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) *

DRUG NAME	Prescribed for/Indication	Manufactured by:	BATCH NO/ EXP DATE	ROUTE	DOSE/ STRENGTH	DATE STARTED	DATE STOPPED

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 ☐

DRUG NAME **(Both Generic and Brand)**	**Dosage**	**Route**	**Date Started**	**Date Stopped**

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 OFFICAIL USE BY DRA:

Date of receipt of the report: _____ Received by: _____

Report ID no. _____ Product MAH:

Action taken: