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Institutional Area, Sector-4, Kharghar, Navi Mumbai 410210

Mechanism of collection, analysis and reporting of ADRs

PPvCs (Coordinator & Program Assistant)



Data from Each Center Analysis of the reports

IPvCs (Coordinator & Program Associate)



Compiled Data of All Centers

NPvC (Coordinator & Technical Program Officer)



DCC, Ministry of AYUSH

Dr. G. D. POL FOUNDATION Y.M.T. AYURVEDIC MEDICAL COLLEGE AND HOSPITAL Institutional Area Sector - 4,

Kharghar, Navi Mumbai - 410 210...

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Pharmacovigilance Program for ASU & H Drugs Reporting Form for Suspected Adverse Reactions

Note:

Personal information will be kept confidential.
All suspected reactions are to be reported with relevant details.

C-1-CD-11	10.4	 I DD N	/ 177	
Code of Periphera	Centre	ADR Numb	or / Voor	

1. Patient / consumer identification (please complete or tick boxes below as appropriate)

Patient Initials		Patient Record Number (PRN		
Place of Birth	IPD / OPD			
Address		Age:		
Village / Town		Sex: Male / Female / Others		
Post / Via				
District / State				
Diagnosis:	Constitution and Temp	perament:		

2. Description of the suspected Adverse Reactions

Date and time of initial observation	
Description of reaction	

3. Whether the patient is suffering with any chronic disorders?

Hepatic Renal

Cardiac Diabetes

Any Others (Specify, if others)

4. Addictions, if any? If yes, please specify:

5. H/O previous allergies / Drug reactions, if any: If yes, please specify:

VD. SANGEEV YADAV

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6. List of all ASU & H drugs used by the patient during the period of one month:

Name	Manufacturer /Batch no.	Dose	Form / Route of administration	Date of		Dansan	Any
of the drug				Starting	Stopped / Continued	Reason for use	unwanted occurrences
		× • • • •					

7. List of other drugs used by the patient during the period of one month:

Name	Manufacturer /Batch no.	Dose	Form / Route of administration	D	ate of	Reason for use	Any unwanted occurrences
of the drug				Starting	Stopped / Continued		

8. Details of the drug suspected to cause ADR:

- a. Name of the drug:
- b. Manufacturing date and Expiry date (if available):
- c. Remaining pack / label (if available):
- d. Consumed orally along with (water / milk / honey / or any other)
- e. Whether any dietary precautions have been prescribed?If yes, please specify:
- f. Whether the drug is consumed under medical supervision or used as self-medication.
- g. Any other relevant information associated with drug use:

VD. SAHJEEV YADAV PRINCIPAL

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9. Management provided / taken for suspected adverse reaction

10. Please indicate outcome of the suspected adverse reaction (tick appropriate)

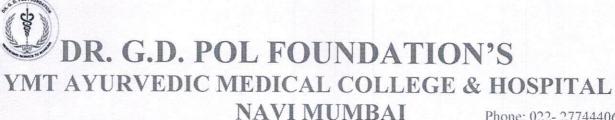
Recovered:	Not recovered:	Unknown:	Fatal:	If Fatal Date of death:	
Severe: Yes / No.	Reaction	abated after dru	g stopped or	dose reduced:	
	Reaction	reappeared after	r re administ	ration of drug:	
Was the patient admi yes, give name and ac					

11. Any abnormal findings of relevant laboratory investigations related to the episode done pre and post episode of ADR:

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The ADR Probability Scale (Program Coordinator has to fill this scale)

	Questions	Yes	No	Don't Know
1	Are there previous conclusive reports on the reactions?	+1	0	. 0
2	Did the ADR appear after the suspected drug was administered?	+2	-1	0
3	Did the ADR improve when the drug was discontinued a specificantagonist was administered?	+1	0	0
4	Did the adverse reaction reappear when the drug was re-administered?	+2	-1	0
5	Are there alternatives causes that could solely have caused the ADR?	-1	+2	0
6	Was the drug detected in the blood (or other fluids) in a concentrationknown to be toxic?	+1	0	0
7	Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?	+1	0	0
8	Did the patient have a similar reaction to the same or similar drugs inany previous exposure?	+1	0	0
9	Was the adverse event confirmed by objective evidence?	+1	0	0
	Total Score			

Score: > 9 = Certain; 5-8 = Probable; 1-4 = Possible; 0 = Unlikely

	Grade - 1 (Mild)	
The suspected Adverse Event is	Grade - 2 (Moderate)	
The suspected Adverse Event is	Grade - 3 (Severe)	
	Grade - 4 (Threatening)	
TI (141 F ()	Serious	
The suspected Adverse Event is	Non-Serious	
	Physician	
The avenueted Adverse Event is due to	Patient	
The suspected Adverse Event is due to	Drug	
	Other Factors* (Explain other factors)	

12. Particulars of ADR Reporter:

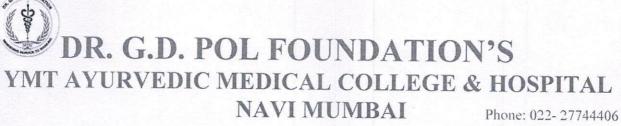
Please tick:	Patient / Attendant / Nurse / Doctor / Pharmacist / Health worker / Drug Manufacturer / Any others (please specify)	
Name:		
Address:		
Telephone / I	E - mail:	

Signature of the reporter:

Dr. G. D. POL FOUNDATION
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Date:

Signature of the Program Coordinator



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Please send the completed form to: The centre from where the form is received or to The Coordinator, National Pharmacovigilance Coordination Centre All India Institute of Ayurveda, Sarita Vihar, New Delhi - 110 076

Email: pharmacovigilanceayush@gmail.com / ayush-pharmavig@aiia.gov.in

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