How to fill ADR Reporting Form and Causality Assessment

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ADR Reporting Forms

- Suspected Adverse Drug Reaction Reporting Form

  (For voluntary reporting of Adverse Drug Reactions by Healthcare Professionals)

- ADR Reporting Form for Consumer

- Transfusion Reaction Reporting Form (TRRF)

  (Haemovigilance Program of India)

- Medical Device Adverse Event Reporting Form

  (Materiovigilance Program of India)

Who can report?

Doctor

Dentist

Nurse

Pharmacist

Patient

Where to report

- Nearest ADR Monitoring Center (AMC)
  - AIIMS Raipur
  - Pt. JNMC, Raipur
- Directly to NCC, IPC Ghaziabad
- pvpi.ipcindia@gmail.com
  pvpi@ipcindia.net
- Toll free no. – 1800 180 3024
- ADR Reporting Android app

What to report?

- Serious or Non-serious ADR
- Known or Unknown ADR
- Frequent or Rare
  - Related to medicine, vaccine, herbal products

Version-1.2

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION

(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002

Report Type: Initial / Follow-up

FOR AMC/NCC USE ONLY

AMC Report No. :

Worldwide Unique No. :

A. PATIENT INFORMATION

1. Patient Initials _____

2. Age at time of Event or Date of Birth _____

3. M ☐ F ☐ Other ☐

4. Weight _____ Kgs

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy)

6. Date of recovery (dd/mm/yyyy)

7. Describe reaction or problem

12. Relevant tests/ laboratory data with dates

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)

14. Seriousness of the reaction: No ☐ if Yes ☐ (please tick anyone)

☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Required intervention to Prevent permanent
☐ Hospitalization/Prolonged impairment/damage
☐ Disability ☐ Other (specify)

15. Outcomes

☐ Recovered ☐ Recovering ☐ Not recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S)

S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates		Indication	Causality Assessment
								Date started	Date stopped		
i											
ii											
iii											
iv											

S.No as per C	9. Action Taken (please tick)						10. Reaction reappeared after reintroduction (please tick)			
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if reintroduced
i										
ii										
iii										
iv										

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

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates		Indication
					Date started	Date stopped	
i							
ii							
iii							

Additional Information:

D. REPORTER DETAILS

16. Name and Professional Address: _____

Pin: _____ E-mail _____

Tel. No. (with STD code) _____

Occupation: _____ Signature: _____

17. Date of this report (dd/mm/yyyy):

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

National Coordination Centre
Pharmacovigilance Programme of India
Ministry of Health & Family Welfare,
Government of India
Sector-23, Raj Nagar, Ghaziabad-201002
Tel.: 0120-2783400, 2783401, 2783392
Fax: 0120-2783311
www.ipc.nic.in

Pharmacovigilance Programme of India for Assuring Drug Safety

ADVICE ABOUT REPORTING

A. What to report

- Report serious adverse drug reactions. A reaction is serious when the patient outcome is:
  - Death
  - Life-threatening
  - Hospitalization (initial or prolonged)
  - Disability (significant, persistent or permanent)
  - Congenital anomaly
  - Required intervention to prevent permanent impairment or damage
- Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines and Herbal products.

B. Who can report

- All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurses) can report adverse drug reactions

C. Where to report

- Duly filled Suspected Adverse Drug Reaction Reporting Form can be send to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC).
- Call on Helpline (Toll Free) 1800 180 3024 to report ADRs.
- Or can directly mail this filled form to pvpi@ipcindia.net or pvpi.ipcindia@gmail.com
- A list of nationwide AMCs is available at:
  http://www.ipc.gov.in, http://www.ipc.gov.in/PvPI/pv_home.html

D. What happens to the submitted information

- Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
- The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
- The information is submitted to the Steering committee of PvPI constituted by the Ministry of Health & Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required.

E. Mandatory field for suspected ADR reporting form

- Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) and reporter information.

For ADRs Reporting Call on PvPI Helpline (Toll Free)

1800 180 3024

(9:00 AM to 5:30 PM, Working Days)

A. Patient Information

1	Patient Initials
2	Age at the time of Event or Date of Birth
3	Sex Male ☐ Female ☐ Other ☐
4	Weight (kg)

B. Suspected Adverse Reaction

5	Date of Reaction started (dd/mm/yyyy)
6	Date of recovery (dd/mm/yyyy)
7	Describe reaction or problem

C. Suspected Medication

8	Name (Brand and/or Generic)
	Manufacturer (if known)
	Batch No. /Lot No.
	Exp. Date (if known)
	Dose used
	Route used
	Frequency (OD, BD, etc)
	Therapy dates Date Started Date Stopped
	Indication
	Causality Assessment

C. Suspected Medication

9	Action Taken (Please tick)					
	Drug Withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown
i						
ii						
iii						
iv						

C. Suspected Medication

10	Reaction reappeared after reintroduction (please tick)			
	Yes	No	Effect unknown	Dose (if reintroduced)
i				
ii				
iii				
iv				

C. Suspected Medication

11	Concomitant medical products Including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)						
	Name (Brand/ Generic)	Dose used	Route Used	Frequency (OD, BD, etc.)	Therapy dates		Indication
					Date Started	Date Stopped	
i							
ii							
iii							
iv							

12	Relevant tests/laboratory data with dates
13	Relevant medical / medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)

14	Seriousness of the reaction: No ☐ If Yes ☐ (Please tick anyone)

	Death (dd/mm/yyyy)
	Life threatening
	Hospitalization (initial or prolonged)
	Disability
	Congenital anomaly
	Required intervention to prevent permanent impairment / damage
	Other (specify)

15 Outcomes

	Recovered
	Recovering
	Not recovered
	Fatal
	Recovered with sequelae
	Unknown

D. Reporter Details

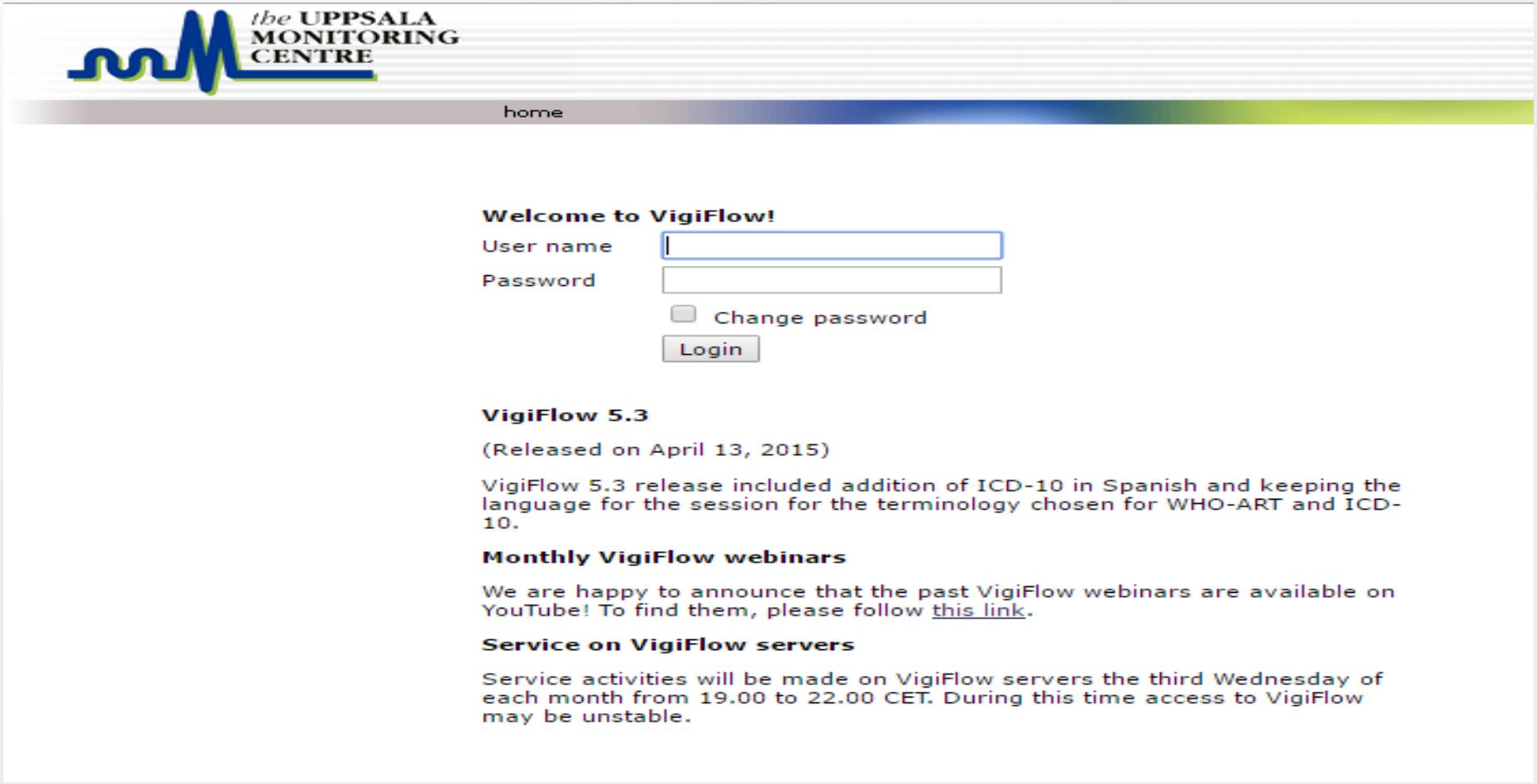
16	Name and Professional Address Pin Email Tel. No. (with STD Code) Occupation Signature
17	Date of this report (dd/mm/yyyy)

Mandatory Fields for Suspected ADR Reporting Form

1	Patient initials
2	Age at onset of reaction
5	Date of onset of reaction
7	Reaction term(s)
8	Suspected medication
16, 17	Reporter information

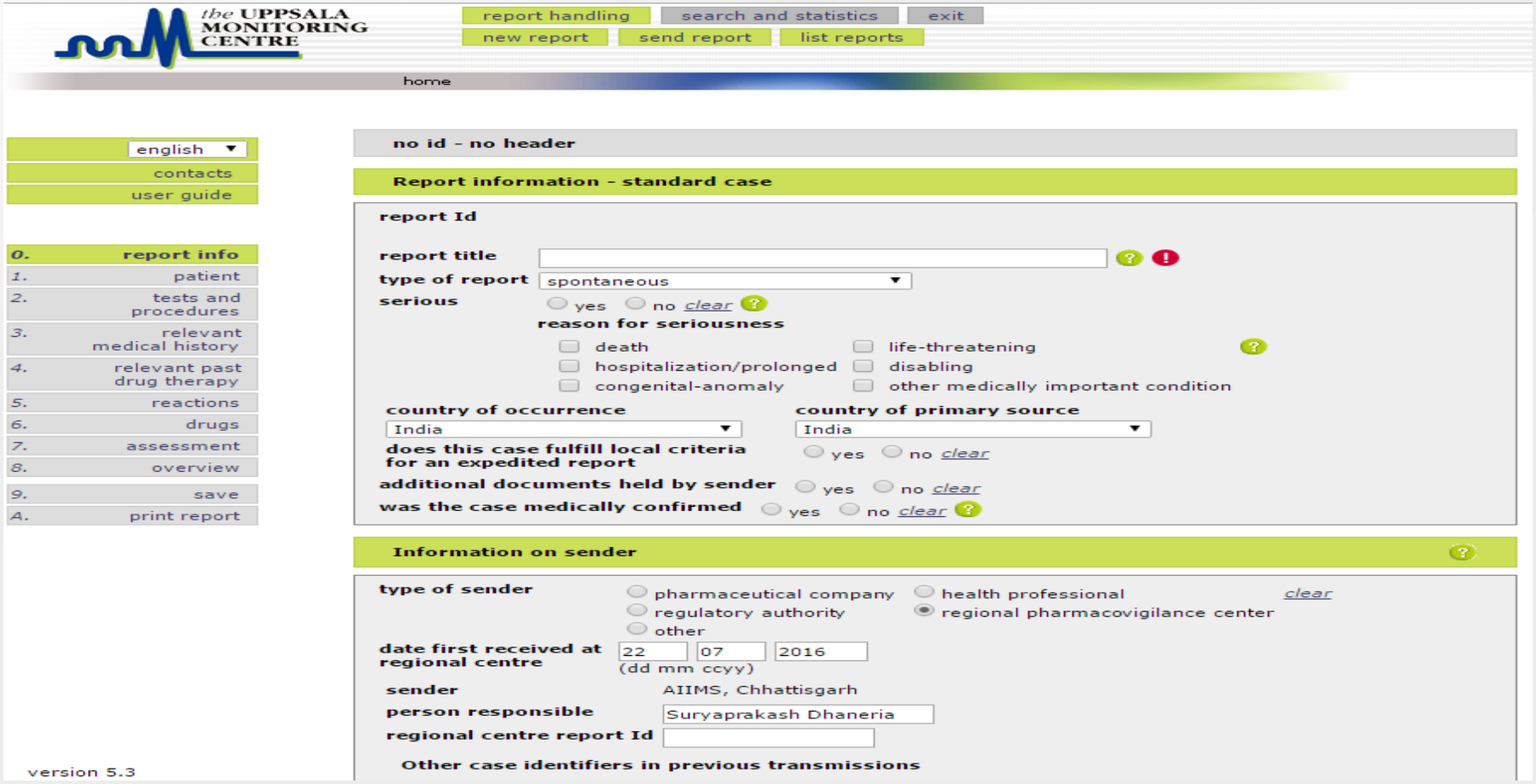
Safety Database

- **Vigiflow** software



Safety Database

- **Vigiflow** software



ADR Case – 1

Madan Lal, a 65-years old male patient admitted to hospital on 12.01.2016 with chief complaints of pain in upper abdomen and nausea since last 5 days. On physical examination, he had yellowish discoloration of palm, conjunctiva and nail bed. His weight was 72 kg.

He had few episodes of psychotic attacks, for which he was on Chlorpromazine therapy since last 4 weeks. On enquiry, he told that he was taking Tab. Largactil (Chlorpromazine) 100 mg, 4 tablets at bed time.

He was also taking Tab. Diclofenac 50 mg twice-a-day (self-medication) for abdominal pain for three days before admitting to hospital. He was investigated on the day of admission for laboratory parameters which are as follows:

- Alkaline Phosphatase = 180 U/L (Normal range: 25 – 100 U/L)
- ALT = 205 U/L (Normal range: 10 – 40 Units/L)
- Total Bilirubin = 5.0 mg/dL (Normal range: 0.8 – 1.2 mg/dL)

On admission, Chlorpromazine and Diclofenac therapy was stopped. After 7 days of stopping the medications, the intensity of pain decreased. Also, he was re investigated for above parameters which are as follows:

- Alkaline Phosphatase = 110 IU/L
- ALT = 98 Units/L
- Total Bilirubin = 1.8 mg/dL

- **Note:** Tab Chlorpromazine

Brand Name: LARGACTIL,
Manufacturer: Wedley labs
Batch number: LGL0881,
Expiry date: Dec 2018

A. Patient Information

1	Patient Initials – ML
2	Age at the time of Event or Date of Birth – 65 years
3	Sex Male ☑ Female ☐ Other ☐
4	Weight (kg) – 72 kg

B. Suspected Adverse Reaction

5	Date of Reaction started (dd/mm/yyyy): 07.01.2016
6	Date of recovery (dd/mm/yyyy):
7	Describe reaction or problem Patient was taking Chlorpromazine since 12.12.2015. He developed pain in abdomen and nausea since 07.01.2016. Examination revealed yellowish discoloration of conjunctiva, palm and nails. Pt. was admitted on 12.01.2016 and investigated. Liver function tests indicated raised serum bilirubin, ALT and alkaline phosphatase. Drugs were discontinued. On discontinuation of drug, reaction subsided in one week.

C. Suspected Medication

8	Name (Brand and/or Generic): Tab. Chlorpromazine (Largactil)
	Manufacturer (if known): Wedley labs
	Batch No. /Lot No.: LGL0881
	Exp. Date (if known): Dec. 2018
	Dose used: 400 mg
	Route used: Oral
	Frequency (OD, BD, etc): OD
	Therapy dates Date Started 12.12.2015 Date Stopped 12.01.2016
	Indication: Psychosis
	Causality Assessment: Probable

C. Suspected Medication

9	Action Taken (Please tick)					
	Drug Withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown
i	✓					
ii						
iii						
iv						

C. Suspected Medication

10	Reaction reappeared after reintroduction (please tick)			
	Yes	**No**	**Effect unknown**	**Dose (if reintroduced)**
i				
ii				
iii				
iv				

C. Suspected Medication

11	Concomitant medical products Including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)						
	Name (Brand/ Generic)	Dose used	Route Used	Frequency (OD, BD, etc.)	Therapy dates		Indication
					Date Started	Date Stopped	
i	Tab. Diclofenac	50 mg	Oral	BD	09.01. 2016	12.01. 2016	Pain in abdomen
ii							
iii							
iv							

12	Relevant tests/laboratory data with dates **12.01.2016** Alkaline Phosphatase = 180 U/L ALT = 205 U/L Total Bilirubin = 5.0 mg/dL **19.01.2016** Alkaline Phosphatase = 110 U/L ALT = 98 U/L Total Bilirubin = 1.8 mg/dL
13	Relevant medical / medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)

14	Seriousness of the reaction: No ☐ If Yes ☑ h (Please tick anyone)

	Death (dd/mm/yyyy)
	Life threatening
☑ f	Hospitalization (Initial or prolonged)
	Disability
	Congenital anomaly
	Required intervention to prevent permanent impairment / damage
	Other (specify)

15 Outcomes

	Recovered
✓ g	Recovering
	Not recovered
	Fatal
	Recovered with sequelae
	Unknown

D. Reporter Details

16	Name and Professional Address: Dr. A. K. Jain, Dept. of Medicine, AIIMS Raipur Pin 492099 Email akjain@gmail.com Tel. No. (with STD Code): 0771-2563452 Occupation Doctor Signature 
17	Date of this report (dd/mm/yyyy): 23.01.2016

Causality Assessment – ADR Case 1

Categories	Time sequence	Other drug disease ruled out	Dechallenge	Rechallenge
Certain	Yes	Yes	Yes	Yes
Probable	Yes	Yes	Yes	No
Possible	Yes	No	No	No
Unlikely	No	No	No	No

ADR Case – 2

Mr Sushant A Gupta, a 30-years old male with 68 kg weight was diagnosed as a case of bacterial meningitis. He was started empirically with Inj Ceftriaxone 1 g IV BD and Inj Vancomycin 500 mg IV QID on 12.01.2016. First dose of Inj. Ceftriaxone was given at 8 am and Inj. Vancomycin was given at 9 am on 12.01.2016. After 10 minutes of second drug administration, he started developing chills, rigors, fever, urticaria and intense flushing. He was treated with Inj. Pheniramine 25 mg IM, following which the reaction completely subsided. Inj. Ceftriaxone was continued. However, next doses of Inj. Vancomycin scheduled on day 1 were not given. On day 2, the Inj Vancomycin was re-introduced at 9 am to the patient. Similar symptoms developed again and quickly resolved after Inj. Pheniramine 25 mg IM.

Note:

- Inj Vancomycin
  - Brand Name: Vanzid
  - Manufacturer: SWACH Healthcare
  - Batch number: KKIL098
  - Expiry date: Mar 2016

- Inj Ceftriaxone
  - Brand Name: Taximax
  - Manufacturer: Wedley Labs
  - Batch number: OPO659
  - Expiry date: Dec 2016

Causality Assessment – ADR Case 1

Categories	Time sequence	Other drug disease ruled out	Dechallenge	Rechallenge
Certain	Yes	Yes	Yes	Yes
Probable	Yes	Yes	Yes	No
Possible	Yes	No	No	No
Unlikely	No	No	No	No

Will reporting have any negative consequences on the healthcare professionals or the patient?

- Submission of an ADR report does not have any legal implication on the reporter
- Confidentiality of the reporter and patient will be maintained
- The information is only meant for better understanding of medicines used in India and to safeguard the health of Indian Population

ADRs reporting is to evaluate benefit risk ratio of a medicine and there by ensuring safe use of medicines.

Thank you…!