SERVICE NAME :	**ADVERSE DRUG REACTION EVENT**
DATE CREATED :	**25/06/2022**
APPROVED BY :	**DR. JYOTI SADASIVAN**
REVIEWED BY :	**DR. NIKHIL DIWAKAR SHARMA**

AMENDMENT SHEET

S. No.	Section and Page	Date	Amendment	Signature

A. Purpose:
To provide guideline instruction for monitoring adverse drug reaction event and ensure its proper reporting.

A. **Scope:** Hospital wide

B. Protocol:
In case of any drug reaction / adverse reaction actions taken are as follows:

1. The person noticing the reaction i.e. Doctor / Patient immediately informs the concerned doctor and clinical management is initiated then & there.
2. The Doctor informs in charge pharmacy & Main Medicine store.
3. The ADR [Adverse drug reaction] form is filled up by the concerned doctor
4. Drug responsible for adverse reaction is identified.
5. Batch of the drug identified.
6. All Patient rooms & areas where the drug has been issued are advised not to use the drug of that particular batch.
7. Information regarding any such similar reactions anywhere in the hospital is gathered and documented and forwarded to the Medical Superintendent.
8. All such events are monitored and evaluated and appropriate action taken depending on the nature of the adverse reaction.
9. Such action may take the form of observation or in extreme cases withdrawal of the drug throughout the hospital.
10. Drug causing adverse reaction is closely monitored and analyzed by drug and therapeutic committee.

1. Drug Recall Procedure

1. Once the drug causing adverse reaction is identified, particular batch of the drug is immediately withdrawn by pharmacy, wherever issued within the hospital.
2. Company & distributor are immediately informed regarding the adverse reaction and called to find out the reasons & actions to be taken.
3. Total medicine of that particular batch is returned to supplier.
4. Report is presented before Quality management committee and further action is taken.

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by health care professionals

Report #

To be filled in by Pharmacovigillance centres receiving the form.

A. Patient information

1. Patient identifier initials _____ In confidence
2. Age at time of event: or _____ Date of Birth:
3. Sex ☐ M ☐ F
4. Weight_____ Kgs

B. Suspected Adverse Reaction

5. Date of reaction started (dd/mm/yy):
6. Date of recovery (dd/mm/yy):
7. Describe reaction or problem

12. Relevant tests/ laboratory data, including dates

13. Other relevant history, including pre-existing medical conditions (e.g., allergies, race, pregnancy, smoking alcohol use, hepatic/ renal dysfunction, etc.)

14. Seriousness of the reaction
- ☐ Death (dd/mm/yy)_____
- ☐ Life threatening
- ☐ Hospitalization-initial or prolonged
- ☐ Disability
- ☐ Congenital anomaly
- ☐ Required intervention to prevent permanent impairment/ damage
- ☐ Other (specify)_____

15. Outcomes
- ☐ Fatal ☐ Recovering ☐ Unknown
- ☐ Continuing ☐ Recovered ☐ Other (specify)_____

C. Suspected medication(s)

Sl. No.	8. Name (brand and / or generic name)	Manufac-turer (If known)	Batch No. / Lot No. (If known)	Exp. Date (If known)	Dose used	Route used	Frequency	Therapy dates (if unknown, give duration)		Reason for Use or prescribed for
								Date started	Date stopped	
i										
ii										
iii										
iv										

Sl. No. As per C	9. Reaction abated after drug stopped or dose reduced					10. Reaction reappeared after reintroduction				
	Yes	No	Unknown	NA	Reduced dose	Yes	No	Unknown	NA	If reintroduced, dose
i										
ii										
iii										
iv										

11. Concomitant medical products and therapy dates including self medication and herbal remedies (exclude those used to treat reaction)

D. Reporter (see confidentiality section in first page)

16. Name and Professional Address: _____
_____
_____
Pin code: _____ E-mail: _____
Cell No. / Tel. No. with STD Code: _____

Speciality: _____ Signature:

17. Occupation

18. Date of this report