SUSPECTED ADVERSE REACTIONS FORM v 5 (4/2012)
"Saving Lives Through Vigilant Reporting"
****FIELDS MUST BE COMPLETED.***

For FDA use only ***All reports are confidential.***
AER No. 2012-0001
Date received: _____

PATIENT'S PARTICULARS

***Patient's Name or Initials**_____ *** Sex:** ☐ **Male** ☐ **Female** **Weight** _____**Kg** **Height (cm)** _____

Address or Contact Number: _____ ***Age**_____ **Date of Birth (mm/dd/yr)**_____

Medical History/Admitting Diagnosis: _____ **Ethnic group:** ☐ **Filipino** ☐ **Chinese** ☐ **Caucasian**

Any Known Allergy: ☐ **No** ☐**Yes, Specify:**_____ **Pregnancy Status:** ___ **No**

Hospital/facility , if admitted:_____ ___ **Yes (1st, 2nd, 3rd trimester)**

*DETAILS OF THE ADVERSE REACTION

Date of onset:_____; ____**am,** ____**pm**

Do you consider the reaction to be serious? ☐ **Yes**, if yes indicate why: ☐ **No**

Describe the reaction, including pertinent laboratory data:

☐ Patient died due to reaction
☐ Involved or prolonged in-patient hospitalization
☐ Life threatening
☐ Involved persistent or significant disability
☐ Congenital anomaly in the newborn
☐ Other outcome, please give details:

Can this be due to Medication Error? ☐ **No**
☐ **Yes**, if yes, which type:

___Prescribing
___Transcription
___Dispensing
___Administration

Can the adverse reaction be due to :

1. **Product quality defect** ___**No** ___**Yes, Specify, encircle:** color change ; caking; powdering ; counterfeit; odor change; defective container; contaminants; separation of components; undissolved suspension/powder
2. **Therapeutic failure:** ___**No** ___**Yes, Specify, encircle:** antimicrobial resistance, drug interaction, poor compliance, counterfeit, expired; improper storage; under-dosing, inappropriate medication; inappropriate route of administration; excipients/preservatives

*Suspected drug product(s) Indicate brand name	Daily Dose	Route	Date started	Date stopped	Reason (s) for using the product (Indication)	Manufacturer and Batch/Lot #

List all other drug/s taken at the same time and/ or 3 months before. If none, check box. ☐ ***No Other drug/s taken***

Brand name of the drug	Daily Dose	Route	Date started	Date stopped	Reason/s for using the drug	Manufacturer and Batch & Lot No.

*MANAGEMENT OF ADVERSE REACTION

Was treatment given? ☐ **No** ☐ **Yes** (If yes, please specify): _____

Outcome:
☐ Recovered (Date of recovery):_____ ☐ Unrecovered **Other diseases**: _____liver _____renal _____HPN
☐ Fatal (Date of death):_____ ☐ Unknown _____ Diabetes _____CVS ____Endocrine ____Cancer

Sequela/e: (any permanent complications or injuries as a result of the ADR) **Re-challenge?** ☐ **Yes Result**_____
☐ **Yes (Please specify)**_____ ☐ **No** ☐ **Unknown** ☐ **No**

* REPORTER'S PARTICULARS

***Printed Name of Reporter:** _____
Signature of reporter: _____
Date reported (mm/dd/yr): _____

***Contact no:**_____
Email address: _____
***Profession**: __MD ___ RPh ___RN___Patient ___Dentist ___other
***Facility:** ___Clinic ____Trial site _____Other

National Pharmacovigilance Center
"Saving Lives Through Vigilant Reporting"
Send completed form to: ADR Unit, FDA, Civic Drive, Filinvest Estate, Alabang, Muntinlupa ,1781.
Or fax to: (02) 807-85-11, c/o The ADR Unit. **Send sample, if any, of suspect drug for analysis.**
Website: www.fda.gov.ph

CONFIDENTIALITY

Any information including attachment/s related to the identities of the reporter and patient will be kept confidential.

GUIDELINES FOR REPORTING

Please report any of the following:

- All suspected adverse drug reactions for medicines and vaccines, including established medicines, traditional medicines, household and herbal remedies & suspected counterfeit
- All serious expected and/or unexpected adverse drug reactions
- All suspected adverse drug reaction for new medicines
- All suspected adverse drug reaction occurred in special populations including children, pregnant women and elderly
- All medication errors that result in an adverse reaction
- Report even if you are not sure that the drug caused the event

For follow-up reports:
Any follow-up information that has already been reported may be sent to us in another form or through other reporting channels. Please indicate follow up report.

Send this report thru:

✓ Mail or Direct submission to:

Pharmacovigilance Unit
Center for Drug Regulation and Research
FOOD AND DRUG ADMINISTRATION
Civic Drive, Filinvest Corporate City,
Alabang, Muntinlupa City

✓ Fax: (02) 809 5596
✓ Telephone: (02) 809 5596
✓ Email: adr@fda.gov.ph
✓ Online reporting:
http://www.fda.gov.ph/adr-report-new

This form can be downloaded from FDA website http://www.fda.gov.ph/industry-corner/downloadables/265-suspected-adverse-reaction-form

For more information :
Contact the National Pharmacovigilance Center at (02) 809 5596

Thank you for reporting