

**PS806: PHARMACOEPIDEMIOLOGY, PHARMACOECONOMICS AND PHARMACOVIGILANCE
(Open Elective – III)**

B. Pharm IV Year II sem

L	T	P	C
3	1	0	3

Course Objectives: This course is designed to impart knowledge and skills in vigilance, epidemiology, economics and of various diseases. This will enable the students to understand cost effectiveness in the management of disease and ADRS

Course Outcome: At completion of this subject, the students are expected to understand risk of pharmacoepidemiology history and need of pharmacoeconomics and assessment of pharmacovigilance.

UNIT - I: Introduction to adverse drug reactions. Definitions and classification of ADRs. Detection and reporting. Causality assessment. Severity and seriousness assessment. Predictability and preventability assessment. Management of adverse drug reactions. Role of pharmacist in management of ADRs.

UNIT - II: Pharmacovigilance Scope, definition and aims of Pharmacovigilance. Introduction to pharmacovigilance. History and development of pharmacovigilance. Importance of safety monitoring/ Why pharmacovigilance. National and international scenario: Pharmacovigilance in India, Pharmacovigilance global perspective, WHO international drug monitoring programme. Drug dictionaries and coding in pharmacovigilance: WHO adverse reaction terminologies. Med DRA and Standardised Med DRA queries. WHO drug dictionary, EudraVigilance medicinal product dictionary.

UNIT - III: Basic terminologies used in pharmacovigilance: Terminologies of adverse medication related events. Regulatory terminologies.

Information resources in pharmacovigilance: Basic drug information resources. Specialised resources for ADRs Critical evaluation of medication safety literature

Pharmacovigilance methods: Passive surveillance – Spontaneous reports and case series. Stimulated reporting. Active surveillance – Sentinel sites, drug event monitoring and registries. Comparative observational studies – Cross sectional study, case control study and cohort study. Targeted clinical investigations. Vaccine safety surveillance

UNIT - IV: Pharmacoepidemiology: Definition and scope: Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications. Measurement of outcomes in pharmacoepidemiology. Pharmacoepidemiological methods: Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods Drug utilization review, case reports, case series, surveys of drug use, cross-sectional studies, cohort studies, case control studies, case-cohort studies, meta-analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

UNIT - V: Pharmacoeconomics: Definition, history, need of pharmacoeconomic evaluations Role in formulary management decisions. Pharmacoeconomic evaluation Outcomes assessment and types of evaluation, includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Cost – minimization, cost - benefit, cost – effectiveness, cost utility Applications of Pharmacoeconomics, Softwares used and case studies.

TEXT BOOKS:

1. Textbook of Pharmacovigilance: Concept & practice- KG. Revikumar.
2. Textbook of Pharmacovigilance: Concept & practice- Mohanta, Pharmamed press.
3. SK GUPTA Textbook of Pharmacovigilance Icri Institute of Clinical Research, India.

REFERENCES:

1. Goodman & Gilman's The Pharmacological basis of Therapeutics Ed. J.G. Hardman, L.E. Limbird, P.B. Molinoff and R. W. Ruddon. International Edition. McGraw Hil.
2. G Katzung, Basic and Clinical Pharmacology. Bertram, 9th edn Lange Publications, 2004.