MINISTRY OF HEALTH AND MEDICAL SERVICES

REPORT OF SUSPECTED ADVERSE DRUG REACTION

(**Note:** Identities of Reporter, Patient and Institution will remain Confidential)

I. Particulars of Patient

Patient initials or national health number: _____ Sex: _____

Date of birth (dd-mm-yyyy) or age: _____ Weight (kg): _____

II. Details of Adverse Drug Reaction

Description of reaction: _____

_____

_____

_____

Date reaction started: ___/___/____ **Time reaction started:** _____

Date reaction stopped: ___/____/___ **Time reaction stopped:** _____

Other relevant information: e.g., medical history *(diseases, conditions such as pregnancy, surgical procedures, psychological traumas, risk factors, etc.),* **drug history: _____**

_____

_____

_____

_____

If done, please enclose any relevant laboratory results including dates.

III. Details Of Suspected Drug and All Other Drugs Used (including the Diluent)

All medicines in use, please: *(i) asterisk Suspect Drug(S)*
(ii) include traditional medicines/ supplements/ over the counter (OTCs)

Medicine(s)/ Traditional medicine(s)/ OTC Use Generic Names (Trade name in brackets)	Dosage Regimen	Batch Number	Route	Therapy Date		Reason for use
				Start	Stop	

Please send the completed form As Soon As Possible to: fijiMRA@govnet.gov.fj or to adr.report.fj@gmail.com or to viber # 9888076, or to The Pharmacovigilance Officer, Medicines Regulatory Authority, Fiji Pharmaceutical & Biomedical Service Centre, GPO Box 106 Suva.

IV. Management of Adverse Reaction

Reaction subsided after stopping the suspected drug/reducing the dose:
☐ Yes ☐ No ☐ Unknown

Reaction reappeared after reintroducing the drug: ☐ Yes ☐ No ☐ Unknown

Do you consider the reaction to be serious: ☐ Yes ☐ No

Reason for seriousness:

☐ Death
☐ Hospitalization/prolonged
☐ Congenital-anomaly
☐ Life-threatening
☐ Disabling
☐ Other medically important condition

Treatment of Reaction: ☐ No ☐ Yes (if yes please specify): _____
_____
_____
_____

Outcome of the Reaction: ☐ Not recovered ☐ Recovered ☐ Unknown
☐ Recovered with sequelae ☐ Fatal (Date of death): _____

Any comment(s) if available: _____
_____
_____
_____

V. Reporter Details

Reporting Person Name: _____

Designation: ☐ Physician ☐ Pharmacist ☐ Nurse ☐ Other: _____

Department: _____

Institution: _____

Phone: _____ **Email Address:** _____

Signature: _____ **Date:** _____

……

CAUSALITY ASSESSMENT: PLEASE CIRCLE (OFFICE USE ONLY)

☐ CERTAIN ☐ PROBABLE ☐ POSSIBLE ☐ UNLIKELY
☐ UNCLASSIFIABLE/ CONDITIONAL ☐ UNCLASSIFIED

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