

Pharmacovigilance center

Preamble:

1. India is emerging rapidly as a hub of Global Clinical trials & a destination for Drug Discovery & Development and now being recognized as the 'Global pharmacy of Generic Drugs' providing generic quality drugs at affordable cost. National pharmacovigilance programme of government of India started in the year 2010 under the supervision of Central drug standard control organisation and drug controller general of India with a aim to develop structured programme to build synergies for monitoring ADRs, collect, collate and analyze data to arrive at an inference to recommend regulatory interventions, besides communicating risks to healthcare professionals and the community. Consequently, Pharmacovigilance center of the ZMCH is established in pursuance to Medical Council of India regulations.

2. Goal:

- a. The broad goal of the committee will be to generate awareness about the need of identifying and
- b. reporting of Adverse Drug Reactions (ADR), amongst all sections of health care providers (doctors,
- c. consultants, nurses, pharmacists and undergraduate students, service providers etc) of the ZMCH and to pick up and identify ADR occurring in patients admitted to medical college
- d. Hospital and report the same to the appropriate authorities.

3. Objectives:

- a. To conducts routine Pharmacovigilance awareness programmes for health care providers including nurses, pharmacists, health care personnel
- b. To scan medicine prescription to ensure safe and effective consumption of medicine in ZMCH
- c. To analyses drugs prescriptipns and report ADR occuring in inpatients of ZMCH
- d. To evaluate the rationality of medicines prescribed to patients in hospital
- e. To prevent drug abuse and unethical practices in society
- f. To create awareness programs about adverse drug reactions amongst the healthcare personals & community
- g. To provide information about safe use of drugs to health care providers including nurses, pharmacists, health care personnel
- h. To monitor & analyses ADR, indications, contra-intications of drugs under altered physiological states of health
- i. To participate in national pharmacovigilance programme and strength its ongoing activities.

4. Composition: The pharmacovigilance committee shall comprises of following members:

- a. Chairman Head of Department of Pharmacology
- b. Co-chairman Medical Supreitendent
- c. Members one faculty Representative from each department of Medicine, Surgery, Orthopaedics, Anaesthesia, Obstetrics and Gynacelogy, Ophthalmology, Paediatrics, ENT & Epidemiologists, Nursing superintendent, Senior Pharmacists.
- d. Membrer Secretary Associate Professor from Pharmacology

5. Meetings: The committee shall meet once in 3 months.

6. Duties of Pharmacovigilance Committee:

7. The shall be responsible for planning and implementing activities of Pharmacovigilance unit and work as facilitator to the stakeholders of the hospital.
8. The chairman of Committee shall be preferably the senior faculty of Pharmacology and functions as administrative head.
9. The duration of members of the committee shall be three years w.e.f. date of its constitutions.
10. The Member secretaary of the committee shall have to:
 - a. Prepare agenda for periodic meetings, and organise meetings
 - b. To maintain minutes & documentations
 - c. Prepare stadard operating procedures for organisation of awareness programmes, analysis of prescription of drugs in various departments of hospital, training of health professionals for drug delivery and monitoring.
 - d. Prepare information brocure about about safe use of drugs to health care providers including nurses, pharmacists, health care personnel and community.
 - e. The member of the committee serves as subject expert, and will be involved in training/mentoring of young faculty, residents and students for analysis of prescription and adverse drug reactions.