

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

Syllabus of the academic discipline

**ORGANIZATION AND REGULATION OF ACTIVITIES OF ENTERPRISES OF THE
PHARMACEUTICAL INDUSTRY**

Volume	90 hours (lectures - 10 hours, practical training - 20 hours), independent work of students - 60 hours)/ 3 credits ECTS
Semester, year of study	5 th / 3 rd year of study
Days, time, place	According to the timetable Department Organization and Economics of pharmacy
Teacher (s)	Sen. Teacher Vyshnytska Iryna Volodymyrivna
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Consultations	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 status of the discipline for the educational and professional program (EPP) - at the choice of the student. The subject of study is the theoretical foundations of public administration; the acquisition of systemic knowledge about legal, economic and organizational issues of management activities, as well as the formation of professionally important skills to ensure the effective functioning of enterprises in the pharmaceutical industry, taking into account modern international standards.

Pre-requisites and post-requisites of the course:

Interdisciplinary communication of the study of the discipline: based on general knowledge in such academic disciplines as "Introduction to Pharmacy", "Philosophy", "Ethics and Deontology in Pharmacy".

Acquired knowledge, skills and competences are the framework for further study pharmaceutical management and marketing, organization and economics of

pharmacy and social pharmacy, providing for the integration of teaching with these disciplines to form the ability to apply knowledge in the process of further education and in professional activity.

Purpose of the course.

The purpose of the discipline is to understand the specifics of state regulation of pharmaceutical activities in Ukraine at the present stage; study of the legal framework for regulating the activities of enterprises in the pharmaceutical industry; the use of modern approaches to managing the activities of enterprises, taking into account the requirements of international standards and current legislation; making rational management decisions, taking into account the organizational, legal and socio-economic foundations of state regulation of pharmaceutical activities; advanced training students have knowledge and skills in sanitary and educational activities in pharmacy.

Objectives of the course:

The main tasks of the discipline are:

- mastering the practice of state registration (re-registration) of medicines;
- mastering the methods and forms of pharmaceutical information and health education, which are necessary for the activities of pharmaceutical enterprises;
- mastering the features of the formation of the List of Essential Medicines, as well as the formulary list of medicines for a multidisciplinary hospital.

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 2. Apply knowledge of general and special disciplines in professional activities.

PLO 5. Position your professional activities and personal qualities in the pharmaceutical labor market; formulate the goals of their own activities, taking into account public and industrial interests.

PLO 9. Carry out professional activities with the use of information technology, "Information databases", navigation systems, Internet resources, software and other information and communication technologies.

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

DESCRIPTION OF THE COURSE

The training course consists of lectures (10 hours) and practical classes (20 hours), independent work of students (60 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 discipline

Topic 1. Procedure for state registration (re-registration) of medicines.

Topic 2. Organizational technologies for the collection, processing, storage and distribution of pharmaceutical information.

Topic 3. Pharmaceutical information in the work of pharmaceutical companies.

Topic 4. Organization of sanitary and educational work in pharmacies.

Topic 5. Rational pharmaceutical management for effective provision and use of medicines.

Topic 6. Pharmaceutical logistics. Development, scientific and practical essence.

Topic 7. Logistic approach in the implementation of strategic management of pharmaceutical organizations, subject to changes in the operating environment.

Topic 8. Features of the social roles of pharmaceutical specialists and the importance of the media in shaping public opinion about them.

Topic 9. Logistic support of pharmaceutical services in pharmacies.

LIST OF RECOMMENDED LITERATURE

Basic:

1. Organization and regulation of the activities of enterprises of the pharmaceutical industry: 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, 2021. 96 p.

Additional literature

1. Pharmacoeconomics: Lecture notes / Edited by prof. L.V. Yakovleva .- Kharkov, 2015 .- 69 p.

2. Pharmacoeconomics: a textbook for students of specialty 226 "Pharmacy. Industrial pharmacy "/ Unguryan L.M., Vishnitskaya I.V., Belyaeva O.I. and etc. ; ed. L.M. Unguryan. Odessa: ONMedU, 2020.92 p.

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.

4. 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

5. Justine Pila and Paul Torremans. European Intellectual Property Law: Second Edition, 2019.712 p.

6. 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.

7. 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 formulary of medicines. Thirteenth edition. Internet resource - <http://www.pharma-center.kiev.ua/view/formylar>
3. State Register of Medicines Internet resource - <http://www.drlz.com.ua>
4. Legislation of Ukraine: website. URL: <http://zakon.rada.gov.ua/laws>
5. State Employment Service: website. URL: <http://www.dcz.gov.ua/>
6. State Statistics Service of Ukraine: website. URL: <http://www.ukrstat.gov.ua/>
7. Economy of Ukraine: website. URL: <http://www.economukraine.com.ua/>
8. Economy of Ukraine (political and economic journal): website. URL: https://journals.ua/business/ekonomka_ukraini/
9. Electronic Journal "Effective Economy" URL: <http://www.economy.nayka.com.ua>
10. Ministry of Economic Development and Trade of Ukraine: website. Url:<http://www.me.gov.ua/>
11. FDA [E-resource]. - Access: <https://www.fda.gov>
12. Personal Data in Competition, Consumer Protection and Intellectual Property Law: Towards a Holistic Approach? / Mor Bakhoun, Beatriz Conde Gallego, Mark-Oliver Mackenrodt, Gintarė Surblytė-Namavičienė: MPI Studies on Intellectual Property and Competition Law, 2018 (eBook). Url:<https://doi.org/10.1007/978-3-662-57646-5>
13. WHO [E-resource]. - Access: <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 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
"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.