SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

Government of Nepal
Ministry of Health and Population
Department of Drug Administration

Initial Case ❑ Follow-up Case ❑
Reg. No./IPD No./OPD No./CR No.

Report Title:

Report Type: (Please tick anyone)
Spontaneous/Report from Study/Other/ Not Available

To be filled by NRA (National Regulatory Authority)
Received date (dd/mm/yyyy):
Received from: Health Professional/Pharmaceutical Company/Regional PV center /Patient/Consumer/Other
Received via:

A. PATIENT INFORMATION *

1. Patient Name:

2. Age at onset of reaction:

Date of birth:

3. Gender: M ❑ F ❑ Other ❑
4. Pregnant: ❑
5. Lactating: ❑

6. Weight (in Kg)
7. Height (in cm)

11. Relevant investigations with dates:

B. SUSPECTED ADVERSE REACTION *

8. Reaction/Event Onset date(dd/mm/yyyy) : Time:

9. Reaction/Event End date (dd/mm/yyyy) : Time:

Duration: _____Second/Minute/Hour/Day/Week/Month/Year/Decade (**Tick Anyone**)

10. Describe Event/Reaction management with details, if any

12. Relevant medical / Drug history (e.g. allergies,pregnancy, addiction, hepatic, renal dysfunction etc.)

13. Seriousness of the reaction : No ❑ if Yes ❑ **(please tick anyone)**
❑ Death (dd/mm/yyyy) ❑ Congenital-anomaly
❑ Life threatening ❑ Disability
❑ Hospitalization-Initial/Prolonged ❑ Other Medically important

14. Outcome:
❑Recovered ❑Recovering ❑Not Recovered
❑Fatal ❑Recovered with sequelae ❑Unknown

C. SUSPECTED MEDICATION(S) *

S. No.	Name (Brand/Generic)	Manufacturer (if known)	Batch No./ LotNo.	Expiry Date (if known)	Dose	Route	Frequency	Therapy Administration		Indication	Causality Assessment Performed (Y/N)
								Date Started	Date Stopped		
i											
ii											
iii											
iv#											

15. Action taken after reaction (***please tick***)

16. Reaction reappeared after reintroduction ofsuspected medication **(*please tick*)**

S. No.	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if re-introduced)
i										
ii										
iii										
iv#										

17. Concomitant medical product including self-medication add herbal remedies with therapy dates (Exclude those used to treat reaction)

S. No.	Name (Brand / Generic)	Dose	Route	Frequency (OD, BD, etc.)	Therapy Administration		Indication
					Date Started	Date Stopped	
i							
ii							
iii#							

Do you suspect quality issues (including falsified) on the products? Y/N
If Yes, Explain briefly :

D. REPORTER DETAILS *

18. Name & Address : _____

Qualification: _____ Organization: _____

Email: _____ Contact No-: _____

Signature : _____

19. Date of report (dd/mm/yyyy) :

Confidentiality : The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

Use separate page for more information * Mandatory Fields for suspected ADR Reporting Form