CONFIDENTIAL

For office use only:
BRN _____
Initial report _____
Follow-up report ____

National Adverse Drug Reaction Monitoring Centre
Ministry of Health, Brunei Darussalam

SUSPECTED ADVERSE DRUG REACTION REPORT FORM

Please report **all** suspected adverse drug reactions including those for self-medication, traditional medicines and health supplements. Do not hesitate to report if some details are not known. **MANDATORY FIELDS** are marked with *. **Identities of reporter and patient** will be kept confidential.

(1) PATIENT DETAILS *

Patient name:_____ Date of birth:_____ Weight, if known (kg): ___

Gender: ☐ Male ☐ Female Medical record no. / BruHims no. / Identity card no. :_____

Nationality: _____ Ethnic group: ☐ Malay ☐ Chinese ☐ Other (please specify):_____

(2) ADVERSE DRUG REACTION (ADR) DETAILS *

Description of ADR(s): _____

_____

Time to onset of ADR(s): _____mins/ hours/ days/ months/ years *(please circle)* Date ADR(s) started: _____ Date ADR (s) stopped: _____

Do you consider the ADR(s) to be serious? ☐ Yes ☐ No

*If **yes**, please indicate why the ADR is considered to be serious (please tick all that apply):*

☐ Patient died due to reaction ☐ Life threatening ☐ Involved or prolonged in-patient hospitalisation
☐ Congenital abnormality ☐ Involved persistent or significant disability or incapacity
☐ Medically significant; please give details: _____

- Description of treatment of reaction: _____
- Outcome of reaction: ☐ Recovered ☐ Recovering ☐ Recovered with sequelae (any permanent complications or injuries)
  ☐ Not recovered ☐ Fatal (Date of Death): _____ ☐ Unknown

(3) SUSPECTED DRUG(S) * *(Additional pages may be attached)*

Product name, active ingredient & strength	Dosage form	Dosage regimen (dosage, frequency & route)	Product details: Batch No. (if known)	Date started	Date stopped	Prescribed for
1.						
2.						
3.						

(4) OTHER DRUG(S) (INCLUDING SELF-MEDICATION, TRADITIONAL MEDICINES & HEALTH SUPPLEMENTS CONSUMED AT THE SAME TIME AND/ OR IN THE LAST 3 MONTHS BEFORE THE ADR) *(Additional pages may be attached)*

Product name, active ingredient & strength	Dosage form	Dosage regimen (dosage, frequency & route)	Product details: Batch No. (if known)	Date started	Date stopped	Prescribed for
1.						
2.						

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3.						
4.						
5.						

(5) OTHER RELEVANT INFORMATION *(Additional pages may be attached)*

Relevant Medical History (Include Allergies, Pregnancy Status, Smoking, Renal/ Hepatic Dysfunction etc) ***(For congenital abnormalities, please state all other drugs taken during pregnancy and the last menstrual period)***	**Relevant Investigations (Rechallenge If Performed/ Laboratory Data)**

(6) REPORTER DETAILS *

Name: _____ Signature: _____

Profession: _____ Institution Address : _____

Date: _____ Tel No: _____ Email: _____

Thank you for taking the time to complete this form.

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GUIDANCE ON ADR REPORTING

WHAT TO REPORT?

An adverse drug reaction is a response to a drug that is noxious (harmful) and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.

The Ministry of Health encourages the reporting of **all** suspected adverse reactions to drugs and medicinal substances (including self-medication, traditional medicines or health supplements). In particular, please report:

- All suspected reactions to established products and new medicines regardless of their nature and severity.
- All serious adverse reactions which include reactions suspected of causing death, danger to life, admission to hospital, prolongation of hospitalisation, birth defects, persistent or significant disability or incapacity and if medically significant.
- All suspected drug interactions

HOW TO REPORT?

The Suspected Adverse Drug Reaction Report form can be obtained from the National Adverse Drug Reaction Monitoring Centre and the nearest government pharmacy facility (hospital/ health centre). This form should be filled as completely as possible and returned to the address below or to the nearest government pharmacy facility (hospital/ health centre).

SUBMISSION OF FOLLOW-UP REPORTS

Any follow-up information for an ADR that has already been reported can be sent to us in another form or *via* any other modes of reporting. Please state that it is a follow-up report, indicating the date and reference number of the initial report.

FOLD HERE SECOND

To:

National Adverse Drug Reaction Monitoring Centre (NADRMC)
c/o Pharmacovigilance Section
1st Floor, Department of Pharmaceutical Services Building
Simpang 433, Rimba Highway
Kg Madaras, Bandar Seri Begawan
BB1514
Brunei Darussalam
Telephone Number: +673 2393298/ 2393301 Ext 201, 206, 207
Fax Number: +673 2393097
E-mail: nadrmc.dps@moh.gov.bn