Study program: **PHARMACY**

Type and level of studies: Integrated Academic Studies, Level 1/2

Course unit: **PHARMACOVIGILANCE**

Teacher in charge: Professor Marko Folic, MD, PhD

Language of instruction: ENGLISH

ECTS: 7

Prerequisites: Enrolled in the ninth block of the study program of IAS Pharmacy

Semester*:* WINTER SEMESTER

Course unit objective:
Introducing students to the methods of recognition and spontaneous reporting of adverse drug reactions. Enabling students to independently design and conduct research in the field of pharmacovigilance.

Learning outcomes of Course unit:
Upon completion of the course in Pharmacovigilance, the student is expected to acquire knowledge about:

- adverse drug reactions (frequency in outpatient and inpatient settings, predisposing factors, methods of prevention, methods of detecting adverse drug reactions, causality assessment and reporting adverse drug reactions)
- drug interactions, as potential factors for the development of drug side effects (mechanisms of interactions: chemical, physiological, pharmacological, pharmacokinetic, steps for preventing drug interactions)
- common treatment mistakes (reasons for errors in treatment, strategies to minimize the risk of error).

At the end of the Pharmacovigilance course, the student is expected to master the skills of:

- verification of the development of adverse drug reaction
- spontaneous reporting of adverse drug reactions
- implementation of measures that could prevent the occurrence of adverse drug reactions
- adequate familiarization of patients with the side effects of the drugs they use
- designing and conducting drug side effect study
- statistical processing of research results and their interpretation.

Course unit contents
Theoretical classes

- Contemporary aspects of pharmacovigilance
- Methods of collecting and reporting adverse drug reactions
- Causal interpretation of drug adverse events
- Designing a drug side effect study

Practical classes

- Practical aspects of detecting and reporting adverse drug reaction
- Conducting a research in the field of pharmacovigilance.

Literature

- Andrews E, Moore N (eds). Mann's Pharmacovigilance. 3rd Edition. Wiley-Blackwell, 2014.
- Waller P, Harrison-Woolrych M. An Introduction to Pharmacovigilance. 2nd Edition. Wiley-Blackwell, 2017.
- ICH E2E. Parmacovigilance Planning (PVP). London: EMEA, 2004, CPMP/ICH/5716/03
- Gupta SK. Textbook of Pharmacovigilance. Jaypee Brothers Medical Publishers, 2011.

Number of active teaching hours				**Other classes**
Lectures: 30	Practice: 30	Other forms of classes: 15	Independent work: 135	

Teaching methods: Lectures, Problem-based learning.

Examination methods (maximum 100 points)

Exam prerequisites	**No. of points:**	**Final exam**	**No. of points:**
Student's activity during lectures	**30**	oral examination	**70**
practical classes/tests		written examination	
Seminars/homework		.....	
Project			
Other			

Grading system		
Grade	**No. of points**	**Description**
10	91 - 100	Excellent
9	81 - 90	Exceptionally good
8	71 - 80	Very good
7	61 - 70	Good
6	51 - 60	Passing
5	< 51	Failing