SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

Regional Pharmacovigilance Center

Department of Pharmacology, BPKIHS, Dharan, Nepal

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Reporting of Adverse drug reaction is an essential part of National Pharmacovigilance Program to monitor the safety of medicines and protect public health ensuring patient safety. The information you've provided is valuable and helps us to identify potential safety risks. All reporter information is held in strict confidence. We appreciate your time and contribution.

A. Report title (Name of the ADRs):
B. Patient's Reg. No./IPD No./OPD No.:

A. PATIENT INFORMATION*

1. Patient Name:	**2. Age:**
3. Gender: M ❑ F ❑ Other ❑ **4. Pregnant:** ❑ **5. Lactating**: ❑	**6. Weight** (in Kg) …….. **7. Height** (in cm)……

B. DETAILS OF THE SUSPECTED ADVERSE DRUG REACTION*

8a. Date of Onset of ADR (dd/mm/yyyy): **8b. ADR Onset Time:** am/pm

9a. Date of End of ADR (dd/mm/yyyy**):** **9b. ADR End Time:** am/pm

Duration of the ADR: _____Second/Minute/Hour/Day/Week/Month/Year/Decade (Tick Anyone)

10. Describe ADR (in brief) and its management, if any:

11. Relevant investigations with dates:

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

13. Seriousness of the ADR : No ❑

if Yes ❑ (please tick any one) ❑ Death (dd/mm/yyyy) ❑ Congenital-anomaly ❑ Life threatening ❑ Disability ❑ Hospitalization-Initial/Prolonged ❑ Others……..

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

C. DETAILS OF THE SUSPECTED MEDICATION(S) *

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

15. Action taken after occurrence of ADR (please tick)

S. No.	Name of the Drug	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown
i.							
ii.							
iii.							
iv.							
v.							
vi.#							

16. ADR reappeared after reintroduction of the suspected medication (please tick)

Yes	No	Effect unknown	Dose (if reintroduced)

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

S. No.	Name (Brand / Generic)	Dose	Route	Frequency	Therapy Administration		Indication(s)
					Date Started	Date Stopped	
i.							
ii.							
iii.							
iv.#							

Do you suspect quality issues (including falsified) of the suspected drug(s)? Yes/No
If Yes, Explain briefly:

D. Details of the ADR REPORTER*

18. Name of the reporter: _____ Qualification: _____
Contact No-: _____ Signature : _____

19. Date of ADR 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.

To be Filled by Regional Pharmacovigilance center, BPKIHS

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

Received date (dd/mm/yyyy):
Received from: Health Professional/Pharmaceutical Company/ Patient/others……..

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

"Thank you for submitting the Adverse Drug Reaction report." We appreciate your valuable contribution to the patient safety."