____ Dosage Form _____ Frequency _____ Batch/Lot number _____ Manufacturer _____	
Describe event including relevant tests and laboratory results: 		
Date the event started _____	Date the event was reported _____	Date the event stopped _____
Was the adverse event treated? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please specify 		
Action taken after the reaction <input type="checkbox"/> Dose stopped <input type="checkbox"/> Dose reduced <input type="checkbox"/> No action taken	Did reaction subside after stopping/reducing the dose of the suspected product? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable Did reaction appear after reintroducing the suspected product? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable	

Seriousness of the adverse event: <input type="checkbox"/> Not serious <input type="checkbox"/> Hospitalization or prolongation of hospitalization <input type="checkbox"/> Disability or permanent damage <input type="checkbox"/> Congenital anomaly/birth defect <input type="checkbox"/> Life threatening <input type="checkbox"/> Other serious <input type="checkbox"/> Death	Outcomes attributed to the adverse event: <input type="checkbox"/> Recovered <input type="checkbox"/> Recovered/resolved with sequela <input type="checkbox"/> Not recovered <input type="checkbox"/> Unknown <input type="checkbox"/> Fatal (date of death: _____)
Other relevant history (including pre-existing medical conditions, allergies, pregnancy, smoking, alcohol use, liver or kidney problems, hypersensitivity, history of ADRs, etc.): 	

C. OTHER CONCOMITANT PRODUCT INFORMATION

	Product 1	Product 2	Product 3	Product 4
Brand name				
Generic name				
Indication				
Dosage form				
Route				
Dose				
Frequency				
Date started				
Date stopped				

D. REPORTER INFORMATION

Name _____	Designation _____
Address _____ _____	
Email address _____	
Mobile phone _____	Land phone _____
Signature _____	Date of submission _____

General instructions for completing the form

- Detailed information about each field can be found in the instructions.
- Fill in as much information as possible. Do not leave anything blank. If unknown, write “unknown” or “n/a” if not applicable.

• What to report:

- Serious adverse drug reactions
- Unknown or unexpected ADRs
- All suspected reactions to new drugs
- Unexpected therapeutic effects
- All suspected drug interactions
- Product quality problems
- Treatment failures
- Medication errors

Send all completed forms to:
 Directorate General of Drug Administration
 105-106, Motijheel Commercial Area, Dhaka-1000, Bangladesh
 Tel: 8802 9556126; Fax: 8802 9568166; Email: drugs@citech.net