

TERMS OF REFERENCE FOR PHARMACOVIGILANCE COMMITTEE

1. Objectives:

This committee is constituted as per the guidelines of Pharmacovigilance Programme of India

- To identify, monitor, assessment and documentation of the nature and frequency of Adverse Drug Reactions (ADRs).
- To improve patient care and safety by rational use of medications.
- To promote awareness, education and training in pharmacovigilance activities and its effective communication to healthcare professionals and patients.

2. Scope:

Applicable to all clinical areas of Justice K. S. Hegde Charitable Hospital.


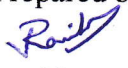

3. List of abbreviations

ADR	-	Adverse Drug Reactions Reporting
AMC	-	Adverse Drug Reactions Monitoring Centres
PvPI	-	Pharmacovigilance Programme of India
JKSHCH	-	Justice K. S. Hegde Charitable Hospital
KSHEMA	-	K. S. Hegde Medical Academy
NCC	-	National Coordination centre
WHO	-	World Health Organization
UMC	-	Uppsala Monitoring Centre

4. Terms and Definitions

Pharmacovigilance: It is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.

Adverse drug reaction: A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.

 NITTE (Deemed to be University) JUSTICE K S HEGDE CHARITABLE HOSPITAL			Rev. No: 4.0 Rev. Date: 16.05.2025
Doc. Name: Terms of reference for Pharmacovigilance Committee	Prepared by:  DR RAVICHANDRA V. Member Secretary	Approved by:  Suma R. Shetty Chairman	
Doc. No.:			
Issued by: Medical Superintendent	Issued to: Members	Issue Date: 06.09.2017	Page 1 of 3




Adverse event: Any untoward medical occurrence that may appear during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with the treatment.

Side effect: Any unintended effect of a pharmaceutical product occurring at a dose normally used in man, which is related to the pharmacological properties of the drug.

Unexpected Adverse Reaction: An adverse reaction, the nature or severity of which is not consistent with domestic labelling or market authorization, or expected from characteristics of the drug.

5. Constitution of the Committee

1. Dr. Sumalatha R Shetty, Medical Superintendent, JKSHCH – Chairman
2. Dr. Rajendra Holla, Prof & Head, Dept. of Pharmacology, KSHEMA, Nitte (DU)- Co- Chairman
3. Dr. Ravichandra V, Professor, Dept. of Pharmacology, KSHEMA, Nitte (DU) - Member Secretary
4. Dr. Roopa B S, Asst. Professor, Dept. of Pharmacy Practice, NGSMIPS, Nitte (DU) –Member
5. Dr. Siral Hegde, Asst. Medical Superintendent, JKSHCH – Member
6. Dr. Advaita, Medication Safety officer, JKSHCH - Member
7. Dr. Uday Venkat Mateti, Associate Professor, Dept. of Pharmacy Practice, NGSMIPS, Nitte (DU) - Member
8. Dr. Juno J Joel, Associate Professor & Head, Dept. of Pharmacy Practice, NGSMIPS, Nitte (DU) - Member
9. Dr. Tonita Mariola Noronha, Prof. & HOD, Dermatology, JKSHCH - Member
10. Dr. Seema Pavaman, Prof. & HOD, Paediatrics, JKSHCH - Member
11. Dr. Shrinivasa Bhat U, Patient Safety Officer, JKSHCH - Member
12. Dr. Sudhindra Rao M, Prof. & HOD, General Medicine, JKSHCH - Member
13. Dr. K. R. Bhagavan, Prof. & HOD, General Surgery, JKSHCH - Member
14. Dr. T. Krishna Sharan, Prof. & HOD, Oncology, JKSHCH - Member
15. Dr. Vikram Shetty, Chairman, Pharmaco-Therapeutics Committee – Member
16. Dr. Swathi Acharya, Member Secretary, Pharmaco-Therapeutics Committee - Member
17. Dr. Chandrika Rao, Blood Bank Officer, JKSHCH- Member
18. Dr. Nanjesh, Prof & HOD, Dept. of Community Medicine- Member
19. Ms. Jacinta Crasta, Nursing Superintendent- Member
20. Dr. Chinju Raphy, Asst. Quality Manager - Member

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21. Dr. C.S. Shastry, Director (Research & Strategic Initiatives), NGSM Institute of Pharmaceutical Sciences, Nitte (DU) – Ex-Officio

6. Committee Meetings:

- a) Frequency: Once in every 3 months
- b) Conveners: Member Secretary

7. Quorum:

The quorum shall be minimum 6 members and the quorum shall not be complete without the participation of one Clinician, one Pharmacologist and one Clinical Pharmacist.

8. Reporting and actions by JKSHCH Pharmacovigilance Committee:

As per the SOP of JKSHCH Pharmacovigilance Committee- Annexure-I

9. Records to be maintained


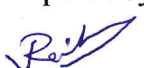
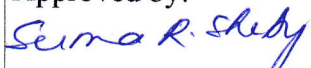
- Adverse Drug Reactions Reporting Form
- Minutes of the Pharmacovigilance Committee Meeting
- Communications of ADRs Reporting to the PvPI centers
- Acknowledgement of ADR reported
- Communications to the respective clinical departments
- Any other documents related to the Pharmacovigilance Committee

10. Retention & Storage

All records will be retained as per JKSHCH retention policy (Ref: JKSHCH/IMS/006/001). Such documents will be stored in the office of Dept. of Pharmacology, JKSHCH.

11. Term of Office

Committee appointed for a period of 2 years.

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