MINISTRY OF HEALTH OF UKRAINE

ODESA NATIONAL MEDICAL UNIVERSITY

Department of *Organization and Economics of Pharmacy*

CONFIRMED by
Vice-rector for scientific and pedagogical work

_____ Eduard BURIACHKIVSKYI
September 1st, 2023

WORKING PROGRAM IN THE DISCIPLINE

INTERNATIONAL ASPECTS OF PHARMACEUTICAL LAW

Level of higher education: second (master's degree)

Field of knowledge: "22 Health care"

Specialty: 226 "Pharmacy, industrial pharmacy"

Educational and professional program: Pharmacy, industrial pharmacy

2023

The working program is compiled on the basis of the educational and professional program "Pharmacy, industrial pharmacy" for the training of specialists of the second (master's) level of higher education in the specialty 226 "Pharmacy, industrial pharmacy" of the field of knowledge 22 "Health care", approved by the Academic Council of ONMedU (minutes No. 8 dated 29/06/2023).

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The working program is approved at the meeting of the department of Organization and Economics of Pharmacy
Minutes No. 1 dated 28/08/2023.

Head of the department _____ Oksana BIELIAIEVA

Approved by the guarantor of
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Approved by the subject-cycle methodological commission for pharmacy's disciplines of ONMedU
Minutes No. 1 dated 29.08.2023

Head of the subject-cycle methodological commission for pharmacy's disciplines of ONMedU

_____ Natalia FIZOR

Revised and approved at the meeting of the department of Organization and Economics of Pharmacy with post-diploma specialization

Minutes No. 1 dated 04/09/2023.

Head of the department _____ Oksana BIELIAIEVA

Revised and approved at the meeting of the department of _____

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Minutes No. ____ dated ____/____/20____.

Head of the department _____

1. Description of the discipline:

Name of indicators	Field of knowledge, specialty, specialization, level of higher education	Characteristics of the academic discipline
The total number of: Credits: 3.0 Hours: 90 Content modules: 1	Branch of knowledge 22 "Health care" Specialty 226 "Pharmacy, industrial pharmacy" Level of higher education second (master's)	*Full-time education* *Elective discipline*
		Year of training: 4
		VII semester
		Lectures (0 hours)
		Practical (30 hours)
		Seminars (0 hours)
		Lab classes (0 hours)
		Independent work (60 hours) *including individual assignments (0 hours)*
		The form of final control – test

2. The Purpose and Objectives of the Discipline, Competencies, and Program Learning Outcomes.

Purpose: acquisition of knowledge by a higher education seeker and formation of professionally oriented competencies in the field of pharmacy, and improvement of skills and competences acquired during the study of previous disciplines. Formation of theoretical foundations of international law and pharmaceutical legislation in future specialists; acquisition of systemic legal knowledge regarding the regulation of pharmaceutical activities in different countries.

The tasks of the discipline are the following:

1. To facilitate the formation of professionally necessary knowledge, skills and abilities in accordance with the educational qualification characteristics
2. To provide a theoretical basis for further study of other pharmaceutical and economic disciplines of the curriculum
3. Create a base that determines the professional competence and general erudition of a pharmacist.
4. To study theoretical concepts and categories of international pharmaceutical law
5. Know the systems of protection of rights and prevention of offenses in the field of pharmaceutical law.

The process of studying the discipline is aimed at forming elements of the following competencies:

- **General (GC):**

GC02. Knowledge and understanding of the subject area and understanding of professional activity.

GC07. The ability to realize one's rights and responsibilities as a member of society; to realize the values of a civil (free democratic) society and the need for its sustainable development, the rule of law, the rights and freedoms of a person and a citizen in Ukraine.

GC09. Ability to use information and communication technologies.

GC11. Ability to apply knowledge in practical situations.

GC14. Ability to adapt and act in a new situation.

- **Special (SC):**

SC01. Ability to integrate knowledge and solve complex pharmacy problems in broad or multidisciplinary contexts.

SC04. The ability to clearly and unambiguously convey one's own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, in particular to people who are studying.

SC13. The ability to organize the activities of the pharmacy to supply the population, health care institutions with medicines and other products of the pharmacy assortment and to introduce appropriate reporting and accounting systems into them, to carry out commodity analysis, administrative records taking into account the requirements of pharmaceutical legislation.

SC24. Ability to use knowledge of regulatory and legislative acts of Ukraine and recommendations of proper pharmaceutical practices in professional activity.

Program learning outcomes (PLO):

PLO03. Have specialized knowledge and skills/skills for solving professional problems and tasks, including for the purpose of further development of knowledge and procedures in the field of pharmacy.

PLO09. Formulate, argue, clearly and concretely convey to specialists and non-specialists, including those seeking higher education, information based on one's own knowledge and professional experience, the main trends in the development of world pharmacy and related industries.

PLO29. To carry out professional activities using information technologies, "Information databases", navigation systems, Internet resources, software and other information and communication technologies.

PLO36. Plan and implement professional activities on the basis of normative legal acts of Ukraine and recommendations of proper pharmaceutical practices.

As a result of studying the academic discipline, the student of higher education must:

- **know:**

- methods of implementing knowledge in solving practical issues;
- current trends in the development of the industry and analyze them;
- structure and features of professional activity;
- have deep knowledge in the field of information and communication technologies used in professional activities;
- legal systems in the world;
- theoretical foundations of pharmaceutical provision in the countries of the world;
- the description of the rights to health care in the normative legal acts of organizations at the regional level;
- health care models and general principles of organization and financing;
- international experience in the formation of state policy in the field of health care and pharmacy;
- peculiarities of pharmaceutical activity in different countries of the world.

- be able to:

- to form one's civic consciousness, to be able to act in accordance with it;
- use professional knowledge to solve practical situations;
- to interpret the requirements of legislative and regulatory acts;
- analyze professional information, make informed decisions, acquire modern knowledge;
- to carry out professional activities that require updating and integration of knowledge;
- apply knowledge from general and specialized disciplines in professional activity;
- to plan and implement professional activities based on regulations and recommendations of proper pharmaceutical practices using the experience of other countries.

3. Content of the Discipline

Topic 1. Types of Legal Systems around the World.

Topic 2. The formation and development of the right to healthcare and pharmaceutical provision in countries around the world.

Topic 3. Enshrining the right to health care in international legislation. The right to health care in regulatory legal acts of organizations at the regional level.

Topic 4. Health care models, general principles of organization and financing.

Topic 5. International experience of state policy formation in the field of health care and pharmacy.

Topic 6. Pharmaceutical activity in different countries of the world.
Topic 7. Methods and forms of state regulation. Normative and legal regulation of pharmaceutical activity in the countries of the European Union.

4. The structure of the Discipline

4.1 *Full-time education*

Names of topics		**Number of hours**				
	Total	**Including**				
		Lectures	**Practical classes**	**Seminars**	**Lab classes**	**ISW**
Topic 1. Types of Legal Systems around the World	10	-	4	-	-	8
Topic 2. Formation and development of the right to health care and pharmaceutical provision in the countries of the world.	14	-	4	-	-	8
Topic 3. Enshrining the right to health in international law. The right to health care in the legal acts of regional level organisations.	16	-	6	-	-	10
Topic 4. Health care models, general principles of organization and financing.	12	-	4	-	-	8
Topic 5. International experience of state policy formation in the field of health care and pharmacy.	12	-	4	-	-	8
Topic 6. Pharmaceutical activity in different countries of the world.	12	-	4	-	-	8
Topic 7. Methods and forms of state regulation. Normative and legal regulation of pharmaceutical activity in the countries of the European Union.	14	-	4	-	-	10
Total hours:	**90**	-	**30**	-	-	**60**

5. Topics of lectures / Seminars / Practical / Laboratory classes

5.1. Topics of lectures
Lectures are not provided.
5.2. Topics of seminar classes
Seminar classes are not provided.

5.3. Topics of practical classes

No	Topic name	Hours
1.	Practical lesson 1. Topic 1. Spread of legal systems in the world.	2
2.	Practical lesson 2-4. Topic 2. Formation and development of the right to health care and pharmaceutical provision in the countries of the world.	6

3.	Practical lesson 5-7. Topic 3. Enshrining the right to health care in international legislation. The right to health care in regulatory legal acts of organizations at the regional level.	6
4.	Practical lesson 8-9. Topic 4. Health care models, general principles of organization and financing.	4
5.	Practical lesson 10-11. Topic 5. International experience of state policy formation in the field of health care and pharmacy.	4
6.	Practical lesson 12-13. Topic 6. Pharmaceutical activity in different countries of the world.	4
7.	Practical lesson 14-15. Topic 7. Methods and forms of state regulation. Normative and legal regulation of pharmaceutical activity in the countries of the European Union.	4
	Together	**30**

5.4. Topics of laboratory classes

Laboratory classes are not provided**.**

6. Independent Student Work

No	Title of the topic / types of assignments	Hours
1.	Topic 1. Preparation for practical classes 1	8
2.	Topic 2. Preparation for practical classes 2-4	8
3.	Topic 3. Preparation for practical classes 5-7	10
4.	Topic 4. Preparation for practical classes 8-9	8
5.	Topic 5. Preparation for practical classes 10-11	8
6.	Topic6.Preparation for practical classes 12	8
7.	Topic7.Preparation for practical classes 13-14	10
	Together	60

7. Teaching methods

Practical training: discussion, debate,conversation,discussion of problematic situations,role games,solutioncases, preparation of necessary documentation and its filling, preparation of reports by applicants.

Independent work: independent with methodological developments, recommendations, instructions;solving tests, situational tasks; work with the recommended basic and additional literature, with electronic information resources, regulatory and legal acts, preparation of reports, presentations.

8. Forms of Control and Assessment Methods (including criteria for evaluating learning outcomes)

Current control: oral survey, control written works, evaluation of reports, evaluation of activity in the class, testing (pen-and-paper or computerized), evaluation of required skills

Final control: test

Evaluation of the current educational activity in a practical class:

1. Evaluation of theoretical knowledge on the subject of the class:
   - methods: survey, solving a situational problem
   - the maximum score is 5, the minimum score is 3, the unsatisfactory score is 2.
2. Evaluation of reports on the subject of the class:
   - methods: evaluation of the quality of execution of the applicant's report
   - the maximum score is 5, the minimum score is 3, the unsatisfactory score is 2.

The grade for one practical class is the arithmetic average of all components and can only have a whole value (5, 4, 3, 2), which is rounded according to the statistical method.

Current evaluation criteria in practical training

Rating	Evaluation criteria
"5"	The applicant is fluent in the material, takes an active part in the discussion and solution of the situational/case problem, logically expresses and argues his opinions on the topic of the lesson
"4"	The applicant has a good command of the material, participates in the discussion and solution of the situational/case problem, expresses and argues well his opinions on the subject of the lesson
"3"	The applicant does not have sufficient knowledge of the material, participates uncertainly in the discussion and solution of the situational/case problem, expresses opinions on the subject of the lesson with significant errors.
"2"	The applicant does not own the material, does not participate in the discussion and solution of the situational/case problem, does not express an opinion on the topic of the lesson.

Test is given to the applicant who completed all tasks of the worksing program of the discipline, took an active part in practical classes, has an average current grade 3.0 and more and has no academic debt.

Test is carried out: in the last class before the beginning of the examination session. The grade for the test is the arithmetic mean of all components on a traditional four-point scale and has a value that is rounded according to the statistical method with two decimal places.

9. Distribution of points received by students of higher education

The obtained average score for the academic discipline for applicants who have successfully mastered the working program of the discipline is converted from a traditional four-point scale to points on a 200-point scale, as shown in the table:

Table of Converting the Traditional Grades into the Multi-Point Grading Scale

National Grade	200-Point Grading Scale
Excellent ("5")	185 - 200
Good ("4")	151 - 184
Satisfactory ("3")	120-150
Unsatisfactory ("2")	Below 120

A multi-point scale (200-point scale) characterizes the actual success of each applicant in learning the educational component. The conversion of the traditional grade (average score for the academic discipline) into a 200-point grade is performed by the information and technical department of the University.

According to the obtained points on a 200-point scale, the achievements of the applicants are evaluated according to the ECTS rating scale. Further ranking according to the ECTS rating scale allows you to evaluate the achievements of students from the educational component who are studying in the same course of the same specialty, according to the points they received.

The ECTS scale is a relative-comparative rating, which establishes the applicant's belonging to the group of better or worse among the reference group of fellow students (faculty, specialty). An "A" grade on the ECTS scale cannot be equal to an "excellent" grade, a "B" grade to a "good" grade, etc. When converting from a multi-point scale, the limits of grades "A", "B", "C", "D", "E" according to the ECTS

scale do not coincide with the limits of grades "5", "4", "3" according to the traditional scale. Acquirers who have received grades of "FX" and "F" ("2") are not included in the list of ranked acquirers. The grade "FX" is awarded to students who have obtained the minimum number of points for the current learning activity, but who have not passed the final examination. A grade of "F" is assigned to students who have attended all classes in the discipline, but have not achieved a grade point average (3.00) for the current academic activity and are not admitted to the final examination.

Applicants who study in one course (one specialty), based on the number of points scored in the discipline, are ranked on the ECTS scale as follows:

Converting the Traditional Grade and the Sum of Points on the ECTS Scale

Evaluation on the ECTS scale	Statistical indicator
A	Top 10% students
B	The next 25% students
C	The next 30% students
D	The next 25% students
E	The next 10% students

10. Methodological support

- Working program on the educational component
- Syllabus
- Guidelines for practical classes
- Guidelines for independent work of higher education applicants
- Multimedia presentations
- Situational/case tasks

11. Questions for preparing for the final control

1. Define the term "legal system".
2. Specify and describe the main elements of the legal system.
3. Describe the legal systems in the world and in Ukraine.
4. Describe the process of formation and development of the right to health care and pharmaceutical provision in the countries of the world.
5. Cite the international documents that enshrine the right to health care.
6. Describe the right to health care in Ukraine.
7. Define the concept of "health care system".
8. Formulate the goals and principles of the health care system.
9. Identify the main types of economic models of health care and which countries have them.
10. Reveal the content of the main international acts and declarations on the provision of medical care.
11. Describe pharmaceutical activity in terms of ensuring the physical and economic availability of medicines to the population.
12. Describe the forms and methods of state regulation of pharmaceutical activity in order to ensure the physical availability of medicinal products in foreign practice.
13. Formulate modern approaches to opening pharmacies in foreign countries.
14. Specify new organizational forms of activity of pharmacies, determine the perspective of their implementation in Ukraine.
15. Specify the main forms of legal regulation of pharmaceutical activity in the countries of the world.
16. Determine which international organizations influence the processes of harmonization of the legislation of the countries of the world.
17. Define the concept of "regulatory activity" and formulate its principles.
18. Formulate the main directions of state policy in the sphere of regulation of drug circulation.

19. Specify the main regulatory functions in the implementation of state regulation of drug circulation.
20. International documents regulating quality assurance of pharmaceuticals in Ukraine.
21. The procedure for licensing pharmaceutical activity in different countries.
22. Define the concept of "standardization" and name the historical prerequisites for its emergence.
23. Describe the regulatory regulation of standardization and name the objects of standardization.
24. Describe the role of the pharmacopoeia as a quality standard. Pharmacopoeias of different countries.
25. Name the international standards of pharmaceutical activity and their degree of harmonization with domestic standards.
26. What is the role and purpose of the PIC/S activity, at what level is Ukraine's cooperation with this organization?
27. List the ISO standards and name the organization that develops these standards.
28. Define the concept of "certification" and name its components in relation to pharmaceuticals.
29. Which bodies are involved in the certification of pharmaceutical enterprises in Ukraine?
30. Justification of the need for state registration of drugs and this procedure in different countries of the world.
31. The concept of "advancement (promotion) of drugs".
32. Define the concept of "drug advertising". List its main components in accordance with Directive 2001/83/EC of the European Parliament and the Council.
33. What are the restrictions on drug advertising?

12. Recommended literature

Required:

1. Pharmacy Laws and regulations: Washington State Department of Health, 2017. 845 p.
2. J. Herring Medical Law and Ethics: sixth edition, Oxford university press, 2016. 710 p.

Additional:

1. Comorbidities as factors influencing choice of drug in arterial hypertension therapy/ Vyshnytska Iryna, Unhurian Liana, Bieliaieva Oksana, Pietkova Iryna. Medical theory: collective monograph / Bulavenko Olga, Muntian Olga, Muntian Maksym, Yarovenko Anatolii, etc. International Science Group. Boston: Primedia eLaunch, 2020. P. 68-76. Available at: DOI : 10.46299/isg.2020.MONO.MED.II
2. Implementation of Standards of Good Pharmacy Practice in the World: A Review/ Liana Unhurian, Oksana Bielyaieva, Irina Vyshnytska, Natalia Suschuk, Irina Petkova // Asian Journal of Pharmaceutics. Jan-Mar 2018 (Suppl). 12 (1). - R. 42-46.
3. Pharmaceutical Law and Legislation: the textbook for applicants for higher education / A.A. Kotvitskaya, IV Kubarieva, AV Volkova et al. Kharkiv : NUPh : Golden Pages, 2019.204 p.

13. Electronic information resources

1. Medscape Search Database: Website. URL: https://www.medscape.com/pharmacists.
2. Regulatory base of NTA of Ukraine: website. URL: https://www.hta.ua
3. Compendium online: website. URL: https://compendium.com.ua/
4. National library of medicine. URL: https://pubmed.ncbi.nlm.nih.gov
5. FDA. URL: https://www.fda.gov
6. WHO. URL: https://www.who.int
7. Health economics. URL: https://www.healtheconomics.com/