FACULTY OF PHARMACY

STUDY PROGRAM 0916.1 PHARMACY

DEPARTMENT OF PHARMACOLOGY AND CLINICAL PHARMACY

APPROVED
at the meeting of the Commission for Quality Assurance and Evaluation of the Curriculum
Faculty of Pharmacy
Minutes No. 2 of 09.11.2021
Chairwoman of the Committee, PhD, associate professor
UNCU Livia _____

APPROVED
at the meeting of the Faculty Council, Faculty of Pharmacy
Minutes No. 3 of 16.12.2021
Dean of the Faculty, PhD, associate professor
CIOBANU Nicolae _____

APPROVED
approved at the meeting of the Department of Pharmacology and Clinical Pharmacy
Minutes No. 2 of 15.09.2021
Head of Department, PhD, associate professor,
SCUTARI Corina _____

SILLABUS

DISCIPLINE: **DRUGS SAFETY AND RISKS OF USE**

Integrated studies

Type of course: **Free choice discipline**

Curriculum developed by the team of authors:

Peredelcu Rodica, PhD, university assistant

Scutari Corina, PhD, associate professor

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I. PRELIMINARY

- General presentation of the discipline: its place and role in specific competences formation of professional/specialty training program

The free choice course *Drugs safety and risks of use* is a component of pharmaceutical education and aims to study the side effects of drugs and their impact on the body.

During the lectures are presented the general notions about the safety profiles of medicines, the assessment of risk factors that may influence medication errors, the development of the pharmacovigilance plan in order to manage the risks of medicines, including those subject to additional monitoring, are presented. This course will help to learn how to evaluate the safety of medicines in medical practice and to exercise advisory assistance to physicians and patients regarding effective and harmless medication.

- Mission of the curriculum (aim) in professional training

One of the main objectives of the free choice course is to ensure a positive balance between the benefits and risks of a medicine during real conditions administration period. Controlled and randomized studies rarely accurately present real-life experience. The role of pharmacists is to proactively monitor and manage the risks associated with all medicines produced. No drug is risk-free, that's why the benefits of a drug must always be weighed against its risks. The relationship between benefits and risks must be carefully analyzed and given due weight. Failure to address the risk management process can lead to crisis situations, with harmful consequences for patient safety and public health.

- **Languages of the course:** Romanian, English.
- **Beneficiaries:** students of the fourth year, faculty of Pharmacy, specialty of Pharmacy.

II. MANAGEMENT OF THE DISCIPLINE

Code of the discipline			
Name of the discipline		**Drugs safety and risks of use**	
Person(s) in charge of the discipline		PhD, university assistant, **Peredelcu Rodica**	
Year	**IV**	Semester	**8**
Total number of hours, including:			**60**
Lectures	**15**	Practical/laboratory hours	**-**
Seminars	**30**	Individual work	**15**
Form of assessment	**E**	Number of credits	**2**

III. TRAINING AIMS IN WITHIN THE DISCIPLINE

At the end of the discipline study, the student will be able to:

✓ ***At the level of knowledge and understanding:***

- To know the principles of classification of side effects;
- To determine the causality of side effects;
- To select the direct and indirect consequences of side effects;
- To master the methods of detection and management of side effects.

✓ ***At the application level:***

• To be able to determine the risk factors that can influence medication errors;
• To be able to analyze the mechanism of occurrence and the evolution of side effects of the drugs used for the treatment of the respective diseases;
• To be able to assess the impact of side effects on the body;
• To be able to evaluate and predict the possible side effects of medicinal products;
• To be able to determine methods of preventing and combating side effects;
• To be able to provide rational and harmless medication, to provide the possibility of substituting one preparation with a safer one in the treatment of a specific condition.

✓ ***At the integration level:***

- To be able to analyze, evaluate and record drug side effects other than those listed in the leaflet;
- To be able to analyze the main pharmacological groups used and the side effects;
- To be able to prepare and submit a case report;
- To be able to evaluate and predict the possible side effects of medicines;
- To be able to provide rational and harmless medication, the possibility of substituting one preparation with another in the treatment of a condition.

IV. PROVISIONAL TERMS AND CONDITIONS

Student of the fourth year requires the following:

- Certified skills in fundamental sciences (physiology, pathological physiology, pharmacology, pharmacotherapy, pharmacotoxicology);
- Digital competences (use of the Internet, document processing, electronic tables and presentations, use of graphics software);
- Ability to communicate and team work;
- Qualities - tolerance, compassion, autonomy.

V. THE MESAND ESTIMATE ALLOCATION OF HOURS

Lectures, practical hours/seminars and self-training

No	Theme	Number of hours		
		Lectures	Practical works	Self training
1.	Introduction to Pharmacovigilance: definition, general aspects.	1	2	1
2.	National and international pharmacovigilance bodies for medicinal products.	1	2	1
3.	Organization of pharmacovigilance in the Republic of Moldova and the European Union, involved institutions.	1	2	1
4.	The structure of the pharmacovigilance file and the elaboration method; the contribution of the doctor and the pharmacist.	1	2	1
5.	The manner of obtaining the marketing authorization in Republic of Moldova and the influence of pharmacovigilance data on the withdrawal from the pharmaceutical market.	1	2	1
6.	The criteria underlying the preparation of the pharmacovigilance file for a medicinal product.	1	2	1
7.	Pharmacovigilance guide prepared by the Drug Agency, presentation and debate.	1	2	1
8.	Factors that may influence the occurrence of side effects of various medicinal products.	1	2	1
9.	Single dose and repeated dose toxicity - their importance in pharmacovigilance.	1	2	1
10.	Carcinogenicity and teratogenicity - their contribution in establishing the withdrawal of APPs for medicinal products.	1	2	1
11.	Side effects and toxicity of withdrawal medicinal products for the newborn.	1	2	1
12.	Influence of side effects and toxicity on pregnancy and lactation when preparing the pharmacovigilance record.	1	2	1
13.	The role and importance of the pharmacist in organizing the pharmacovigilance process in Republic of Moldova and worldwide.	1	2	1
14.	The future strategy of AMMD and MoH regarding the development of the pharmacovigilance program.	1	2	1
15.	Methods of detection and management of side effects	1	2	1
Total		**15**	**30**	**15**

VI. CLINICAL SKILLS ACQUIRED AT THE END OF THE COURSE

Mandatory essential practical tasks are:

• To be able to determine the risk factors that may influence medication errors and drug side effects;

• To be able to analyze the mechanism of occurrence and the evolution of side effects of the drugs used for the treatment of the respective diseases;

• To be able to assess the impact of side effects on the body;

• To be able to evaluate and predict the possible side effects of medicinal products;

• To be able to determine methods of combating and preventing side effects;

• To be able to provide rational and harmless medication, to provide the possibility of substituting one preparation with a safer one in the treatment of a condition.

VII. REFERENCE OBJECTIVES AND CONTENT UNITS

OBJECTIVES	CONTENT UNITS
Chapter 1. Organization of pharmacovigilance in the Republic of Moldova and the European Union, involved institutions.	
✓ To know the basic notions and general aspects of Pharmacovigilance ✓ To know the principles of classification of side effects ✓ To know the particularities of the pharmacodynamics and pharmacokinetics of drugs that cause side effects ✓ To interpret the side effects of medications ✓ To know the National and International Organizations dealing with pharmacovigilance for medicinal products ✓ To know the organization of pharmacovigilance in the Republic of Moldova and the institutions involved	1. Basic notions and general aspects of Pharmacovigilance. Principles of classification of side effects. 2. Peculiarities of pharmacodynamics and pharmacokinetics of drugs causing side effects. 3. National and international bodies dealing with pharmacovigilance.
Chapter 2. Factors that may influence the side effects of various medicinal products.	
✓ to know single and repeated dose toxicity - their importance in pharmacovigilance. ✓ To know carcinogenicity and teratogenicity - their contribution in establishing the withdrawal of APPs for medicinal products. ✓ To know side effects and toxicity of withdrawal medicinal products for the newborn. ✓ To know the influence of side effects and toxicity on pregnancy and lactation when preparing the pharmacovigilance record.	1. Non-clinical drug toxicity studies. 2. Clinical studies of drug toxicity. 3. Side effects and toxicity for newborns and on pregnancy and lactation.
Chapter 3 The role and importance of the pharmacist in organizing the pharmacovigilance process.	

OBJECTIVES	CONTENT UNITS
✓ To know the criteria underlying the preparation of the pharmacovigilance file for a medicinal product ✓ To know the pharmacovigilance guide prepared by the NMA, presentation and debate ✓ to know the structure of the pharmacovigilance file and the elaboration method; the contribution of the doctor and the pharmacist ✓ to know the manner of obtaining the marketing authorization in Republic of Moldova and the influence of pharmacovigilance data on the withdrawal from the pharmaceutical market ✓ to know the role and importance of the pharmacist in organizing the pharmacovigilance process in Republic of Moldova and worldwide.	1. Pharmacovigilance guide. the criteria underlying the preparation of the pharmacovigilance file. 2. The role and importance of the pharmacist in organizing the pharmacovigilance process in the Republic of Moldova and worldwide.

VIII. PROFESSIONAL (SPECIFIC (PS)) AND TRANSVERSAL (TC) SKILLS AND STUDY OTCOMES

✓ Professional Skills (PS)

PS1: design, formulation, preparation and packaging of medicines and other health products.
PS2: storage, preservation, distribution of medicines and other health products.
PS3: release of medicines and other products for health and pharmaceutical care.
PS4: advice and expertise in medicines and other health products.
PS5: knowledge of the methodology of preclinical and clinical research of the drug; identification of scientific research problems in the field of pharmacology, scientific correlation with biopharmaceutical knowledge.
PS6: use of problem-solving skills; the use of information technologies to solve tests and render pharmacological effects through digital technologies.

✓ Transversal Skills (TS)

TS 1: promotion of effective, harmless and pharmacoeconomically advantageous drugs in the therapy of various pathologies; compliance with the norms of ethics and pharmaceutical deontology in the prescription of OTC medicines and the issuance of medicinal remedies to the population and medical institutions.
TS 2: formation of personal attitude; the ability of pharmacist-patient interaction, pharmacist-doctor, group activity with different roles of drug counseling; improving the capacity for decision-making autonomy in prescribing, selecting and delivering medicines.
TS 3: Performing teamwork by carrying out scientific projects; promoting the spirit of initiative, dialogue and cooperation through various techniques of acquiring the material; respecting the positive attitude, empathy and respect for others, critical analysis and drawing conclusions, in the daily work of the pharmacist.

✓ Study Outcomes

At the end of the course the student will be able to:

- •determine the role of side effects on the clinical course of various diseases;
- • determine the incidence and mechanisms of side effects;
- • evaluate the safety of medicines in medical practice;
- • know the pharmacological and pharmacotoxicological particularities of medicines;
- • be competent to monitor side effects to evaluate and communicate the risk-benefit balance for the most commonly used medicinal remedies;
- • be competent to elucidate and specify the impact of side effects on the body;

inform the patient about the rational use of the drug, possible side effects, prophylaxis and control.

IX. STUDENT'S INDIVIDUAL WORK

No.	Expected Produc	Implementation Strategies	Assessment criteria	Implementation terms
	Working with information	Read the lecture or the material in the manual to the theme carefully. Reading self-	Ability to extract the essentials;	During the semester

No.	Expected Produc	Implementation Strategies	Assessment criteria	Implementation terms
	sources:	training questions in the subject that require reflection on the matter. To get acquainted with the list of additional information sources on the topic. Select the source of additional information for that theme. Reading the text entirely, carefully and writing the essential content. Wording of generalizations and conclusions regarding the importance of the theme/subject	interpretative skills; the volume of work	
	Working with the practical hours' notebook:	Until solving the tasks in the notebook, analyze the information on the subject in the lecture and the manual. Solving consecutive tasks: brief characterization of laboratory data in various pathological conditions, solving clinical cases with explanation of laboratory data. Selection of additional information, using electronic addresses and bibliographic sources.	Workload, situational problem solving skills, ability to formulate conclusions	During the semester
	Preparing and defending presentations /portofolios:	Selection of the research theme, establishment of the research plan, setting the terms of realization. Establishing PowerPoint presentation components - theme, purpose, results, conclusions, practical applications, bibliography Peer reviews. Teacher reviews	The volume of work, the level of insight into the essence of the presentation, the level of scientific argumentation, the quality of the conclusions, the elements of creativity, the formation of the personal attitude, the coherence of the exposure and the scientific correctness, the graphic presentation, the way of presentation	During the semester

X. METHODOLOGICAL SUGGESTIONS FOR TEACHING-LEARNING-ASSESSMENT

Teaching and learning methods used

The teaching of the discipline Drugs safety and risks of use uses different didactic methods and procedures, oriented towards the efficient acquisition and achievement of the objectives of the didactic process. In the theoretical lessons, along with traditional methods (lesson-exposure, lesson-conversation, synthesis lesson), modern methods (lesson-debate, lecture-conference, problem-lesson) are also used. During practical works are used following forms of activities: individual, frontal, group-based. Control work (characterization of preparations, indications in intoxications with various preparations) in writing to highlight the initial level of knowledge. Practical activities (group work): solving

of situational problems and clinical case studies, demonstration of video films. During lessons and extracurricular activities are used Communication Technologies - PowerPoint presentations.

Verifying knowledge on questions from methodological guidelines and putting tasks on the next topic of practical works (individual work).

Final: exam (semester VIII).

- ***Applied teaching strategies/technologies (specific to the discipline);***

"Brainstorming", "The round table"; "Group Interview"; "Case Study"; "Portfolio".

Methods of assessment *(including the method of final mark calculation).*

Current*:* frontal and/or individual control via:

- Motivation (current topic). Determining the purpose of practical works, answering students' questions.
- Written control (test) to highlight the initial level of knowledge.
- Practical Activities: Solving of Problems and Questions in Methodological Instructions for Laboratory Work in Drugs safety and risks of use.
- Verification of final knowledge and assignment of tasks for the next topic of the practical work (self-training).

During the study year, there are two totalizations at the discipline Drugs safety and risks of use. At the end of semester, the student's self-training work is graded.

Thus, formative evaluation consists of two totalizations and one mark for self-training work.

The annual average is formed from the sum of the points accumulated during the study year based on the totalizations scores and the individual work score.

Final: At the Exam to *Drugs safety and risks of use*, students with the average annual score below grade 5 are not admitted, as well as students who have not recovered absences from lectures and practical works.

The Exam in *Drugs safety and risks of use* (summative assessment) is made up of the oral test, which is done by including two questions in the tickets for the Drugs safety and risks of use and a Case Problem.

Final mark consists of two components: average annual mark (coefficient 0.5) and oral test (coefficient 0.5)

The roundup of the grades at the evaluation steps

INTERMEDIATE MARKS SCALE (annual average, marks from the examination stages)	National assessment system	ECTS Equivalent
1.00-3.00	**2**	**F**
3.01-4.99	**4**	**FX**
5.00	**5**	**E**
5.01-5.50	**5.5**	
5.51-6.0	**6**	
6.01-6.50	**6.5**	**D**

6.51-7.00	**7**	
7.01-7.50	**7.5**	**C**
7.51-8.00	**8**	
8.01-8.50	**8.5**	**B**
8.51-8.00	**9**	
9.01-9.50	**9.5**	**A**
9.51-10.0	**10**	

The average annual mark and the marks of all stages of final examination (computer assisted and oral test) - are expressed in numbers according to the mark scale (according to the table), and the final obtained mark is expressed in a number with two decimals, which is transferred to student's record-book.

Absence on examination without good reason is recorded as "absent" and equivalent to 0 (zero). The student has the right to have two re-examinations on failed subject.

XI. RECOMMENDED BIBLIOGRAPHY

A. Mandatory:

1. Mogoșan Cristina, Farcaș Maria, Bucșa Camelia. Introducere în farmacovigilență. România, Cluj-Napoca: Risoprint, 2013, 149p.
2. Чумаев В.Т, Морозов А.Н. Руководство по фармаконадзору за лекарственными средсвами которые приминяются в медицынской практике, 2010, 142 с.

B. Additional:

1. Reglementarea Consiliului European 2309/1993.
2. Legislaţia europeană în domeniu- Directiva 75/319/EEC.