

**Odessa National Medical University**  
**International Faculty**  
**Department organization and economics of pharmacy**

**Syllabus of the academic discipline**

**Pharmaceutical Law and Legislation**

<b>Volume</b>	90 hours (lectures - 20 hours, practical training - 30 hours), independent work of students - 40 hours)/ 3 ECTS credits
<b>Semester, year of study</b>	5 <sup>th</sup> / 3 <sup>th</sup> year of study
<b>Days, time, place</b>	According to the timetable Department Organization and Economics of pharmacy
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<b>Consultations</b>	Consultations are held on Tuesdays from 14:30 to 16:00 and Saturdays from 9:00 to 13:00 according to the approved schedule

**COMMUNICATION**

E-mail [oef@onmedu.edu.ua](mailto: oef@onmedu.edu.ua); Microsoft Teams, Zoom; messengers: Viber, Telegram, WhatsApp

**COURSE ANNOTATION**

*The subject of the discipline*

The subject of the study of the regulatory discipline is the legislation of Ukraine, as well as international institutions and branches of health and pharmaceutical law.

*Pre-requisites and post-requisites of the course:*

Pharmaceutical law and legislation as an academic discipline is based on the study of disciplines such as introduction to pharmacy, ethics and deontology in pharmacy, integrates with such curriculum disciplines as drug technology and intellectual property; the discipline is the basis for the study of pharmaceutical management and marketing, organization and economics of pharmacy, pharmaceutical and medical commodity science, labor protection in the industry, social pharmacy, international marketing in pharmacy, intellectual property, work with information sources, provides for the application of knowledge in the process of further education and in professional activities; discipline lays the foundations for professional culture, fosters pride and a sense of the need for a pharmaceutical specialty.

*Purpose of the course.*

The purpose of teaching the academic discipline "Pharmaceutical Law and Legislation" is to study the role and place of pharmaceutical law in the legal system of

Ukraine and countries of the world and to form the theoretical foundations of law and pharmaceutical legislation among future specialists; the acquisition of systemic legal knowledge on the regulation of pharmaceutical activities 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 enterprises and pharmaceutical provision of the population.

***Discipline objectives:***

The main objectives of studying the discipline "Pharmaceutical Law and Legislation" are to promote the formation of professionally necessary knowledge, skills and abilities in accordance with the educational and qualification characteristics; to provide a theoretical basis for further study of other pharmaceutical and economic disciplines of the curriculum; create a base that determines the professional competence and general erudition of pharmacists.

***Expected results:***

*Program learning outcomes for the discipline:*

PLO 1. To carry out professional activities in social interaction based on humanistic and moral principles; identify future professional activities as socially significant for human health.

PLO 11. Use methods for assessing performance indicators; to identify reserves for increasing labor efficiency.

PLO 20. To carry out a set of organizational and managerial measures to provide the population and health institutions with medicines and other pharmacy commodities. To carry out all types of accounting, administrative records, analysis of pharmaceutical products

PLO 21. To calculate the main economic factors, as well as taxes and fees. Expect all types of prices (purchase and retail) for drugs and other pharmaceutical products.

PLO 22. To provide manage pharmacy organizations and to determine its effectiveness using management functions. Make management decisions based on the leadership and communication skills of pharmacy personnel for strategic planning of enterprises.

PLO 23. Take into account the data of socio-economic processes in society for the pharmaceutical supply of population, determine the effectiveness and availability of pharmaceutical care in terms of health insurance and reimbursement of the drug cost

PLO 24. Plan and implement professional activities on the basis of regulations of Ukraine and recommendations of good pharmaceutical practices.

PLO 27. Justify the technology and organize the production of drugs at pharmaceutical enterprises and draw up technical documentation for the production of drugs at pharmaceutical enterprises.

## **COURSE DESCRIPTION**

### ***Forms and methods of teaching***

The training course consists of lectures (20 hours), practical classes (30 hours) and individual work of students (40 hours).

Problem-based presentation, case studies, discussions, work in a computer class (moodle-testing), electronic (review or problem) lectures, presentations, "business games" are used as teaching methods

## **Content of the course**

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

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

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

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

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

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

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

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

## **LIST OF 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 literature*

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. J. Herring Medical Law and Ethics: sixth edition, Oxford university press, 2016.710 p.

4. Pharmacy Laws and rules: Washington State Department of Health, 2017.845 p.

### *Informational 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>

## EVALUATION

There are various forms of control for classes (oral, written, combined, testing, practical skills, etc.). The results of the academic progress for students exhibited in the form of evaluation on a national scale, 200-point scale, ECTS and have standardized, generalized assessment criteria:

### *Criteria for assessing the student's current learning activity*

- the mark "excellent" ("5") is given to a student who has systematically worked, has shown versatile and deep knowledge of the program material, is able to successfully complete the tasks provided by the program, has mastered the content of the main and additional literature, realized the relationship of individual sections of the discipline, their importance for the future profession, showed creative abilities in understanding and using educational and program material, showed the ability to independently update and replenish knowledge; the level of competence is high (creative);

- the mark "good" ("4") is given to a student who has shown complete knowledge of the educational and program material, successfully fulfills the tasks provided by the program, has mastered the basic literature recommended by the program, has shown a sufficient level of knowledge in the discipline and is capable of independently replenishing and updating them in the course of further education and professional activities; the level of competence is sufficient (constructive and variable);

- the mark "satisfactory" ("3") is given to a student who has shown knowledge of the basic educational and program material in the amount necessary for further study and subsequent work in the profession, copes with the tasks provided by the program, made some mistakes in answers, but has the necessary knowledge to overcome the mistakes made under the guidance of a scientific and pedagogical worker; competence level - average (reproductive);

- the mark "unsatisfactory" ("2") is given to a student who did not reveal sufficient knowledge of the basic educational and program material, made fundamental mistakes in performing the tasks provided for in the program, cannot use knowledge in further training without the help of a teacher, and could not master the skills of independent work; the level of competence is low (receptive-productive).

### *The procedure for assessing the student's educational activity:*

***- assessment of current academic performance of the discipline***

Current academic performance of the discipline's topics is evaluated according to the traditional 4-point scale. In a practical lesson, students should be interviewed at least once every 2-3 practical lessons (no more than 75% of students). At the end of the semester, the average number of students' grades in a group should be the same.

At the end of the study of the discipline, the current performance is calculated - the average current score (the arithmetic mean of all current grades on the traditional scale, rounded to two decimal places). To increase the average score in the discipline, the current marks "3" or "4" are not re-evaluated.

***- assessment of independent work of students***

The task of independent work of students is to obtain additional information for a more in-depth study of the discipline in practical classes. Independent work of students, which is provided by the topic of the lesson is assessed during the current control of the topic in the corresponding lesson.

***- final control of knowledge by discipline***

The form of the final control is a graded test, which is assessed on a 4-point scale.

Graded test is given in the last class in the discipline based on the results of the final interview with the obligatory performance by the student of all types of work stipulated by the curriculum and rated for current educational activities on average not lower 3.00.

The grade received for the answer on the graded test and the average current academic performance in the study of the discipline are used to calculate the arithmetic mean, which is the overall grade for the discipline.

In the student's record book, the teacher enters the grade for the discipline on the traditional and 200-point scale.

Conversion of the traditional national assessment into a multi-point one (maximum 200 points) is required. If a student receives a minimum grade point average of 3.00 in current performance, even if there are unsatisfactory grades that have not been completed, he / she receives a discipline test.

**Converting Traditional Discipline Assessment on a multi-point scale**

A multi-point scale characterizes the actual progress of each student in mastering the academic discipline. The conversion of the traditional grade in the discipline into a 200-point grade is carried out by the information and computing center of the university by the "Contingent" program according to the formula:

$$\text{grade point average (current / by discipline)} \times 40$$

National Assessment	Points
"5"	185-200
"4"	151-184
"3"	120-150

**on the ECTS scale**

The ECTS rating scale evaluates the achievements of students in the discipline who study in one course of one specialty, according to the points they received, by ranking, namely:

ECTS score	Statistical indicator
"A"	top 10% of students
"B"	next 25% of students
"C"	next 30% of students
"D"	next 25% of students
"E"	the remaining 10% of students

The ECTS scale establishes the student's belonging to the group of the best or worst among the reference group of fellow students (faculty, specialty), that is his rating. When converting from a multi-point scale, as a rule, the boundaries of grades "A", "B", "C", "D", "E" do not coincide with the boundaries of grades "5", "4", "3" on the traditional scale. The "A" grade on the ECTS scale cannot be equal to the "excellent" grade, and the "B" grade - the "good" grade, etc.

Students who have received grades "FX" and "F" ("2") are not included in the list of ranking students. Such students, after retaking, automatically receive an "E" score.

The mark "FX" is given to students who have scored the minimum number of points for the current educational activity, but who are not credited with the final control. Grade "F" is given to students, attended all classroom lessons in the discipline, but did not score an average score (3.00) for the current educational activity and were not admitted to the final control.

## **COURSE POLICY**

### ***Deadline and retake policy***

Students for education are expected to attend all lectures and practical classes. If they missed classes, it is necessary to make-up them (according to the schedule posted on the information stand of the department and according to the permission of the dean's office, if necessary).

The retake of the control of the acquisition of practical skills is carried out during the semester on an individual basis with the determination of the time of the training.

Retake of unsatisfactory grades is carried out during the term of studying the discipline, provided that the average score for the current educational activity is less than 3.00 (carried out according to the schedule posted on the information stand of the department).

### ***Academic Virtue Policy***

Respect for academic virtue by education seekers includes:

- independent fulfillment of educational tasks, tasks of current and final control (current controls and discipline exam) of learning outcomes (for persons with special educational needs, this requirement is applied taking into account their individual needs and capabilities);

- links to sources of information when using ideas, developments, statements, information;

- provision of reliable information about the results of their own (scientific, creative) activities, the research methods used and sources of information.

It is unacceptable in educational activities for participants in the educational process to use prohibited auxiliary materials or technical means (crib notes, earpieces, phones, smartphones, tablets, etc.) during control events.

For violation of academic virtue, education seekers may be held liable for such academic responsibility

- decrease in the results of assessment (control work, exam);
- re-passing the assessment (test, exam);
- appointment of additional control measures (additional individual tasks, control works, tests, etc.).

### *Attendance policy*

Attendance at lectures and practical classes is compulsory. If you are more than 15 minutes late, the lesson is considered missed and requires working out.

### *Mobile devices*

During practical exercises, the use of a smartphone, tablet or other device for storing and processing information is allowed only with the permission of the tutor.

When conducting any form of control, the use of mobile devices and their accessories is strictly prohibited.

### *Audience behavior*

During the classes it is allowed: to leave the audience for a short time, if necessary and with the permission of the teacher; photograph presentation slides; actively participate in the class.

During the lessons it is prohibited: to eat (except for persons whose special medical condition requires another - in this case, medical confirmation is required), smoking, drinking alcoholic and low-alcohol drinks or drugs; use obscene language or use words that offend the honor and dignity of colleagues and faculty; gamble; damage the material and technical base of the university (spoil inventory, equipment; furniture, walls, floors, litter premises and territories), make noise, shout or listen to loud music in classrooms and even in the corridors during classes.