Suspected Adverse Event Reporting Form

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

FOR OFFICE USE ONLY

AE report number _____ Date received _____

A. PATIENT INFORMATION

Name/Initial:
Address:

Contact number:

*Age--------- Weight(Kg)-------*Gender ☐Male ☐ Female ☐ Other

Pregnant : ☐ Yes ☐No ☐Unknown ☐Not applicable

B. SUSPECTED ADVERSE EVENT INFORMATION

*Type of event	Suspected product
☐ Adverse drug reaction	Brand/Trade name _____ * Generic name with strength _____
☐ Product quality problem	*Indication _____
☐ Medication error	*Medication Start Date _____ End Date _____
☐ Others(Please specify)	Dosage Form _____ * Frequency (Daily Dose) _____
	Batch/Lot number _____ Manufacturer _____

***Describe event including relevant tests and laboratory results:**

***Event start Date** _____

***Event stopped Date** _____

Was the adverse event treated? ☐ Yes ☐ No

If yes, please specify:

Action taken after reaction:

☐ Dose stopped
☐ Dose reduced
☐ No action taken

Did reaction subside after stopping / reducing the dose of the suspected product? ☐ Yes ☐ No ☐ Not applicable

Did reaction appear after reintroducing the suspected product?
☐ Yes ☐ No ☐ Not applicable

Seriousness of the adverse event:

☐ Not serious
☐ Hospitalization or prolongation of hospitalization
☐ Disability or permanent damage
☐ Congenital anomaly / birth defect
☐ Life threatening
☐ Death
☐ Other Medically important

***Outcomes attributed to the adverse event:**

☐ Recovered
☐ Recovered/resolved with sequeIIa
☐ Not recovered
☐ Unknown
☐ Fatal (date of death: _____)

Other relevant history: (pre-existing medical history)

☐ Hypersensitivity ☐ Allergies ☐ Liver or kidney problems ☐ Smoking ☐ Alcohol ☐ Diabetes

☐ Others (Please specify) :

C. *OTHER CONCOMITANT MEDICINE INFORMATION

Brand/Trade Name	Generic name	Indication	Dosage form	Strength & Frequency

D. *REPORTER INFORMATION

*Name & Address _____

_____

*Email address _____ *Mobile phone _____

*Occupation _____ *Signature _____

*Date of this report submission _____

*** Mandatory Information**

General instructions for completing the form:	**What to report :**
• Fill in as much information as possible. Do not leave anything blank. If unknown, write "unknown" or "n/a" if not applicable. • Additional pages can be used/added if necessary.	• 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

How toreport:

Suspected and observed drug-related reactions must be reported using the electronic version of the reporting form in a fillable pdf available on the ACME website (www.acmeglobal.com).

ADE reports can be submitted via Email (drugsafety@acmeglobal.com)

In emergency cases when forms are not readily available ADE reports can also be made to the MSPD by helpline number (+8801799998997)

ঔষধ ব্যবহারকারীদের নির্দেশনাঃ	**Send all completed forms to:**	Suspected Adverse Drug Reaction (ADR) সংক্রান্ত আপনার একটি রিপোর্ট ঔষধটির Unkown Side Effects থেকে অসংখ্য মানুষকে রক্ষা করতে সাহায্য করবে।
১। চিকিৎসকের ব্যবস্থাপত্র ব্যতীরেকে এন্টিবায়োটিক বা অন্য কোন ঔষধ ক্রয় ও ব্যবহার করবেন না। ২। চিকিৎসকের ব্যবস্থাপত্র অনুযায়ী সঠিক মাত্রায়, সঠিক পদ্ধতিতে পূর্ণকোর্স এন্টিবায়োটিক ব্যবহার করুন। ৩। শারীরিকভাবে সুস্থ্যতা অনুভব করলেও এন্টিবায়োটিকের পূর্ণকোর্স সম্পন্ন করুন।	**Medical Services & Pharmacovigilance Dept.** The ACME Laboratories Ltd. 1/4, Kallayanpur, Mirpur, Dhaka 1207, Bangladesh Tel: 9004194-6, Ext. 170, Helpline number: +8801799998997 Fax: 88-02-9121153, E-mail: aakhter.msd@acmeglobal.com drugsafety@acmeglobal.com	

ঔষধের বিরূপ প্রতিক্রিয়ার রিপোর্টিং এবং ঔষধের মান সম্পর্কিত সকল তথ্য জানতে হেল্পলাইন নাম্বারটি ব্যাবহার করুন