Case scenarios for reporting adverse drug reactions

ADR case-1

Madan Lal, a 65-year old male patient weighing 72 kgs was admitted to hospital on 12.11.2021 with chief complaints of pain in upper abdomen and nausea since last 5 days. On physical examination, he had yellowish discoloration of palm, conjuctiva and nail bed.

He has 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 50mg 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 - 180U/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 reinvestigated for above parameters which are as follows:-

Alkaline phosphatase - 110U/L
ALT - 98 Units/L
Total Bilirubin - 1.8 mg/L

Report this ADR using standard form

Details of the drugs:-

a) Tab Chlorpromazine
Brand Name: LARGACTIL
Batch number: LGL0881
Manufacturer: XXX labs
Expiry date: Dec 2023

b) Tab Diclofenac
Brand Name: DICLO
Batch Number: DC082020
Manufacturer: ABC pharma
Expiry date: June 2025

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

Version -1.3

For VOLUNTARY reporting of Adverse Drug Reaction 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

A. PATIENT INFORMATION

1. Patient Initials	2. Age at the time of Event or Date of Birth	3. M ☑ F ☐ Other ☐
M.L	65 years	4. Weight 72 Kgs

Reg. No. /IPD No. /OPD No. /CR No. :
AMC Report No. :
Worldwide Unique No. :

B. SUSPECTED ADVERSE REACTION

5. Event/Reaction start date (dd/mm/yyyy) 07/11/2021
6. Event/Reaction stop date (dd/mm/yyyy) 19/11/2021
6 (A). Onset Lag Time
7. Describe Event/Reaction with treatment details, if any

A 65yrs old man taking Chlorpromazine since 12/10/2021. He developed pain in abdomen and nausea since 7/11/21. Examination revealed yellowish discolouration of palms, conjuctiva and nails. Patient was admitted on 12/11/2021 revealed rise in serum bilirubin, ALT and ALP. Chlorpromazine was discontinued and the reactions subsised within one week.

12. Relevant tests/ laboratory data with dates

12/11/2021	19/11/2021
ALP: 180 U/L	ALP: 198 U/L
ALT: 205 U/L	ALT: 98 U/L
Total Bilirubin: 5.0 mg/dl	Total bilirubin: 1.8 mg/dl

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

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

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: Date started	Therapy dates: Date stopped	Indication	Causality Assessment
i	LARGACTIL	XXX labs	KL0881	Dec 2023	400 mg	Oral	OD	12/10/2021	12/11/2021	Psychotic attacks	Probable
ii											
iii											
iv*											

S.No as per C	9. Action Taken (please tick): Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	10. Reaction reappeared after reintroduction (please tick): 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: Date started	Therapy dates: Date stopped	Indication
i							
ii							
iii*							

Additional Information:
Tab. Diclofenac used for abdominal pain.

D. REPORTER DETAILS

16. Name and Professional Address: Jyoti Kumari, Suraram
Pin: 500055 E-mail pharma@gmail.com
Tel. No. (with STD code) 012-3456789
Occupation: Student Signature: Jyoti

17. Date of this report (dd/mm/yyyy):
Sig. and Name of Receiver -

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

ADR case-2

Mr. Ajay kumar, age 68 years, weight 62 kg come to surgery OPD on 02/11/2021 for the complaints of frequent urination during day and at least three times during night, poor urinary stream with hesitancy, post micturition dribbling and sensation of incomplete emptying of the bladder since last 6 months.

Transrectal sonography show increase in prostate size with diffuse parenchymal calcification and residual urine volume is 85 ml.

There is no suspicison of malignancy. Patient was diagnosed as a case of benign hypertrophy of prostate. He was prescribed Tab. Prazosin 0.5 mg orally twice a day and Tab finasteride 5mg orally once a day for 15 days.

On next day, he came again and complaining of dizziness and fainting.

He was asked to take Tab. Tamsulosin 0.4mg orally once a day in place of Tab. Prazosin and continue the Tab. Finasteride as per schedule. He was advised to follow up after 1 week.

On scheduled next visit, he was better from the day of withdrawal of Prazosin. No dizziness and fainting and advised to continue Tamsulosin and finasteride.

Report this ADR using standard ADR form.

Details of drugs:-

Tab Prazosin - Manufacturer: Abott,
Batch no: Z-135
Expiry date: November 2023

Tab finasteride - Manufacturer: Nyularck
Batch no: R-153
Expiry date: Dec 2023

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reaction 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

A. PATIENT INFORMATION

1. Patient Initials	2. Age at the time of Event or Date of Birth	3. M ✓ F ☐ Other ☐	4. Weight
A.K.	68 years		62 Kgs

Reg. No. /IPD No. /OPD No. /CR No. :
AMC Report No. :
Worldwide Unique No. :

B. SUSPECTED ADVERSE REACTION

5. Event/Reaction start date (dd/mm/yyyy): 02/11/2021
6. Event/Reaction stop date (dd/mm/yyyy): 03/11/2021
6 (A). Onset Lag Time:
7. Describe Event/Reaction with treatment details, if any:

68 year old Male patient come with complaints of frequency of urination during day and night, poor urinary stream, post micturition dribbling. He was diagnosed with BPH for which he was kept on Tab. Prazosin 0.5mg and Tab. Finasteride 5mg for 15 days. On next day as he was complaining of dizziness and fainting and in place of Tab. Prazosin he was asked to take Tab. Tamsulosin 0.4mg, and continue Tab. Finasteride.

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

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

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: Date started	Therapy dates: Date stopped	Indication	Causality Assessment
i	Tab. Prazosin	Abott	Z-435	Nov 2023	0.5mg	oral	BD	02/11/21	03/11/21	BPH	Probable
ii	Tab. finasteride	Wyulaick	R-453	Dec 2023	5mg	oral	OD	2/11/21		BPH	
iii											
iv*											

S.No as per C	9. Action Taken (please tick): Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	10. Reaction reappeared after reintroduction (please tick): 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: Date started	Therapy dates: Date stopped	Indication
i							
ii							
iii*							

Additional Information:
Tab. Prazosin 0.5mg was withdrawn and Tab. Tamsulosin 0.4mg orally was given.

D. REPORTER DETAILS

16. Name and Professional Address: Jyoti Kumari, Suraram
Pin: 500055 E-mail pharma@gmail.com
Tel. No. (with STD code) 012-3456789
Occupation: Student Signature: Jyoti

17. Date of this report (dd/mm/yyyy):
Sig. and Name of Receiver-

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does no constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submissio of an ADR report does not have any legal implication on the reporter.

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