Suspected Adverse Event Reporting Form

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

স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়

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	**Suspected product**
◯Adverse drug reaction	Brand name_____ Generic name_____
◯Product quality problem	Indication_____
◯Medication error	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? ◯Yes ◯No
If yes, please specify

Action taken after the reaction	**Did reaction subside after stopping/reducing the dose of the suspected product?**
◯Dose stopped ◯Dose reduced ◯No action taken	◯Yes ◯No ◯Not applicable **Did reaction appear after reintroducing the suspected product?** ◯Yes ◯No ◯Not applicable

Seriousness of the adverse event:	**Outcomes attributed to the adverse event:**
☐ Not serious ☐ Hospitalization or prolongation of hospitalization ☐ Disability or permanent damage ☐ Congenital anomaly/birth defect ☐ Life threatening ☐ Other serious ☐ Death	☐ Recovered ☐ Recovered/resolved with sequela ☐ Not recovered ☐ Unknown ☐ 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