

**SYLLABUS OF THE EDUCATIONAL COMPONENT
PHARMACEUTICAL LAW AND LEGISLATION**
for applicants for higher education of 3 year of study (4,10 year of study)
of educational program «Pharmacy»
in specialty «226 Pharmacy, industrial pharmacy»
field of knowledge «Health care»
training for second (master) level

TEACHERS



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- 1. The name of higher education establishment and department:** National University of Pharmacy, Department of Social Pharmacy.
- 2. Address of the department:** Kharkiv, Valentinovskaya street, 4, 4th floor, phone 057-67-91-81.
- 3. Web site of the department:** <http://socpharm.nuph.edu.ua>
- 4. Information about teachers:**

Volkova Alina Viktorivna – candidate of Pharmaceutical Sciences, Associate Professor, Head of the Department of Social Pharmacy. Experience of scientific and pedagogical activity – 13 years. Teaches educational components "Introduction to the Specialty", "Pharmaceutical law and legislation", "Social pharmacy", "Pharmaceutical Marketing and Management", "Academic Integrity". Research interests: socio-economic and regulatory aspects of pharmaceutical provision of the population.

Surikova Iryna Oleksandrivna – candidate of Pharmaceutical Sciences, Assistant of the Department of Social Pharmacy. Experience of scientific and pedagogical activity – 5 years. Teaches educational components: "Introduction to the specialty", "Pharmaceutical law and legislation", "Organization and economics of pharmacies", "Social pharmacy". Research interests: regulatory and legal regulation of medical and pharmaceutical activities, the formation of the principles of social pharmacy in national practice.

5. Consultations take place in an online format according to the teachers' schedule posted on the department's website.

6. Brief summary of the educational component: The training of a modern master of pharmacy, who has professional knowledge of pharmaceutical law and legislation, is a reasonable demand today and one of the primary tasks of reforming the health care and pharmaceutical sector. The educational component "Pharmaceutical Law and Legislation" is mandatory during the professional training of specialists of the "Pharmacy" educational program.

7. The purpose statement of studying the educational component: studying the role and place of pharmaceutical law in the legal system of Ukraine and the world and the formation of future specialists of the theoretical bases of law and pharmaceutical legislation; acquisition of systematic legal knowledge regarding the regulation of pharmaceutical activity and turnover of medicines, as well as the formation of professionally important skills of reasoned decision-making to ensure the effective functioning of pharmaceutical companies and pharmaceutical provision of the population.

8. Competences in accordance with the educational program:

Soft- skills / General competences (CG):

GC 1. Ability to act socially responsible and civic conscious.

GC 2. Ability to apply knowledge in practical situations, make reasonable decisions.

GC 4. Ability to abstract thinking, analysis and synthesis, to learn and be modernly trained.

GC 6. Knowledge and understanding of the subject area and understanding of professional activity.

GC 7. Ability to adapt and act in a new situation.

GC 13. Ability to realize 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.

Hard-skills / Professional (special) competences (PC):

PC 12. Ability to use in professional activities the knowledge of regulations, legislation of Ukraine and recommendations of good pharmaceutical practices

9. The program learning outcomes: (PLO):

PLO 4. To demonstrate the ability to independently search, analyze and synthesize information from various sources and use these results to solve typical and complex specialized tasks of professional activity.

PLO 6. To argue information for decision-making, to be responsible for it in standard and non-standard professional situations; to adhere to the principles of deontology and ethics in professional activities.

PLO 7. To perform professional activities using creative methods and approaches.

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

10. Status of the educational component: compulsory

11. Prerequisites of the educational component: is based on the study of the educational component Introduction to the profession; the educational component is the basis for studying the organization and economics of pharmacy, pharmaceutical marketing and management, pharmaceutical and medical merchandising, social pharmacy, which involves the integration of teaching with the above-mentioned educational components for the formation of skills to apply knowledge in the process of further education and professional activity;

12. The volume of the educational component: 3 ECTS credits: 90 hours of classroom attendance, 16 of them are lectures, 27 hours are practical classes; 47 hours of individual work.

13. Organization of training: conducting lectures and practical classes for a better understanding of the topic.

Content of the educational component:

Content module 1. Theoretical foundations of law, pharmaceutical law system and the system of pharmaceutical legislation. The legal basis of pharmaceutical companies.

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) in the sphere of turnover of medicine and medical products.

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

Content module 2. The legal basis of pharmaceutical companies. Regulatory and legal support development, production and quality control of drugs.

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.

14. Forms and types of academic achievements supervision:

Current control: oral survey, writing test tasks, solving situational (calculation) problems

Control of content modules: 2 content modules are provided. CM1 and CM 2 includes answers to 10 test questions.

Semester control form: semester credit

Conditions for admission to control of content modules: for admission to control of content module 1, a minimum of 27.5 points for 5 topics is required, for control of content module 2 – 16.5 points.

Conditions for admission to the semester control: current rating of more than 60 points, absence of missed laboratory, practical and seminar classes, fulfillment of all requirements stipulated by the work program of the educational component.

15. Evaluation system of the educational component

The evaluation system for the educational component.

The results of the semester control in the form of a semester credit are evaluated on a 100-point, undifferentiated scale ("passed", "failed") and on the ECTS scale.

The system of assessment of knowledge of higher education students in the course
"Pharmaceutical law and legislation"

Rating system for assessing students' knowledge

Ongoing assessment and independent work									
Content Module 1									
T1	T2	T3	Control of CM 1	T4	T5	T6	T7	T8	Control of CM 2
9	9	9	14	9	9	9	9	9	14
41				59					

The following scoring system is used for each topic of content module 1 (minimum number of points for one topic 6 points, maximum – 9 points):

Assessment of practical skills - students are given from 0 to 4 points:		
of task being assessed	System evaluation knowledge, points	Evaluation criteria
Practical (situational) task	4,0-5,0	The practical task (situational task) is performed by the student independently without errors.
	3,0-1,0	The practical task was performed independently, however, mistakes were made in the using of legal acts, interpretation of terms, principles of preparation of multimedia materials, etc.
	0	The student could not perform practical and situational tasks, did not draw up a working journal.
Practical skills and abilities - applicants for higher education are given from 0 to 5 points:		
Assessment of theoretical knowledge, practical skills and abilities (written or oral answer)	5,0	is given to students who at the oral or written answer to a question has revealed comprehensive, systematized, deep knowledge of a program material, is able to interpret the received results competently; demonstrate knowledge of basic and additional literature provided at the level of creative use
	4,5-2,5	is given to the student, if during the oral or written answer to the question the applicant for higher education revealed complete knowledge of the program material, provided at the level of similar production, but made some insignificant errors

	2,5-1,0	is given, if during the oral or written answer to the question the student found insufficient knowledge of the main program material, in the amount necessary for further study and work provided by the program at the level of reproductive reproduction.
	0	is given, if at the oral or written answer to a question the student has found serious gaps in knowledge of the basic material, has made fundamental mistakes.

The control of CM1 and CM2 is estimated by the answer of ticket. The structure of the ticket CM 1: 14 test questions of different types. Each question is estimated 1 point. The sum of points for control CM is a maximum of **14** points. Substantive modular control CM1 is considered credited if the applicant has obtained at least **8** points.

Points from the educational component are calculated according to the following ratio:

Types of evaluation	Maximum number of points (% of the number of points per module - for content modules)
Module 1	
Content module 1: Theoretical foundations of law, pharmaceutical law system and the system of pharmaceutical legislation. The legal basis of pharmaceutical companies <i>For example,</i> - evaluation of topics (1-3) (work in classes 1-3): work in classes (oral survey, writing test tasks, solving situational (calculation) problems); - supervision of content module 1 (writing test tasks, solving situational (calculation) tasks)	41 (41 %)
Content module 2: The legal basis of pharmaceutical companies. Regulatory and legal support development, production and quality control of drugs <i>For example,</i> - evaluation of topics (4-8) (work in classes 5-8): work in classes (oral survey, writing test tasks, solving situational (calculation) problems); - supervision of content module 2 (writing test tasks, solving situational (calculation) tasks)	59 (59 %)
Semester Supervision of Module 1	100

The individual work of applicants for higher education is evaluated during the progress supervision and during the content module supervision.

16. Academic policies of the educational component:

It is based on the principles of academic integrity stated in the POL "On measures to prevent cases of academic plagiarism at the National University of Pharmacy". Cheating during the evaluation of an applicant for higher education during supervision activities in practical (seminar, laboratory) classes, supervision of content modules and the semester exam is prohibited (including the use of mobile devices). Abstracts must have correct text references to the used literature. The detection of signs of academic dishonesty in the student's written work is a reason for the teacher not to credit it.

Class attendance policy. An applicant for higher education is obliged to attend classes (POL "On the organization of the educational process of the National University of Pharmacy ") according to the schedule (<https://nuph.edu.ua/rozklad-zanyat/>), to observe ethical norms of behavior.

Policy regarding deadlines, working out, rating increase, liquidation of academic debts. The completion of missed classes by an applicant for higher education is carried out in accordance with the POL "Regulations on the completion of missed classes by applicants and the procedure for eliminating academic differences in the curricula of the National University of Pharmacy" in accordance with the schedule for working out missed classes established by the department. Increasing the rating and liquidating academic debts from the educational component is carried out by the applicants in accordance with the procedure specified in the POL "On the procedure for evaluating the results of training of

applicants for higher education at the National University of Pharmacy ". Applicants of higher education are obliged to comply with all deadlines set by the department for the completion of written works from the educational component. Works that are submitted late without valid reasons are assessed at a lower grade - up to 20% of the maximum number of points for this type of work.

Policy on appeals of evaluation of the educational component (appeals). Applicants for higher education have the right to contest (appeal) the evaluation of the educational component obtained during control measures. The appeal is carried out in accordance with the POL "Regulations on appealing the results of the final supervision of knowledge by applicants of higher education at the National University of Pharmacy".

17. Information and educational and methodical support of the discipline:

The main reading suggestions	<ol style="list-style-type: none"> 1. Pharmaceutical Law and Legislation : the textbook for applicants for higher education / A. A. Kotvitskaya, I. V. Kubarieva, A. V. Volkova, A. V. Cherkashyna, I. V. Zhirova, A. A. Surikov, I. A. Surikova. – Kharkiv : NUPh : Golden Pages, 2019. – 204 p. 2. Pharmaceutical law and legislation: training manual for students of higher school / A.A. Kotvitska, A.V. Volkova, A.V. Cherkashyna, et al. – Kharkiv: NUPh, 2020. – 60 p.
Supplementary reading suggestions for in-depth study of the educational component	<ol style="list-style-type: none"> 1. U. Nitin Kashyap. Comparison of Drug Approval Process in United States & Europe / U. Nitin Kashyap, Vishal Gupta, H. V. Raghunandan // J. Pharm. Sci. & Res. – 2013. – Vol. 5, № 6. –P. 131–136. 2. Fassett, W. E. Washington Pharmacy Law: A User’s Guide 2011 / W. E. Fassett. – Spokane, 2011. – 446 p 3. Council of Europe Convention on Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health of 07.06.2012. 4. Directive 2011/83 / EC of the European parliament and of the Council of 6 November 2011 «On the Community code relating to medicinal products for human use»
Current electronic information resources (magazines, websites) for in-depth study of the educational component	<ol style="list-style-type: none"> 1. World Health Organization. Official website. [Electronic resource]. – Access mode: https://www.who.int/home 2. WHO model list of essential medicines - 21st list, 2019. [Electronic resource]. – Access mode: https://www.who.int/publications/i/item/WHOMVPEMPIAU2019.06 3. WHO Model List of Essential Medicines for Children - 7th list, 2019. [Electronic resource]. – Access mode: https://www.who.int/publications/i/item/WHOMVPEMPIAU201907 4. WHO Collaborating Centre for Drug Statistics Methodology. ATC/DDD Index 2020. [Electronic resource]. – Access mode: https://www.whocc.no/atc_ddd_index/ 5. The WHO Programme for International Drug Monitoring [Electronic resource]. – Access mode: https://www.who-umc.org/global-pharmacovigilance/who-programme-for-international-drug-monitoring/
Moodle distance learning system	https://pharmel.kharkiv.edu/moodle/course/view.php?id=2698#section-1

18. Technical and computer soft: computers for testing, a multimedia projector for lectures, Internet access; video conferencing software ZOOM, modular object-oriented dynamic learning environment MOODLE 3.9.8.