DIPARTIMENTO DI SCIENZE

COURSE: **Pharmacovigilance**			
ACADEMIC YEAR: **2019-2020**			
TYPE OF EDUCATIONAL ACTIVITY: **Characterizing**			
TEACHER: **Dr. Vincenzo Brancaleone**			
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Language: **Italian**			
ECTS: **6** (**lessons**)	n. of hours: **48** (**lessons**)	Campus: **Potenza** Dept.: **Science** Program: **Pharmacy (LM-13)**	Semester: **II** (from dal 02/03/2020 to 31/5-20/06/2020)

EDUCATIONAL GOALS AND EXPECTED LEARNING OUTCOMES

Knowledge and understanding: The course aims to provide specific skills in pharmacovigilance and pharmacoepidemiology in order to evaluate issues related with drugs following their marketing.

Ability to apply knowledge and competence: the acquired knowledge must be correctly applied in the approach to highlight and identify adverse reactions to drugs observed in patients.

Learning skills: the acquired knowledge represents the starting point to develop a role in the post-marketing vigilance of the drugs on the market.

Communication and judgements skill: the acquired knowledge will be diplayed through correct identification of drugs adverse reactions and punctual filling out of the adverse reactions forms together with appropriate interplay with other pharmacovigilance operators.

PRE-REQUIREMENTS

Knowledge of fundaments about General Pharmacology, Pharmacotherapy and Toxicology are strictly required. It is highly recommended that students aiming to perform exam of Pharmacovigilance have already passed the exam of Pharmacology and Toxicology.

SYLLABUS

Introduction to Pharmacovigilance (8 hours)

Historical remarks - Pre- and post-marketing experimental pharmacology - Adverse reactions to drugs - Definitions - AR classification - Factors masking AR idnetification - Degree of AR - Causal link with AR - AR criteria - Pharmacokinetics and AR - Pathologies and AR - Drugs and food interactions in AR onset - Drug induced disease - Clinical parameters and AR - Dosage and AR - Manufacturer Quality Control

Passive pharmacovigilance (8 hours)

Spontaneous report - Under-reporting and over-reporting - Factors in AR reports - Reports for event associated to drugs - Proportional Reporting Ratio - Report form

Active pharmacovigilance (8 hours) Antimycotic, Antiviral drugs.

Epidemiological studies - Factors to be considered in drug use - Analysis and management of risk factors - Paramenters in population studies phenomena

Experimental etiological factors (8 hours)

Controlled clinical studies (RCT)- Clinical studies features - Study analysis - Absolute Risk Reduction, Relative Risk and Relative Risk Reduction - Number Needed to Treat (NNT) - Analysis methods - Ethical aspects in controlled clinical studies

Observational etiological factors (8 hours)

Differences with RCT - Applications - Risk/benefit profile - Cohort studies - Control/case studies - Studies and data organization

Descriptive factors (8 hours)

Prescriptive appropriateness evaluation - Control of health costs - Monitoring systems in pharmaceutical prescriptions - Defined Daily Dose (DDD) - National observatory for drug use - Organization of pharmacovigilance system in Italy, in EU and in the World - Vigilance of natural products and OTC drugs.

TEACHING METHODS

The class consists of 48 hours of lessons.

EVALUATION METHODS

Evaluation will be assessed through oral examination. However, students who will attend the course will have the chance to pass the exam undergoing one or two intermediate tests. These will consist of multiple choice questionnaire on restricted part of the program, followed by oral examination for the rest of the subjects.

TEXTBOOKS AND ON-LINE EDUCATIONAL MATERIAL

AIFA website (www.agenziafarmaco.gov.it)

Goodman & Gilman,: *Le basi farmacologiche della terapia*, XI Ed. McGRAW, HILL

Paoletti, Nicosia, Clementi, Fumagalli, *Tossicologia generale e molecolare*, UTET

Katzung, *Farmacologia generale e clinica*, Ed. PICCIN

Calignano et al., *Manuale di Farmacoterapia*, Idelson Gnocchi Editore

Mannaioni, *Tossicologia medica*, UTET

Rang, Dale, Ritter, *Farmacologia*, Ed. AMBROSIANA

INTERACTION WITH STUDENTS

All info about the course and exam will be provided at the beginning of the course. Then, a list of attending students will be prepared. Professor will be officially available on Wednesday and Thursday, from 2.00pm to 3.00pm at his room. However, student can contact professor anytime by email (**vincenzo.brancaleone@unibas.it**) or phone (**0971 205082**).

EXAMINATION SESSIONS (FORECAST)[1]

Sessione I: 19 February, 16 March

Sessione II: 17 June, 15 July

Sessione III: 29 September, 21 October, 16 December

[1]Sessions will be held on indicated dates and will be published on ESSE3 system. However, changes in date could occur and additional sessions could be provided, always reported on ESSE3 system.

SEMINARS BY EXTERNAL EXPERTS YES **X** NO □

FURTHER INFORMATION