**SUSPECTED ADVERSE REACTIONS FORM v 5 (4/2012)**

**“Saving Lives Through Vigilant Reporting”**

**All reports are confidential.**

**FIELDS MUST BE COMPLETED.**

<table>
<thead>
<tr>
<th><strong>PATIENT'S PARTICULARS</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient’s Name or Initials</strong></td>
<td></td>
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<tr>
<td><strong>Sex:</strong> Male</td>
<td>Female</td>
</tr>
<tr>
<td><strong>Weight:</strong> Kg</td>
<td>Height (cm)</td>
</tr>
<tr>
<td><strong>Address or Contact Number:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Age:</strong></td>
<td><strong>Date of Birth (mm/dd/yr):</strong></td>
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**Medical History/Admitting Diagnosis:**

**Any Known Allergy:** No | Yes, Specify: _________________________

**Hospital/facility, if admitted:**

**Ethnic group:** Filipino | Chinese | Caucasian

**PREGNANCY STATUS:**

**Outcome:**

- Life threatening
- Involved or prolonged in-patient hospitalization
- Other disability
- Other outcome, please give details:

**Can this be due to Medication Error?**

- 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)**

<table>
<thead>
<tr>
<th>Indicate brand name</th>
<th>Daily Dose</th>
<th>Route</th>
<th>Date started</th>
<th>Date stopped</th>
<th>Reason(s) for using the product (Indication)</th>
<th>Manufacturer and Batch/Lot #</th>
</tr>
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</table>

**List all other drugs taken at the same time and/or 3 months before. If none, check box.**

<table>
<thead>
<tr>
<th>Brand name of the drug</th>
<th>Daily Dose</th>
<th>Route</th>
<th>Date started</th>
<th>Date stopped</th>
<th>Reason(s) for using the drug</th>
<th>Manufacturer and Batch &amp; Lot No.</th>
</tr>
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</table>

**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: _________________________

**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

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**FDA Food and Drug Administration Philippines**

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