COURSE OF STUDY PHARMACY
ACADEMIC YEAR *2023-2024*
ACADEMIC SUBJECT PHARMACOVIGILANCE AND PHARMACOEPIDEMIOLOGY

General information	
Year of the course	*5 year*
Academic calendar (starting and ending date)	*1°semester from 25/09/2023 to 19/01/2024*
Credits (CFU/ETCS):	6
SSD	*BIO/14 Pharmacology*
Language	*italian*
Mode of attendance	*mandatory*

Professor/ Lecturer	
Name and Surname	*Domenico Tricarico (AE)* *Paola Imbrici (FN)* *Michela De Bellis (OZ)*
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Telephone	
Department and address	*Department of Pharmacy – Drug Sciences*
Virtual room	
Office Hours (and modalities: e.g., by appointment, on line, etc.)	By appointment

Work schedule			
Hours			
Total	Lectures	Hands-on (laboratory, workshops, working groups, seminars, field trips)	Out-of-class study hours/ Self-study hours
60	*60*		
CFU/ETCS			
6	*6*		

Learning Objectives	The training activity aims to provide the knowledge necessary to manage the risk of adverse drug reactions, also deriving from pharmacoepidemiological and pharmacogenomics assessments, through adequate knowledge of pharmacovigilance and post-marketing surveillance procedures. The course promotes the acquisition of skills for carrying out pharmacoepidemiology and pharmacovigilance activities in all public and private healthcare settings in which Pharmacy graduates can carry out their activities.
Course prerequisites	Knowledge of pharmacology and toxicology

Teaching strategies	Lectures with projected teaching aids (i.e. power point presentations shared with the students)
Expected learning outcomes in terms of	

Knowledge and understanding on:	o Objectives of pharmacovigilance and epidemiology o Classification of adverse drug reactions o Pharmacogenetics and drug interactions as mechanisms of ADR o Methods in pharmacovigilance and pharmacoepidemiology o Pharmacovigilance regulations o Meaning of real world data and real world evidence
Applying knowledge and understanding on:	○ Understanding the benefit/risk profile of drugs and vaccines
Soft skills	• *Making informed judgments and choices* ○ Interpretation and analysis of pharmacovigilance and pharmacoepidemiology data • *Communicating knowledge and understanding* ○ Use of appropriate language • *Capacities to continue learning* ○ Reading scientific articles and reports
Syllabus	
Content knowledge	INTRODUCTION TO PHARMACOVIGILANCE and PHARMACOEPIDEMIOLOGY: DEFINITIONS AND OBJECTIVES • Drug development process: preclinical development, clinical evaluation of drugs and the limits of pre-marketing trials. • History and objectives of pharmacovigilance and pharmacoepidemiology. CLASSIFICATION OF MEDICINES AND PROCEDURES OF APPROVAL AND ACCESS • The ATC and DDD classification of medicines • Pharmacoutilization studies • Drug approval procedures • Early drug access procedures, off-label use • Generic drugs, advanced therapies and the concept of innovation. ADVERSE DRUG REACTIONS • Definition of adverse reaction and adverse event • Classification of ADRs, severity and notoriety • Interindividual susceptibility to ADRs • Adverse reactions on a genetic basis • Gender pharmacology • Medicines during pregnancy • Adverse reactions in pediatrics • Adverse reactions in the elderly • Drug interactions PHARMACOVIGILANCE: REGULATORY FRAMEWORK, ROLE AND TASKS OF THE REGULATORY AGENCIES • European and Italian legislation (DM 30 April 2015) in pharmacovigilance. • AIFA and the Italian pharmacovigilance system. The reporting form. Flow of spontaneous reporting. The national pharmacovigilance network, Regional Pharmacovigilance Centers and local managers. • EMA and European Pharmacovigilance System. PRAC, CHMP and other committees. • Good Pharmacovigilance practices. • National web portals and analysis of spontaneous reporting databases. Eudravigilance. Vigibase. FDA-FAERS and VAERS. RAM system. METHODS IN PHARMACOVIGILANCE • Definition of signal. The search for signals in pharmacovigilance. • The evaluation of the causal link. • Reporting rate and disproportionality analysis. • Real World Data and Real World Evidence.

	PHARMACOEPIDEMIOLOGY • Limits of spontaneous reporting. Objectives of pharmacoepidemiology. • Studies in pharmacoepidemiology. Cohort and case-control studies: design, data analysis, examples. • Outlines of systematic reviews and meta-analyses. BIOTECHNOLOGICAL AND BIOSIMILAR DRUGS • Definitions, marketing approval procedure and safety issues RARE DISEASES AND ORPHAN DRUGS VACCINE SURVEILLANCE • AEFI and Surveillance of adverse vaccine reactions in Italy and Europe PHYTOVIGILANCE • Surveillance of adverse reactions from natural products in Italy and Europe SURVEILLANCE OF MEDICAL DEVICES • European and Italian legislation on medical devices. Classification of medical devices. Device surveillance network. Professional figures involved.
Texts and readings	FARMACOLOGIA PRINCIPI DI BASE E APPLICAZIONI TERAPEUTICHE: F. ROSSI, V. CUOMO, C. RICCARDI (Edizioni Minerva Medica); texts shared by the Professor
Notes, additional materials	*Websites of AIFA, EMA, WHO*
Repository	Shared by the Professor / Lecturer (e.g. via Microsoft Teams)

Assessment	
Assessment methods	*Oral exam*
Assessment criteria	• *Knowledge and understanding* o Knowledge of the meaning of pharmacovigilance in studying the benefit/risk profile of a drug o Knowledge of Italian and European pharmacovigilance legislation and systems o Knowledge of the sources and methods used in pharmacovigilance and pharmacoepidemiology • *Applying knowledge and understanding* o Ability to integrate the knowledge about drug safety with the knowledge about drug efficacy acquired throughout this and other courses of pharmacology • *Autonomy of judgment* o Ability to recognize the benefit/risk profile of drugs and ability to manage risk from adverse drug reactions • *Communicating knowledge and understanding* o Clear and tidy presentation o Use of appropriate terminology • *Capacities to continue learning* o Ability to discuss about the various topics of the course and interpret pharmacovigilance data o Reading reports, meta-analyses, reviews
Final exam and grading criteria	Type of assessment used: the final grade is awarded out of 30. The exam is

	considered passed when the grade is greater than, or equal to, 18.
Further information	
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