

# PHARMACY INTEGRATED ACADEMIC STUDIES

FIFTH YEAR OF STUDY

2024/2025

Title of the course:
PHARMACOEPIDEMIOLOGY
The course is evaluated with 7 ECTS credits
There are a total of 5 teaching hours per week: 2 hours of lectures, 1 hour of seminar and 2 hours of practice per week

# **TEACHERS:**

	Name and surname	E-mail adress	Title
1.	Radisa Pavlovic	rpavlovic@fmn.kg.ac.rs	Associate professor
2.	Olivera Milovanovic	olivera.milovanovic@fmn.kg.ac.rs	Associate professor
3.	Srdjan Stefanovic	sstefanovic@fmn.kg.ac.rs	Associate professor
4.	Tamara Nikolic Turnic	tamara.nikolic@fmn.kg.ac.rs	Associate professor
5.	Milena Jurisevic	milenajm@yahoo.com	Assistant professor
6.	Aleksandra Stojanovic	vranicaleksandra90@gmail.com	Assistant professor
7.	Natasa Mijailovic	nacakg@gmail.com	Assistant professor
8.	Katarina Mihajlovic	katarina.mihajlovic@fmn.kg.ac.rs	Assistant professor
9.	Marko Ravic	markoravic@hotmail.com	Assistant
10.	Katarina Djordjevic	kacka96kg@gmail.com	Assistant
11.	Bozidar Pindovic	pindovic.bozidar@gmail.com	Assistant

# **COURSE STRUCTURE:**

Teaching takes place through interactive work with students in the form of lectures, practical classes and study research 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 consultative teaching in order to plan, prepare and conduct research for the writing of systematic review papers on a given topic. Students are obliged to actively participate in all forms of teaching.

# **GRADING:**

Teaching units form a unique subject module. The grade is equivalent to the number of points earned (see table). Points are earned in two ways:

**ACTIVITY DURING CLASSES:** The student can earn up to 30 points by analyzing published studies related to the subject of the teaching week. In accordance with the presented knowledge, the student receives from 0 to 2 points per week.

**EXAMINATION:** The student prepares a final exam essay on a given topic in the field of pharmacoepidemiology. The essay includes an analysis of the most relevant published studies in which pharmacoepidemiological methods were used to explain certain health issues. In this way, a student can earn up to 70 points.

#### **FINAL GRADE:**

The final grade, which depends on the total number of earned points - the sum of points on activities during classes and points obtained on the exam, is formed according to the following table:

A TOTAL NIMBER OF EARNED POINTS	FINAL GRADE
0 - 54	5
55 - 64	6
65 - 74	7
75 - 84	8
85 - 94	9
95 - 100	10

#### ЛИТЕРАТУРА:

- 1. Strom BL, Kimmel SE, Hennessy S. Pharmacoepidemiology, 6th Edition. New York: John Wiley & Sons, 2019.
- 2. Hardon A, Hodgkin C, Fresle D. How to investigate the use of medicines by consumers. World Health Organization and University of Amsterdam, 2004.
- 3. Strom BL, Kimmel SE, eds. Textbook of pharmacoepidemiology. New York: John Willey & Sons, 2006
- 4. van Boxtel CJ, Santoso B, Edwards RI. Drug benefits and risks. International Textbook of clinical pharmacology. 1st ed. Chichester: John Wiley and Sons Ltd. 2001.
- 5. Yang Y, West Srtum D, eds. Understanding pharmacoepidemiology. New York: McGraw Hill Lange, 2011.
- 6. Радовановић 3. Општа епидемиологија, Београд: Наука, 2001

Lecture presentations that will be used in classes are available on the website of the Faculty of Medical Sciences www.medf.kg.ac.rs.

Consultations with teachers will be held every Thursday during the teaching week, from 13:30 to 14:30, in the premises of the Department of Clinical Pharmacy (room 24).

#### **COURSE UNIT 1 (WEEK 1):**

#### INTRODUCTION TO THE PHARMACOEPIDEMILOLOGY

#### Lectures - 2 hours

Introduction to pharmacoepidemiology: definitions, history and development.

The importance of pharmacoepidemiology for the health care system.

#### Seminar - 1 hour

Pharmacoepidemiology in the academic environment, industry, regulatory bodies and legislation

#### Practical classes – 2 hours

Identification of clinical practice problems that require pharmacoepidemiological research.

#### **COURSE UNIT 2 (WEEK 2):**

#### TYPES OF PHARMACOEPIDEMIOLOGICAL STUDIES

#### **Lectures - 2 hours**

Types of pharmacoepidemiological studies. Epidemiological parameters of importance for pharmacoepidemiology.

#### Seminar - 1 hour

Epidemiological studies of the medical devices

#### Practical classes – 2 hours

Analysis of several examples of pharmacoepidemiological studies

## **COURSE UNIT 3 (WEEK 3):**

## **CLASSIFICATION OF DRUGS**

#### **Lectures - 2 hours**

Anatomical-therapeutic-chemical classification (ATC classification). The concept of defined daily doses.

# Seminar - 1 hour

Nomenclature of drugs and other domestic and international drug classification systems

# **Practical classes – 2 hours**

Defined daily drug dose (DDD). Finding defined daily doses for drugs that are most commonly used

#### **COURSE UNIT 4 (WEEK 4):**

# DRUG UTILISATION STUDIES

#### **Lectures - 2 hours**

Drug utilization studies. ABC analysis of drug consumption and the concept of "90% of drug consumption". **Seminar - 1 hour** Pharmacoepidemiology of medical errors

#### **Practical classes – 2 hours**

Calculation of drug consumption expressed in defined daily doses.

# COURSE UNIT 5 (WEEK 5):

# ANALYSIS OF DRUG UTILISATION TRENDS

#### **Lectures - 2 hours**

Analysis of secular trends. World Health Organization drug use indicators: basic and additional.

#### Seminar - 1 hour

Evaluation and improvement of drug prescribing practices

# Practical classes – 2 hours

An analysis of practical examples of studies of the quality of drug prescribing using WHO indicators

#### **COURSE UNIT 6 (WEEK 6):**

#### **Lectures - 2 hours**

Case control and cross-over studies: design, applicability and interpretation of results

# **CASE-CONTROL STUDIES**

#### Seminar - 1 hour

Descriptive case-report and case-series studies: design, applicability and interpretation of results

#### Practical classes – 2 hours

An analysis of practical examples of case-control studies. An examination of their validity and clinical relevance

# **COURSE UNIT 7 (WEEK 7):**

#### **Lectures - 2 hours**

Cohort and cross-sectional studies: design, applicability and interpretation of results

#### **COHORT STUDIES**

# Seminar - 1 hour

Self-controlled studies: design, applicability and interpretation of results.

#### Practical classes – 2 hours

An analysis of practical examples of cohort studies. An examination of their validity and clinical relevance

#### **COURSE UNIT 8 (WEEK 8):**

#### SAMPLE IN PHARMACOEPIDEMIOLOGICAL STUDIES

#### **Lectures - 2 hours**

Selection of the sample and classification of subjects into groups in the research. Method of random selection of respondents and the issue with volunteers

#### Seminar - 1 hour

Deliberate selection of the population to be investigated.

# **Practical classes – 2 hours**

Determining the sample for different types of research in Pharmacoepidemiology

#### COURSE UNIT 9 (WEEK 9):

#### DATA COLLECTION IN PHARMACOEPIDEMIOLOGICAL STUDIES

#### **Lectures - 2 hours**

Data collection in pharmacoepidemiology and use of secondary sources. Structured and semi-structured questionnaires, interview: problems, correction of results and valid conclusion

# Seminar - 1 hour

Spontaneous reporting system, electronic database systems, ad-hoc studies (current and de novo systems)

#### **Practical classes – 2 hours**

Analysis of examples of studies using the questionnaire method.

#### **COURSE UNIT 10 (WEEK 10):**

#### **Lectures - 2 hours**

Planning, research and preparation of a systematic review in the field of pharmacoepidemiology literature research and writing an introduction

# Seminar - 1 hour

Solving practical problems in creating a systematic review in the field of pharmacoepidemiology literature research and writing an introduction

#### Practical classes – 2 hours

Individual research approach and preparation of a systematic review in the field of pharmacoepidemiology —literature research and writing an introduction

### **COURSE UNIT 11 (WEEK 11):**

#### **Lectures - 2 hours**

Planning, research and preparation of a systematic review in the field of pharmacoepidemiology — methodology

#### Seminar - 1 hour

Solving practical problems in creating a systematic review in the field of pharmacoepidemiology — methodology

#### Practical classes – 2 hours

Individual research approach and preparation of a systematic review in the field of pharmacoepidemiology — methodology

# **COURSE UNIT 12 (WEEK 12):**

# **Lectures - 2 hours**

Planning, research and preparation of a systematic review in the field of pharmacoepidemiology – results 1

#### Seminar - 1 hour

Solving practical problems in creating a systematic review in the field of pharmacoepidemiology – results 1

#### Practical classes – 2 hours

Individual research approach and preparation of a systematic review in the field of pharmacoepidemiology – results 1

#### **COURSE UNIT 13 (WEEK 13):**

#### **Lectures - 2 hours**

Planning, research and preparation of a systematic review in the field of pharmacoepidemiology – results 2

#### Seminar - 1 hour

Solving practical problems in creating a systematic review in the field of pharmacoepidemiology – results 2

### **Practical classes – 2 hours**

Individual research approach and preparation of a systematic review in the field of pharmacoepidemiology – results 2

#### **COURSE UNIT 14 (WEEK 14):**

#### **Lectures - 2 hours**

Planning, research and preparation of a systematic review in the field of pharmacoepidemiology – discussion and conclusion 1

#### Seminar - 1 hour

Solving practical problems in creating a systematic review in the field of pharmacoepidemiology – discussion and conclusion 1

#### Practical classes – 2 hours

Individual research approach and preparation of a systematic review in the field of pharmacoepidemiology – discussion and conclusion 1

#### **COURSE UNIT 15 (WEEK 15):**

#### **Lectures - 2 hours**

Planning, research and preparation of a systematic review in the field of pharmacoepidemiology – discussion and conclusion 2

#### Seminar - 1 hour

Solving practical problems in creating a systematic review in the field of pharmacoepidemiology – discussion and conclusion 2

#### Practical classes – 2 hours

Individual research approach and preparation of a systematic review in the field of pharmacoepidemiology – discussion and conclusion 2

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WEEK	ТҮРЕ	TITLE	TEACHER
	L	Introduction and importance of pharmacoepidemiology	Radisa Pavlovic
1	S	Pharmacoepidemiology in different fields	Radisa Pavlovic
	P	Clinical problems	Radisa Pavlovic Katarina Djordjevic Marko Ravic
	L	Types of pharmacoepidemiological studies and parameters	Srdjan Stefanovic
2	S	Epidemiological studies of medical devices	Srdjan Stefanovic
	P	Examples of studies – analysis	Srdjan Stefanovic Aleksandra Stojanovic Bozidar Pindovic
	L	Drug classifications and defined daily doses	Katarina Mihajlovic
3	S	Nomenclature and classification of drugs	Katarina Mihajlovic
	P	Drug consumption expressed in defined daily doses	Katarina Mihajlovic Tamara Nikolić Turnic Bozidar Pindovic
	L	Drug utilization studies and ABC analysis	Radisa Pavlovic
4	S	Pharmacoepidemiology of medical errors	Radisa Pavlovic
	P	Calculation of drug consumption	Radisa Pavlovic Natasa Mijajlovic Bozidar Pindovic
	L	Analysis of secular trends and WHO indicators	Tamara Nikolic Turnic
5	S	Improvement of drug prescribing practices	Tamara Nikolic Turnic
	P	Examples of studies – analysis	Tamara Nikolic Turnic Katarina Djordjevic Marko Ravic

Недеља	Тип	Назив методске јединице	Наставник
	L	Case-control and crossover studies	Srdjan Stefanovic
6	S	Descriptive and case series studies	Srdjan Stefanovic
	P	Examples of studies – analysis	Srdjan Stefanovic Bozidar Pindovic Marko Ravic
	L	Cohort and cross-sectional studies	Aleksandra Stojanovic
7	S	Self-control studies	Aleksandra Stojanovic
	P	Examples of studies – analysis	Aleksandra Stojanovic Katarina Mihajlovic Katarina Djordjevic
	L	Sample selection, classification and randomization	Radisa Pavlovic
8	S	Deliberate selection of the population	Radisa Pavlovic
	P	Determining the sample for different types of research	Radisa Pavlovic Katarina Mihajlovic Natasa Mijailovic
	L	Data collection, questionnaires and interview	Natasa Mijailovic
9	S	Spontaneous reporting system, electronic database	Natasa Mijailovic
	P	Examples of studies – analysis	Natasa Mijailovic Aleksandra Stojanovic Katarina Mihajlovic
	L	Planning, research and preparation of a systematic review in the field of pharmacoepidemiology - literature research and writing an introduction	Radisa Pavlovic
10	S	Solving practical problems in creating a systematic review in the field of pharmacoepidemiology - literature research and writing an introduction	Radisa Pavlovic
-	P	Individual research approach and preparation of a systematic review in the field of pharmacoepidemiology - literature research and writing an introduction	Radisa Pavlovic Natasa Mijailovic Katarina Djordjevic

Недеља	Тип	Назив методске јединице	Наставник
11	L	Planning, research and preparation of a systematic review in the field of pharmacoepidemiology - methodology	Radisa Pavlovic
	S	Solving practical problems in creating a systematic review in the field of pharmacoepidemiology - methodology	Radisa Pavlovic
	P	Individual research approach and preparation of a systematic review in the field of pharmacoepidemiology - methodology	Radisa Pavlovic Tamara Nikolic Turnic Aleksandra Stojanovic
	L	Planning, research and preparation of a systematic review in the field of pharmacoepidemiology - results 1	Radisa Pavlovic
12	S	Solving practical problems in creating a systematic review in the field of pharmacoepidemiology - results 1	Radisa Pavlovic
	P	Individual research approach and preparation of a systematic review in the field of pharmacoepidemiology – results 1	Katarina Mihajlovic Bozidar Pindovic Marko Ravic
	L	Planning, research and preparation of a systematic review in the field of pharmacoepidemiology - results 2	Radisa Pavlovic
13	S	Solving practical problems in creating a systematic review in the field of pharmacoepidemiology - results 2	Radisa Pavlovic
	P	Individual research approach and preparation of a systematic review in the field of pharmacoepidemiology – results 2	Radisa Pavlovic  Aleksandra Stojanovic  Marko Ravic
	L	Planning, research and preparation of a systematic review in the field of pharmacoepidemiology - discussion and conclusion 1	Radisa Pavlovic
14	S	Solving practical problems in creating a systematic review in the field of pharmacoepidemiology - discussion and conclusion 1	Radisa Pavlovic
	P	Individual research approach and preparation of a systematic review in the field of pharmacoepidemiology – discussion and conclusion 1	Katarina Mihajlovic Natasa Mijailovic Bozidar Pindovic
15	L	Planning, research and preparation of a systematic review in the field of pharmacoepidemiology - discussion and conclusion 2	Radisa Pavlovic
	S	Solving practical problems in creating a systematic review in the field of pharmacoepidemiology - discussion and conclusion 2	Radisa Pavlovic

Недеља	Тип	Назив методске јединице	Наставник
	P	Individual research approach and preparation of a systematic review in the field of pharmacoepidemiology – discussion and conclusion 2	Radisa Pavlovic Natasa Mijailovic Katarina Djordjevic
	E	EXAM	