PHARMACOVIGILANCE

UNIVERSITY OF KRAGUJEVAC
FACULTY OF MEDICAL SCIENCES

PHARMACY
INTEGRATED ACADEMIC STUDIES

FIFTH YEAR OF STUDY

2024/2025.

Title of the course:

PHARMACOVIGILANCE

This course is assigned 6 ECTS credits.
It consists of 4 active teaching hours per week: 2 teaching hour of lectures, 1 teaching hour of seminar and 1 teaching hours of practical classes.

TEACHERS:

	Name and surname	E-mail	Title
1.	Aleksandra Stojanovic*	vranicaleksandra90@gmail.com	Assistant professor
4.	Marina Kostic	marrina2006kg@yahoo.com	Full professor
5.	Srdjan Stefanovic	sstefanovic@fmn.kg.ac.rs	Associate professor
7.	Radisa Pavlovic	r.pavlovic2407@gmail.com	Associate professor
8.	Tamara Nikolic Turnic	tamara.nikolic@medf.kg.ac.rs	Associate professor
10.	Marko Ravic	markoravic@hotmail.com	Assistant
11.	Katarina Djordjevic	kacka96kg@gmail.com	Assistant
12.	Bozidar Pindovic	pindovic.bozidar@gmail.com	Assistant trainee
13.	Natasa Mijailovic	nacakg@gmail.com	Assistant professor
14.	Katarina Mihajlovic	katarina.mihajlovic@fmn.kg.ac.rs	Assistant professor

* Head of Course

COURSE STRUCTURE:

Teaching is based through interactive work with students in the form of lectures, seminars and exercises, for a total duration of 15 weeks, of which the first 9 weeks of the semester are intended for teaching by thematic units, and the following 6 weeks for planning and preparing of systematic review papers. Students are obliged to participate in all forms of teaching.

The exam is passed by preparing and defending a systematic review paper on the given topic. The paper should contain the following parts:

1. Title page

Name and headquarters of the faculty, name of the study program, title of the paper, first and last name of the student, index number, year of study and name of the subject for which the paper is written, title, name and surname of the teacher in charge of the subject

2. Summary

It should be structured, up to 300 words and contain the following elements: introduction/objective of the work, material and method, results and conclusions. At the end of the abstract, 3 to 5 keywords should be listed.

3. Introduction

In the introduction, the previous findings on the topic of research should be briefly presented, with special reference to the pharmacological characteristics of the drug that is the subject of research, i.e. the specific adverse effect of interest for the analytical approach, then point out what has not yet been clarified, and then precisely explain the goal of the work.

4. Material and method

It is necessary to include the method of literature search (databases that were searched), keywords that were used, inclusion and exclusion criteria as well as criteria for evaluating the validity and significance of the studies found, that is, the presentation of cases of adverse drug effects. It is also necessary to indicate how many and what kind of works were found with a certain combination of keywords, as well as how many studies from those found, according to the criteria for assessing validity and significance, were included in the analytical procedure

5. Results

Show all studies analyzed, including basic study data (title, authors, etc.), study objective and type, description of intervention, outcome (adverse effect), and length of follow-up. The results should be listed without discussion, in the form of tables: assessment criteria for quality assessment, causality assessment table according to Naranjo score and table with extracted data.

6. Discussion

The discussion should be an explanation of the presented results. At the end of the discussion, the conclusions should be stated.

7. Literature

Contains references that support the claims made in the paper. References are listed in the literature in order of appearance in the text, according to the Vancouver rules. References are given in the text in the form of the serial number under which they are listed in the literature.

The paper should be written in English, Times New Roman, font size 12, with 1.5 spacing. All information provided in the paper must be supported by appropriate references.

Students are obliged to submit the work in printed form (in one copy) and in electronic form work (Microsoft Word) and the presentation (Microsoft PowerPoint) (on compact disc) seven days before the exam date.

GRADING:

ACTIVITY DURING THE LESSON:
Students are obliged to attend and actively participate in all forms of teaching.
Points for activities during classes are earned by solving a test that is taken in the tenth week of classes. The test consists of 30 questions, with a correct answer scoring 1 point. Activity during class carries a maximum of 30 points.

EXAM:
The grade on the exam is obtained by preparing and defending a systematic review paper (maximum 70 points)

FINAL SCORE:
The final grade, which depends on the total number of points earned, i.e. the sum of points gained in the domain of activities during classes and points gained on the exam, is formed according to the following table:

Grading system		
Grade	**Total 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

LITERATURE:

1. Lindquist AM. Seeing and Observing in International Pharmacovigilance. Sweedan: Proefschrift, 2003.
2. Stockley IH. Drug Interactions. Oxford: Blackwell Science, 1994.
3. Salway JG. Drug-Test Interactions Handbook. Edinburgh: Churchill-Livingstone, 1990.
4. Stockley IH. Stockley's Drug Interactions. London: Pharmaceutical Press, 2002.
5. Waller P, Harrison-Woolrych M. An Introduction to Pharmacovigilance, 2nd Edition. John Wiley & Sons. 2017.

SCHEDULE:

COURSE UNIT 1 (WEEK 1):

Lectures: 2 hours	Seminar: 1 hour	Practical classes: 1 hours
Introduction to pharmacovigilance	Adverse drug reactions, adverse events, serious adverse events	Frequency and types of side effects of drugs: A, B and C.

COURSE UNIT 2 (WEEK 2):

Lectures: 2 hours	Seminar: 1 hour	Practical classes: 1 hours
Spontaneous reporting of adverse drug reactions	Structure and functioning of the national center for adverse drug reactions.	Forms and techniques for reporting adverse drug reactions

COURSE UNIT 3 (WEEK 3):

Lectures: 2 hours	Seminar: 1 hour	Practical classes: 1 hours
Determining the causality of reported adverse drug effects: Naranjo scale and WHO scale	The concept of "signals" in the Adverse Reactions Database.	Practical examples of spontaneous reports of adverse drug effects; determination of causality using the Naranjo scale

COURSE UNIT 4 (WEEK 4):

Lectures: 2 hours	Seminar: 1 hour	Practical classes: 1 hours
Case reports of adverse drug reactions published in the medical literature	ADR (Post Marketing Surveillance) reporting encouraged.	Active collection of ADR from "guard" places

COURSE UNIT 5 (WEEK 5):

Lectures: 2 hours	Seminar: 1 hour	Practical classes: 1 hours
Monitoring of each case of drug prescription (Prescription Event Monitoring).	Registers of patients suffering from certain diseases and registers of patients who receive a certain medicine. The use of registries in the study of adverse drug reactions.	Cross-sectional studies: follow all patients at one point or time interval, without regardless of whether they are taking medicine or not. Practical examples of cross-sectional studies.

COURSE UNIT 6 (WEEK 6):

Lectures: 2 hours	Seminar: 1 hour	Practical classes: 1 hours
Cohort studies in pharmacovigilance: design, applicability and interpretation of results	A randomized clinical trial as a study of adverse drug effects	Analyze practical examples of cohort studies. Examine their validity and clinical significance.

COURSE UNIT 7 (WEEK 7):

Lectures: 2 hours	Seminar: 1 hour	Practical classes: 1 hours
Case-control studies: a group of patients with ADR is compared with a group of patients without ADR who did not receive the drug.	Intensive and semi-intensive collection of adverse drug reactions in the hospital	Case-control study sample analysis of statin side effects

COURSE UNIT 8 (WEEK 8):

Lectures: 2 hours	Seminar: 1 hour	Practical classes: 1 hours
Collecting adverse drug reactions directly from patients	The role of primary care pharmacists in reporting adverse events of drugs	Practical methods to promote the reporting of adverse drug reactions.

COURSE UNIT 9 (WEEK 9):

Lectures: 2 hours	Seminar: 1 hour	Practical classes: 1 hours
Interactions between drugs and between drugs and food ingredients.	Pharmacokinetics and Pharmacodynamics interactions	Practical methods of investigating mechanisms of interactions between drugs.

COURSE UNIT 10 (WEEK 10):

Lectures: 2 hours	Seminar: 1 hour	Practical classes: 1 hours
Planning, research and preparation of a systematic overview in the field of pharmacovigilance - literature search and introduction writing	Solving practical problems in the preparation of a systematic overview in the field of pharmacovigilance - literature search and introduction writing	Individual research approach and preparation of a systematic overview in the field of pharmacovigilance - literature search and introduction writing

COURSE UNIT 11 (WEEK 11):

Lectures: 2 hours	Seminar: 1 hour	Practical classes: 1 hours
Planning, research and preparation of a systematic overview in the field of pharmacovigilance – methodology	Solving practical problems in the preparation of a systematic overview in the field of pharmacovigilance - methodology	Individual research approach and preparation of a systematic overview in the field of pharmacovigilance - methodology

COURSE UNIT 12 (WEEK 12):

Lectures: 2 hours	Seminar: 1 hour	Practical classes: 1 hours
Planning, research and preparation of a systematic overview in the field of pharmacovigilance – analysis and results.	Solving practical problems in the preparation of a systematic overview in the field of pharmacovigilance - analysis and results.	Individual research approach and preparation of a systematic overview in the field of pharmacovigilance - analysis and results.

COURSE UNIT 13 (WEEK 13):

Lectures: 2 hours	Seminar: 1 hour	Practical classes: 1 hours
Planning, research and preparation of a systematic overview in the field of pharmacovigilance – discussion 1.	Solving practical problems in the preparation of a systematic overview in the field of pharmacovigilance - discussion 1.	Individual research approach and preparation of a systematic overview in the field of pharmacovigilance - discussion 1.

COURSE UNIT 14 (WEEK 14):

Lectures: 2 hours	Seminar: 1 hour	Practical classes: 1 hours
Planning, research and preparation of a systematic overview in the field of pharmacovigilance – discussion 2.	Solving practical problems in the preparation of a systematic overview in the field of pharmacovigilance - discussion 2.	Individual research approach and preparation of a systematic overview in the field of pharmacovigilance - discussion 2.

COURSE UNIT 15 (WEEK 15):

Lectures: 2 hours	Seminar: 1 hour	Practical classes: 1 hours
Planning, research and preparation of a systematic overview in the field of pharmacovigilance – conclusion and practical application of research results.	Solving practical problems in the preparation of a systematic overview in the field of pharmacovigilance - conclusion and practical application of research results.	Individual research approach and preparation of a systematic overview in the field of pharmacovigilance - conclusion and practical application of research results.

Week	Type	Title	Teacher
1	L	Introduction to pharmacovigilance	Radisa Pavlovic, Lecturer
	S	Adverse drug reactions, adverse events, serious adverse events	Radisa Pavlovic, Lecturer
	P	Frequency and types of side effects of drugs: A, B and C.	Radisa Pavlovic Bozidar Pindovic Katarina Djirdjevic
2	L	Spontaneous reporting of adverse drug reactions	Srdjan Stefanovic, Lecturer
	S	Structure and functioning of the national center for adverse drug reactions.	Srdjan Stefanovic, Lecturer
	P	Forms and techniques for reporting adverse drug reactions	Srdjan Stefanovic Katarina Mihajlovic Natasa Mijailovic
3	L	Determining the causality of reported adverse drug effects: Naranjo scale and WHO scale	Slobodan Jankovic, Lecturer
	S	The concept of "signals" in the Adverse Reactions Database.	Slobodan Jankovic, Lecturer
	P	Practical examples of spontaneous reports of adverse drug effects; determination of causality using the Naranjo scale	Marko Ravic Katarina Djordjevic Bozidar Pindovic
4	L	Case reports of adverse drug reactions published in the medical literature	Katarina Mihajlovic, Lecturer

Week	Type	Title	Teacher
	S	ADR (Post Marketing Surveillance) reporting encouraged.	Katarina Mihajlovic, Lecturer
	P	Active collection of ADR from "guard" places	Bozidar Pindovic Katarina Mihajlovic Natasa Mijailovic
5	**L**	Monitoring of each case of drug prescription (Prescription Event Monitoring).	Marina Kostic, Lecturer
	S	Registers of patients suffering from certain diseases and registers of patients who receive a certain medicine. The use of registries in the study of adverse drug reactions.	Marina Kostic, Lecturer
	P	Cross-sectional studies: follow all patients at one point or time interval, without regardless of whether they are taking medicine or not. Practical examples of cross-sectional studies.	Marko Ravic Katarina Djordjevic Bozidar Pindovic
6	**L**	Cohort studies in pharmacovigilance: design, applicability and interpretation of results	Aleksandra Stojanovic, Lecturer
	S	A randomized clinical trial as a study of adverse drug effects	Aleksandra Stojanovic, Lecturer
	P	Analyze practical examples of cohort studies. Examine their validity and clinical significance.	Bozidar Pindovic Katarina Mihajlovic Natasa Mijailovic
7	**L**	Case-control studies: a group of patients with ADR is compared with a group of patients without ADR who did not receive the drug.	Natasa Mijailovic, Lecturer
	S	Intensive and semi-intensive collection of adverse drug reactions in the hospital	Natasa Mijailovic, Lecturer

Week	Type	Title	Teacher
	P	Case-control study sample analysis of statin side effects	Marko Ravic Katarina Mihajlovic Natasa Mijailovic
8	**L**	Collecting adverse drug reactions directly from patients	Aleksandra Stojanovic, Lecturer
	S	The role of primary care pharmacists in reporting adverse events of drugs	Aleksandra Stojanovic, Lecturer
	P	Practical methods to promote the reporting of adverse drug reactions.	Aleksandra Stojanovic, Katarina Djordjevic Bozidar Pindovic
9	**L**	Interactions between drugs and between drugs and food ingredients.	Aleksandra Stojanovic, Lecturer
	S	Pharmacokinetics and Pharmacodynamics interactions	Aleksandra Stojanovic, Lecturer
	P	Practical methods of investigating mechanisms of interactions between drugs.	Marko Ravic Katarina Mihajlovic Natasa Mijailovic
10	**L**	Planning, research and preparation of a systematic overview in the field of pharmacovigilance - literature search and introduction writing	Aleksandra Stojanovic, Lecturer
	S	Solving practical problems in the preparation of a systematic overview in the field of pharmacovigilance - literature search and introduction writing	Aleksandra Stojanovic, Lecturer

Week	Type	Title	Teacher
	P	Individual research approach and preparation of a systematic overview in the field of pharmacovigilance - literature search and introduction writing	Aleksandra Stojanovic, Katarina Djordjevic Bozidar Pindovic
11	**L**	Planning, research and preparation of a systematic overview in the field of pharmacovigilance – methodology	Aleksandra Stojanovic, Lecturer
	S	Solving practical problems in the preparation of a systematic overview in the field of pharmacovigilance - methodology	Aleksandra Stojanovic, Lecturer
	P	Individual research approach and preparation of a systematic overview in the field of pharmacovigilance - methodology	Aleksandra Stojanovic, Katarina Mihajlovic Natasa Mijailovic
12	**L**	Planning, research and preparation of a systematic overview in the field of pharmacovigilance – analysis and results.	Aleksandra Stojanovic, Lecturer
	S	Solving practical problems in the preparation of a systematic overview in the field of pharmacovigilance - analysis and results.	Aleksandra Stojanovic, Lecturer
	P	Individual research approach and preparation of a systematic overview in the field of pharmacovigilance - analysis and results.	Aleksandra Stojanovic Katarina Djordjevic Bozidar Pindovic
13	**L**	Planning, research and preparation of a systematic overview in the field of pharmacovigilance **–** discussion 1.	Aleksandra Stojanovic, Lecturer
	S	Solving practical problems in the preparation of a systematic overview in the field of pharmacovigilance - discussion 1.	Aleksandra Stojanovic, Lecturer

Week	Type	Title	Teacher
	P	Individual research approach and preparation of a systematic overview in the field of pharmacovigilance - discussion 1.	Marko Ravic Katarina Mihajlovic Natasa Mijailovic
14	**L**	Planning, research and preparation of a systematic overview in the field of pharmacovigilance – discussion 2.	Aleksandra Stojanovic, Lecturer
	S	Solving practical problems in the preparation of a systematic overview in the field of pharmacovigilance - discussion 2.	Aleksandra Stojanovic, Lecturer
	P	Individual research approach and preparation of a systematic overview in the field of pharmacovigilance - discussion 2.	Aleksandra Stojanovic, Katarina Djordjevic Bozidar Pindovic
15	**L**	Planning, research and preparation of a systematic overview in the field of pharmacovigilance **–** conclusion and practical application of research results.	Aleksandra Stojanovic, Lecturer
	S	Solving practical problems in the preparation of a systematic overview in the field of pharmacovigilance - conclusion and practical application of research results.	Aleksandra Stojanovic, Lecturer
	P	Individual research approach and preparation of a systematic overview in the field of pharmacovigilance - conclusion and practical application of research results.	Marko Ravic Katarina Mihajlovic Natasa Mijailovic
	E	**EXAM**	