

MINISTRY OF HEALTH PROTECTION OF UKRAINE
ODESSA NATIONAL MEDICAL UNIVERSITY

Department of Organization and Economics of Pharmacy with post-diploma specialization

Syllabus of the academic discipline
"International Aspects of Pharmaceutical Law"

Scope of the academic discipline	Total number of hours per discipline: 90 hours, 3 credits. Semester: 7. 4th year of study.
Days, time, place of educational discipline	According to the schedule of classes. Department Organization and Economics of Pharmacy with post-diploma specialization Odesa, str. Malinovsky, 37
Teacher(s)	Candidate of Pharm.Sc., Assoc. Prof. Iryna Vyshnytska
Contact Information	E-mail: oef@onmedu.edu.ua 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

Communication with applicants will be conducted in the classroom (face-to-face).

During distance learning, communication is carried out through the Microsoft Teams platform, as well as through e-mail correspondence, Viber messengers (through groups created in Viber for each group, separately through the head of the group).

ABSTRACT OF THE ACADEMIC DISCIPLINE

subject is study of international aspects of pharmaceutical law and peculiarities of regulation of the pharmaceutical industry in different countries of the world.

Prerequisites: based on the study of disciplines such as Introduction to Pharmacy, Pharmacy Ethics and Deontology, integrated with curriculum disciplines such as Drug Technology and Intellectual Property.

Post-requisites: study of pharmaceutical management and marketing, organization and economics of pharmacy, pharmaceutical and medical merchandising, labor protection in the industry, social pharmacy, international marketing in pharmacy, intellectual property, work with information sources, which involves the application of knowledge in the process of further education and professional activity ; discipline lays the foundations of professional culture, fosters pride and a sense of the need for a pharmaceutical specialty.

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the purpose is the acquisition by the student of higher education of knowledge and the formation of elements of professional competences in the field of pharmacy and the 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.

Task: to contribute to the formation of professionally necessary knowledge, abilities and skills 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; to create a base that determines the professional competence and general erudition of a pharmacist.

Expected results.

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 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 professional 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.

DESCRIPTION OF THE EDUCATIONAL DISCIPLINE

Forms and methods of education. The discipline will be taught in the form of seminar classes (30 hours) and organization of students' independent work (60 hours).

Consultations are individual.

When conducting seminar classes, teaching methods are used: verbal, visual, practical; explanatory and illustrative, reproductive, problem-based teaching, partially research, research; independent work of applicants to comprehend and assimilate new work material on the application of knowledge in practice and the development of skills

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and abilities, methods of organization and implementation of educational and cognitive activities; stimulation and motivation of learning, control, self-control.

Content of the academic discipline

Topic 1. Types of Legal Systems around the World

Topic 2. Formation and development of the right to health care and pharmaceutical provision in the countries of the world.

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

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.

List of 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.

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/>

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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

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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 final control in the form of final test is assessed on a two-point scale:

- the mark "passed" is given to a student who has completed the curriculum of the discipline and has no academic debt; , their average grade of current performance is 3.00 or more, in the last lesson they receive a test, which is set as "passed"; the level of competence is high (creative);
- the mark "not passed" is given to a student who has not completed the curriculum of the discipline, has academic debt (average score below 3.0 and / or missing classes), the level of competence is low (receptive-productive).

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

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"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).

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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

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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