SUSPECTED ADVERSE DRUG REACTION (ADR) REPORTING FORM

CONFIDENTIAL

If you are suspicious that an adverse reaction may be related to a drug or a combination of drugs, PLEASE COMPLETE THIS FORM and send it to the nearest Pharmacovigilance Centre / Drug Regulatory Authority.

A. PATIENT INFORMATION

1. Patient Details*

Patient name or Initials: _____________________________________________ Age/Sex: __________

Weight (if known): ___________________________________________ Ward/Dept/Unit: __________

2. Relevant Tests/Laboratory Data(If any):

3. Other Relevant Information (including Pre-existing medical conditions viz. allergies, pregnancy, alcohol use, renal dysfunction, diabetes etc.):

B. SUSPECTED DRUG (S) *

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>Prescribed for/Indication</th>
<th>Manufactured by:</th>
<th>BATCH NO/EXP DATE</th>
<th>ROUTE</th>
<th>DOSE/STRENGTH</th>
<th>DATE STARTED</th>
<th>DATE STOPPED</th>
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C. SUSPECTED DRUG REACTION(S)*

1. PLEASE DESCRIBE THE REACTION & ANY TREATMENT GIVEN /ACTION TAKEN

DATE REACTION STARTED: ________

DATE REACTION STOPPED: ________

OUTCOME: (TICK ALL THAT IS APPROPRIATE)

RECOVERED ☐ RECOVERING ☐ CONTINUING ☐

OTHERS (SPECIFY)___________________
2. DO YOU CONSIDER THE REACTION TO BE SERIOUS?        YES ☐        NO ☐

   IF YES, PLEASE INDICATE WHY THE REACTION IS CONSIDERED TO BE SERIOUS (TICK ALL THAT IS APPROPRIATE)

i. PATIENT DIED DUE TO REACTION ☐  ii. PROLONGED HOSPITALIZATION ☐  iii. LIFE THREATENING ☐
iv. SIGNIFICANT DISABILITY ☐  v. MEDICALLY SIGNIFICANT (including congenital anomaly), GIVE DETAILS: ☐

______________________________________________________________________________________________

D. OTHER MEDICATIONS (INCLUDING SELF-MEDICATION, (HERBAL AND TRADITIONAL MEDICINES)
DID THE PATIENT TAKE ANY OTHER MEDICINES PRIOR TO THIS REACTION?   YES ☐        NO ☐

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<tr>
<th>DRUG NAME</th>
<th>Dosage</th>
<th>Route</th>
<th>Date Started</th>
<th>Date Stopped</th>
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E. REPORTER DETAILS *

NAME: ___________________________________________ DESIGNATION: ______________________________

ADDRESS: ____________________________________________________________________________________________

CONTACT NO. ___________________________ DATE: ______________________________

SIGNATURE: ______________________________

Please send this form to National Pharmacovigilance Centre (DRA), telephone: 337075, fax: 335803, email: ndem@dra.gov.bt or to the nearest Regional Pharmacovigilance centre. Thank you for taking the time to fill in this report!

FOR OFFICIAL USE BY DRA:

Date of receipt of the report: _______________ Received by: ______________________________

Report ID no. ______________________________ Product MAH:

Action taken: