

MINISTRY OF HEALTH OF UKRAINE

ODESA NATIONAL MEDICAL UNIVERSITY

Department of *Organization and Economics of Pharmacy*

*Approved*

CONFIRMED by  
Vice-rector for scientific and pedagogical work

Eduard BURIACHKIVSKYI  
September 1<sup>st</sup>, 2023



**WORKING PROGRAM IN THE DISCIPLINE**

**PHARMACEUTICAL LAW AND LEGISLATION**

**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



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Approved by the guarantor of the educational and professional program



Liana UNHURIAN

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 \_\_\_\_\_

Minutes No. \_\_\_\_\_ dated \_\_\_\_\_/\_\_\_\_\_/20\_\_\_\_.

Head of the department \_\_\_\_\_

## 1. Description of the academic discipline:

Name of indicators	Field of knowledge, specialty, specialization, level of higher education	Characteristics of the academic discipline
The total number of:	Branch of knowledge 22 "Health care"	Full-time education Mandatory discipline
Credits: 3.0	Specialty 226 "Pharmacy, industrial pharmacy"	Year of training: 3 Semesters V
Hours: 90	Specialization 226.01 "Pharmacy"	Lectures (20 hours) Workshops (0 hours) Practical (30 hours) Laboratory (0 h)
Content modules: 2	Level of higher education second (master's)	Independent work (40 hours)
		Final control form – Graded test

## 2. The purpose and tasks of the educational component, competences, program learning outcomes

**Goal:** is to study the role and place of pharmaceutical law in the legal system of Ukraine and countries of the world and to form future specialists with the theoretical foundations of law and pharmaceutical legislation; the acquisition of systemic legal knowledge on the regulation of pharmaceutical activity and the circulation of medicines, as well as the formation of professionally important skills for reasoned decision making to ensure the effective functioning of pharmaceutical companies and pharmaceutical provision of the population.

### **Task:**

- acquiring system knowledge about the legal basis of health care organization in countries of the world and in Ukraine;
- acquisition of system knowledge about systematization of normative legal acts;
- understanding of organizational and legal forms of pharmaceutical activity;
- assimilation of the main issues of state policy and mechanisms of state regulation of health care and treatment of medicines;
- understanding of the legal status of pharmaceutical workers, the peculiarities of regulating their work;
- understanding of the legal responsibility of pharmaceutical workers for professional and occupational offenses;
- assimilation of knowledge on issues of environmental offenses in the case of pharmaceutical activity;
- acquisition of knowledge on the legislative bases of state supervision in the sphere of circulation of medical products and medical products.

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 activities.

GC07. Ability to exercise their rights and responsibilities as a member of society; to realize the values of civil (free democratic) society and the need for its sustainable development, the rule of law, human and civil rights and freedoms 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 problems of pharmacy in broad or multidisciplinary contexts.

SC04. Ability to clearly and unambiguously communicate own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, including students.

SC13. Ability to organize the activities of a pharmacy to provide the population, health care institutions with medicines and other goods of the pharmacy assortment and to implement appropriate reporting and accounting systems, to carry out commodity analysis, administrative workflow, taking into account the requirements of pharmaceutical legislation.

SC24. Ability to use in professional activities knowledge of regulatory and legal acts of Ukraine and recommendations of good pharmaceutical practices.

**Programmatic learning outcomes for the educational component (PLO):**

PLO03. To have specialized knowledge and skills to solve professional problems and tasks, including for the purpose of further development of knowledge and procedures in the field of pharmacy.

PLO09. To formulate, argue, clearly and concretely convey to specialists and non-specialists, including higher education students, information based on their 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 technology, "Information databases", navigation systems, Internet resources, software and other information and communication technologies.

PLO36. To plan and implement professional activities on the basis of regulatory legal acts of Ukraine and recommendations of good pharmaceutical practices.

**As a result of studying the educational component, the student of higher education must:**

**- know:**

- their social and public rights and responsibilities;
- 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;
- subject area and understand professional activity;
- professional Ukrainian and foreign languages (mainly English) at a level that ensures effective professional activity;
- have deep knowledge in the field of information and communication technologies used in professional activities;
- principles of compiling pharmaceutical information and creating information products;
- normative legal acts of Ukraine on the operation of a pharmacy;
- approaches to the formation of prices for medicinal products;
- ethical and legal norms of pharmaceutical activity;
- the organizational structure of the pharmaceutical supply system in Ukraine, its goals, tasks and functions;
- the main mechanisms for ensuring the availability of pharmaceutical care to the population;
- modern principles for providing pharmaceutical assistance to socially vulnerable population groups;

- basics of the legal system and pharmaceutical legislation;
- the main mechanisms of state regulation of pharmaceutical activity;
- principles of organization of provision of pharmaceutical assistance to the population;
- formation of an assortment of medicines;
- basic concepts and principles of quality management from the standpoint of regulatory and legal regulation, etc.

- **be able:**

- to form one's civic consciousness, to be able to act in accordance with it;
- use professional knowledge to solve practical situations;
- analyze professional information, make informed decisions, acquire modern knowledge;
- apply knowledge for the modern development of the enterprise;
- to carry out professional activities that require updating and integration of knowledge;
- form an effective strategy of personal adaptation to new conditions;
- to apply knowledge of the native language, both orally and in writing, to be able to communicate in a foreign language;
- use information and communication technologies in a professional field that requires updating and integration of knowledge;
- to use normative legal acts regulating pharmaceutical activity in Ukraine and abroad;
- monitor and determine changes and additions to domestic pharmaceutical legislation;
- compile information on the material and technical base of the pharmacy and pharmacy point, as well as organizational documents necessary for their activity;
- choose the necessary standards depending on the specifics of the enterprise;
- to develop the main elements of quality management systems according to standard models;
- acquisition of systemic knowledge regarding the legal foundations of health care organization in the countries of the world and in Ukraine;
- acquisition of system knowledge regarding the systematization of normative and legal acts;
- understanding of organizational and legal forms of pharmaceutical activity;
- assimilation of the main issues of state policy and mechanisms of state regulation of health care and circulation of medicinal products;
- understanding of the legal status of pharmaceutical workers, peculiarities of regulation of their work;
- understanding of the legal responsibility of pharmaceutical workers for professional offenses;
- assimilation of knowledge regarding issues of environmental offenses in the case of pharmaceutical activity;
- acquiring knowledge of the legislative foundations of state supervision in the sphere of circulation of medicines and medical products;
- to systematize normative legal acts;
- document the process of obtaining a license for retail and wholesale sale of drugs;
- provide regulatory and legal support for monitoring compliance with the requirements of the sanitary regime for pharmacies and their structural subdivisions;
- use the algorithm for conducting incoming quality control of drugs and medical devices;
- to form the staff of a pharmacy institution in accordance with the qualification requirements for personnel engaged in the production (in the conditions of a pharmacy) and retail trade of drugs;
- use different sources and forms of transmission of pharmaceutical information;
- dispense over-the-counter medicines, provide advice on the rational use and proper storage of medicines;
- conduct pharmaceutical examination of prescriptions received from the population in accordance with legislation;

- organize and conduct incoming quality control of medicinal products;
- to analyze the formation of drug prices, including taking into account the state regulation of drug prices;
- form retail prices for HLZ and medical products;
- qualify offenses in pharmaceutical activity;
- to document the process of state supervision (control) in the field of pharmaceutical activity on various issues;
- distinguish responsibility for violations of legislation at different stages of circulation of medicinal products.

### 3. Content of the Discipline

#### **Content module 1. Theoretical foundations of law, system of pharmaceutical law and system of pharmaceutical legislation. State policy and state formulation of the health care system.**

Theme 1. Pharmaceutical law and pharmaceutical legislation. Normative and legal regulation of pharmaceutical activity.

Theme 2. Permission system in the field of the economic activity. The legislative foundation of the state surveillance (control).

Theme 3. Mechanism of the state registration and market authorization of new medicines for use in Ukraine. Intellectual property rights in health care.

Theme 4. Standardization and certification of the pharmaceutical activity. The drug quality assurance system.

#### **Content module 2. Legal regulation in healthcare and pharmacy of Ukraine and other countries.**

Theme 5. Regulatory and legal support for turnover of various nomenclature and legal and classification-legal drug groups.

Theme 6. Legal aspects of the foreign the economic activity and regulation of export and import of medicinal products.

Theme 7. The legal and regulatory framework of economic accessibility of pharmaceutical care.

Theme 8. Normative and legal aspects of regulation of the pharmaceutical activity in different countries.

### 4. The structure of the Discipline

Names of topics	Number of hours					
	To- tal	including				
		lec- tures	semi- nars	Practical classes	Lab. classes	ISW
<b>Content module 1. Theoretical foundations of law, system of pharmaceutical law and system of pharmaceutical legislation. State policy and state regulation of the pharmaceutical sector.</b>						
Theme 1. Pharmaceutical law and pharmaceutical legislation. Normative and legal regulation of pharmaceutical activity.	6	2	-	2	-	2

Theme 2. Permission system in the field of the economic activity. The legislative foundation of the state surveillance (control).	12	4	-	4	-	4
Theme 3. Mechanism of the state registration and market authorization of new medicines for use in Ukraine. Intellectual property rights in health care.	14	4	-	4	-	6
Theme 4. Standardization and certification of the pharmaceutical activity. The drug quality assurance system.	16	4	-	6	-	6
<i>Total according to content module 1</i>	48	14	-	16	-	18
<b>Content module2. Legal regulation of the circulation of drugs and medical devices, activities of specialists in the pharmaceutical sector of Ukraine.</b>						
Theme 5. Regulatory and legal support for turnover of various nomenclature and legal and classification-legal drug groups.	10	2	-	4	-	4
Theme 6. Legal aspects of the foreign the economic activity and regulation of export and import of medicinal products.	8	2	-	2	-	4
Theme 7. The legal and regulatory framework of economic accessibility of pharmaceutical care.	8	2	-	2	-	4
Theme 8. Normative and legal aspects of regulation of the pharmaceutical activity in different countries.	8	-	-	4	-	4
<i>Total according to content module 2</i>	34	6	-	12	-	16
Graded test	8	-	-	2	-	6
<b>Total hours</b>	<b>90</b>	<b>20</b>	<b>-</b>	<b>30</b>	<b>-</b>	<b>40</b>

## 5. Themes of lectures / seminars / practical / laboratory classes

### 5.1. Theme of lectures

No	Topics name	Number of hours
1	Theme 1. Lecture class 1. Pharmaceutical law and pharmaceutical legislation. Normative and legal regulation of pharmaceutical activity.	2
2	Theme 2. Lecture class 2. Permission system in the field of the economic activity.	2
3	Theme 2. Lecture class 3. The legislative foundation of the state surveillance (control).	2

4	Theme 3. Lecture class 4. Mechanism of the state registration and market authorization of new medicines for use in Ukraine.	2
5	Theme 3. Lecture class 5. Intellectual property rights in health care.	2
6	Theme 4. Lecture class 6. Standardization and certification of the pharmaceutical activity.	2
7	Theme 4. Lecture class 7. The drug quality assurance system.	2
8	Theme 5. Lecture class 8. Regulatory and legal support for turnover of various nomenclature and legal and classification-legal drug groups.	2
9	Theme 6. Lecture class 9. Legal aspects of the foreign the economic activity and regulation of export and import of medicinal products.	2
10	Theme 7. Lecture class 10. The legal and regulatory framework of economic accessibility of pharmaceutical care.	2
	<b>Total</b>	<b>20</b>

### 5.2. Themes of seminar classes

Seminar classes are not provided.

### 5.3. Themes of practical classes

No	Theme name	Number of hours
1.	Theme 1. Practical class 1. Pharmaceutical law and pharmaceutical legislation. Normative and legal regulation of pharmaceutical activity.	2
2.	Theme 2. Practical class 2. Permission system in the field of the economic activity.	2
3.	Theme 2. Practical class 3. The legislative foundation of the state surveillance (control).	2
4.	Theme 3. Practical class 4. Mechanism of the state registration and market authorization of new medicines for use in Ukraine.	2
5.	Theme 3. Practical class 5. Intellectual property rights in health care.	2
6.	Theme 4. Practical class 6. Standardization and certification of the pharmaceutical activity.	2
7.	Theme 4. Practical class 7. The drug quality assurance system.	2
8.	Theme 4. Practical class 8. The drug quality assurance system. Current test control.	2
9.	Theme 5. Practical lesson 9. Regulatory and legal support for turnover of various nomenclature and legal and classification-legal drug groups.	2
10.	Theme 5. Practical lesson 10.	2



	Regulatory and legal support for turnover of various nomenclature and legal and classification-legal drug groups.	
11.	Theme 6. Practical class 11. Legal aspects of the foreign the economic activity and regulation of export and import of medicinal products.	2
12.	Theme 7. Practical class 12. The legal and regulatory framework of economic accessibility of pharmaceutical care.	2
13.	Theme 8. Practical class 13. Normative and legal aspects of regulation of the pharmaceutical activity in different countries.	2
14.	Theme 8. Practical class 14. Normative and legal aspects of regulation of the pharmaceutical activity in different countries.	2
15.	Practical class 15. Graded test	2

#### 5.4. Topics of laboratory classes

Laboratory classes are not provided.

### 6. Independent higher education student work

#### *Preparation of written answers to problematic questions*

No	Title of the theme / types of tasks	Hours
1.	Theme 1. Preparation for practical classes 1	2
2.	Theme 2. Preparation for practical classes 2-3	4
3.	Theme 3. Preparation for practical classes 4-5	6
4.	Theme 4. Preparation for practical classes 6-8	6
5.	Theme 5. Preparation for practical classes 9-10	4
6.	Theme 6. Preparation for practical classes 11	4
7.	Theme 7. Preparation for practical classes 12	4
8.	Theme 8. Preparation for practical classes 13-14	4
9.	Practical lesson 15. Preparation for graded test	6
	<b>Total</b>	40

### 7. Teaching methods

**Lectures:** problem-based lectures, lectures-visualizations, narration, explanation, conversation, instruction, discussion, dispute, discussion of problem situations, situational learning, illustration (including multimedia presentations), demonstration, presentation of the results of own research.

**Practical classes:** Methods by the presentation and perception of information :

- Verbal: narrative, explanation, conversation, instruction, discussion, debate, discussion of problem situations, situational learning.

- Visual: illustration (including multimedia presentations), demonstration, method of direct observation, presentation of the results of own research.

- Practical: assignments; training tasks

**Independent work:** independent work with the recommended basic and additional literature, with electronic information resources, writing abstracts, reports, multimedia presentations, etc.

Independent work in the study of the academic discipline is ensured methodological developments for independent work, information resources of the department, topics of independent work

**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:** graded test.

**Assessment of current learning activities in a practical class:**

1. Assessment of theoretical knowledge on the topic of the lesson:

- methods: survey, solving a situational task
- maximum grade - 5, minimum grade - 3, unsatisfactory grade - 2.

2. Assessment of practical skills on the topic of the lesson:

- methods: assessment of the correctness of practical skills
- maximum grade - 5, minimum grade - 3, unsatisfactory grade - 2.

The grade for one practical lesson is the arithmetic mean of all components and can only have an integer value (5, 4, 3, 2), which is rounded by the statistical method.

**Evaluation of the current educational activity in a practical class:**

1. Evaluation of theoretical knowledge on the topic of the class:

- methods: survey, solving a situational clinical problem;
- the highest grade available is 5, the lowest passing grade is 3, the failing (unsatisfying) grade is 2.

2. Evaluation of practical skills on the subject of the lesson:

- methods: standardized and include control of vocabulary, grammar, and communication skills;
- the highest grade available is 5, the lowest passing grade is 3, and the failing (unsatisfying) grade is 2.

**Current Evaluation Criteria at Practical Classes**

<b>Rating</b>	<b>Evaluation criteria</b>
"5"	The higher education (HE) student is fluent in the material required, demonstrates versatile and deep knowledge of the program material, can perform the tasks provided for in the program successfully; has mastered the content of the required and additional literature, and has realized the interrelationship of individual sections of the discipline and their importance for the future profession; has demonstrated creative abilities in understanding and using educational program material and the ability to update and replenish knowledge independently; level of competence - high (creative);
"4"	The HE student has demonstrated complete knowledge of the educational program material, successfully performs the tasks provided by the program, has mastered the basic literature recommended by the program, and is capable of independent updating and renewal in the course of further education and professional activities, but makes minor mistakes, which are eliminated by the student him/herself when the examiner points them out; the level of competence is sufficient (constructive and variable);
"3"	The HE student does not have sufficient knowledge but knows the fundamental curriculum material to the extent necessary for further education and subsequent work in the profession; copes with the tasks provided by the program, makes some mistakes in the answers at the exam and when completing the exam tasks, but has the necessary knowledge to overcome the mistakes made under the guidance of a scientific and pedagogical worker; level of competence - average (reproductive);
"2"	The HE student does not acquire knowledge of program material, makes fundamental mistakes in the assignments provided by the program, cannot use the knowledge in further studies on their own, did not manage to master the skills of independent work; the level of competence is low (receptive-productive)

Only those applicants who have fulfilled the requirements of the curriculum in the discipline, have no academic debt and their average score for the current academic activity in the discipline is at least 3.00 are allowed to take the final control in the form of a graded test.

Assessment of learning outcomes during the final control

### Evaluation of learning results during the final control

The content of the evaluated activity	Scores
Answers to theoretical questions.	2
Solving a situational problem with evaluation of the obtained results	3

Template of a question paper for graded test:

#### QUESTION PAPER FOR GRADED TEST № \_\_\_\_\_

1. General characteristics of law, its social value. The concept, characteristics, structure of the rule of law.
2. Reimbursement of the cost of pharmaceutical care as an effective socio-economic mechanism for ensuring its availability to the population.
3. Situation task: give an algorithm of actions when a pharmacy visitor asks for advice on a medicinal product for headache: regulatory and legal regulation, providing advice on the rational use and proper storage of medicines

### Criteria for evaluating the learning outcomes of education seekers during graded test

Rating	Evaluation criteria
Excellent	The student correctly, accurately and completely completed all the tasks of the examination ticket, clearly and logically answered the questions posed by the examiners. Thoroughly and comprehensively knows the content of theoretical issues, fluent in professional and scientific terminology. Thinks logically and constructs an answer, freely uses acquired theoretical knowledge when analyzing practical tasks. When solving a situational problem, he correctly interpreted the initial data, answered all the questions correctly and convincingly substantiated his point of view, could propose and justify an alternative solution to certain issues. When solving a calculation task, he strictly followed the algorithm of its execution.
Good	The student completed all the tasks of the examination ticket in a sufficiently complete manner, clearly and logically answered the questions posed by the examiners. He knows the content of theoretical issues deeply and comprehensively, and has professional and scientific terminology. Thinks logically and constructs an answer, uses acquired theoretical knowledge when analyzing practical tasks. But when teaching some questions, there is not enough depth and argumentation, it makes insignificant mistakes, which are eliminated by the applicant himself when the examiner points them out. When solving the situational problem, he assumed insignificant errors or inaccuracies in the interpretation of the initial data, answered all the questions without significant errors, fully substantiated his point of view, but the proposal of an alternative option caused difficulties.
Satisfactorily	The student of education incompletely completed all the tasks of the examination ticket, the answers to additional and leading questions are vague and vague. Possesses a basic amount of theoretical knowledge, uses professional and scientific terminology inaccurately. Experiences significant difficulties in constructing an independent logical answer, in applying theoretical knowledge in the analysis of

	practical tasks. There are significant errors in the answers. When solving a situational problem, he interpreted the raw data with errors, made inaccuracies in the answers to questions, did not properly justify his answers and interpreted the wording, experienced difficulties in completing tasks and proposing alternative options. When solving the calculation task, significant errors were made in the algorithm and execution technique.
Unsatisfactory	The student of education did not complete the task of the examination ticket, in most cases did not answer the additional and leading questions of the examiners. He did not master the basic amount of theoretical knowledge, he showed a low level of mastery of professional and scientific terminology. Answers to questions are fragmentary, inconsistent, illogical, cannot apply theoretical knowledge when analyzing practical tasks. There are a significant number of gross errors in the answers. When solving a situational problem, he could not interpret the original data, or made significant mistakes in his answers; could not justify his decisions or did it unconvincingly. He did not offer alternative options. When solving the calculation task, gross mistakes and errors were made in the execution algorithm.

### 9. Distribution of points, obtained by the student

The grade for the discipline consists of 50% of the grade for the current academic performance and 50% of the grade for the exam. The obtained average score for the academic discipline for applicants who have successfully mastered the work program of the academic 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 given 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
- Methodical developments for practical classes
- Methodical recommendations for independent work of higher education applicants
- Multimedia presentations
- Situational/case tasks
- Scenarios of role-playing games (if necessary)
- Electronic bank of test tasks by subdivisions from the educational component
- Educational and methodical literature:
  1. Pharmaceutical law and legislation: practicum for classroom and independent work for students of specialty 226 "Pharmacy. Industrial pharmacy" / L.M. Unguryan, I.V. Vyshnytska, O.I. Belyaeva. etc.; under the editorship L.M. Unguryan Odesa: ONMedU, 2023. 62 p.

### 11. Graded test questions

1. The law system and the legislation system. National legal systems and the international law.
2. Regulatory legal acts as the sources of the law. Classification of the normative legal acts
3. The structure of the legislation system in pharmacy. The hierarchy of normative legal acts in the pharmaceutical branch by legal force.
4. Features of the pharmaceutical legislation in the European Union: the main types of legal acts in the EU legal framework.
5. The concept and types of legal relationships. Legal relationships arising when implementing the pharmaceutical activities.
6. The concept of an offense and its structure. Types of offenses .
7. The concept, features and bases of the legal responsibility. Types of the legal responsibility.
8. The permission system of Ukraine in the field of the economic activity sphere: basic concepts, structure, functions and principles.
9. Licensing as a component of the control and permission system in the field of the economic activity. The basic principles of the state policy in licensing .
10. Legislative framework of state surveillance (control) in the sphere of turnover of medicine and medical products.
11. The procedure for selecting drug samples for laboratory testing of their quality.
12. Responsibility for offenses related with turnover of medicines and other medical products.
13. Registration of medicines as a mechanism of the pharmaceutical market authorization. The procedure for the expert examination of drugs submitted for the state registration (re-registration).
14. The order of keeping the State Register of Medicinal Products of Ukraine.
15. The concept of intellectual property in healthcare.
16. Objects of the intellectual property law: marks for goods and services, patented inventions, industrial samples, objects of copyright.
17. Legal mechanisms for protection of the intellectual property rights.
18. Standardization and certification in pharmacy.

19. Certification in the pharmaceutical activities as a guarantee of quality.
20. Legal and regulatory framework of the drug quality assurance system.
21. The State control over drug promotion at the market. Advertising of the drugs.
22. Nomenclature and legal and classification-legal groups of medicines. Regulatory lists of medicines.
23. The State regulation and control of the turnover of narcotic drugs, psychotropic substances, precursors in healthcare and pharmacy institutions.
24. Responsibility for violation of legislation in the sphere of circulation of nomenclature and legal and classification-legal groups of medicines.
25. The concept of the foreign economic activity. Instruments for regulating foreign economic activity.
26. International organizations regulating the world trade, monetary and financial relations.
27. The legal and regulatory framework of the import of pharmaceutical products to the territory of Ukraine.
28. The concept of health insurance. Reimbursement of the cost of pharmaceutical care as an effective socio-economic mechanism to provide its accessibility to the population.
29. Privilege dispensing of medicines, its legal and regulatory framework. Privilege categories and population groups.
30. The legislative basis of the pharmaceutical pricing. Features of the formation of the drug price. The state regulation of drug prices.
31. Taxes as an economic, social and legal category. The system of taxation of medicines and medical products.
32. Characteristics of the modern pharmaceutical legislation in the post-Soviet countries of the Transcaucasian and Central Asian region.
33. The legal and regulatory framework of healthcare and pharmacy in African countries.
34. The pharmaceutical law and legislation in the Middle East countries.
35. The features of the legal and regulatory framework of the pharmaceutical activity in different countries abroad.

List of practical skills, the mastery of which is monitored during differentiated assessment

- systematization of normative legal acts;
- documentation of the process of obtaining a license for retail and wholesale sale of drugs;
- regulatory and legal support for monitoring compliance with the requirements of the sanitary regime for pharmacies and their structural subdivisions;
- use of the algorithm for conducting incoming quality control of drugs and medical devices;
- formation of the staff of the pharmacy establishment in accordance with the qualification requirements for personnel engaged in the production (in the conditions of the pharmacy) and retail trade of drugs;
- use of various sources and forms of transmission of pharmaceutical information;
- dispensing over-the-counter medicines, providing advice on rational use and proper storage of medicines;
- pharmaceutical examination of prescriptions received from the population in accordance with legislation;
- organizing and conducting incoming quality control of medicinal products;
- to analyze the formation of drug prices, including taking into account the state regulation of drug prices;
- formation of retail prices for HLZ and medical products;
- qualify offenses in pharmaceutical activity;
- documentation of the process of state supervision (control) in the field of pharmaceutical activity on various issues;

– choose responsibility for violations of legislation at various stages of circulation of medicinal products.

## 12. Recommended literature

### Basic

1. Pharmaceutical Law and Legislation : the textbook for applicants for higher education / A.A. Kotvitskaya, I.V. Kubarieva, A.V. Volkova et al. Kharkiv : NUPh : Golden Pages, 2019.204 p.
2. Pharmaceutical law and legislation: texts of lectures for students of the specialty 226 "Pharmacy. Industrial pharmacy" / Unhurian L.M., Vyshnytska I.V., Bielyaieva O.I. etc.; ed. L. Unhurian. Odessa: ONMedU, 2020.98 p.

### Additional

1. Basics of law and legislation in pharmacy: national subject. for students of higher education / A.A. Kotvitska, I.V. Kubareva, O.O. Surikov and others; under the editorship A.A. Kotvitska - Kharkiv: NFaU: Golden Pages, 2016. - 528 p. (National textbook).
2. Pharmaceutical legislation of Ukraine: collection of normative legal acts as of January 1, 2018 for students of pharmaceutical faculties / A. A. Kotvitska, O. O. Surikov, I. V. Kubareva, A. V. Volkova and others; in general ed. Prof. A. A. Kotvitska. - Kh.: NFaU, 2018. - 588 p.
3. Pharmaceutical law and legislation: teaching manual for university applicants. education in special "Pharmacy, industrial pharmacy" / A. A. Kotvitskaya, I. V. Kubareva, A. V. Volkova and others; under the municipality ed. A. A. Kotvitskoi. - Kharkiv: National University of Applied Sciences: Golden Pages, 2017. - 224 p.
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5. 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
6. 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.
7. J. Herring Medical Law and Ethics: sixth edition, Oxford university press, 2016. 710 p.
8. Pharmacy Laws and rules: Washington State Department of Health, 2017. 845 p.

## 13. Electronic resources:

1. Base of standards of medical care in Ukraine. Internet resource - <http://www.moz.gov.ua/ua/portal/standards.html>
2. State Register of Medicines of Ukraine: website. URL: <http://drlz.com.ua/>
3. Pharmacy weekly: website. URL: <https://www.apteka.ua/>.
4. Legislation of Ukraine: website. URL: <http://zakon.rada.gov.ua/laws>
5. Normative-directive documents of the Ministry of Health of Ukraine: website. URL: <http://mozdocs.kiev.ua>
6. Drug Search Base: Website. URL: <https://tabletki.ua/>.
7. Drug Search Base: Website. URL: <http://likicontrol.com.ua/>.
8. Medscape Search Base: Website. URL: <https://www.medscape.com/pharmacists>.
9. Regulatory framework of NTA Ukraine: website. URL: <https://www.hta.ua>
10. Compendium online: website. URL: <https://compendium.com.ua/>
11. National library of medicine. URL: <https://pubmed.ncbi.nlm.nih.gov>
12. FDA. URL: Access: <https://www.fda.gov>
13. WHO. URL: <https://www.who.int>