

National Pirogov Memorial Medical University, Vinnytsya

“APPROVE”

Higher Educational Institution
Vice-Rector for Scientific and
Academic Work and International Links
Inna ANDRUSHKO

“30” *Inna Andrushko* 2024 year

“AGREED”

Head of the Department Forensic
medicine and law

Valery Gunas
“30” *Valery Gunas* 2024 year

SYLLABUS
of academic discipline (elective course)
Pharmaceutical law and legislation

Specialty	226 Pharmacy, industrial pharmacy
Educational level	the second (master's) level
Educational program	EPP Pharmacy, 2023
Academic year	2024-2025
Department	Forensic medicine and law
Lecturer (if lectures are given)	Raisa ZHARLINSKA
Contact information	Department of forensic medicine and law, forensic@vnmnu.edu.ua, National Pirogov Memorial Medical University, Vinnytsya, Pirogov's st. 56
Syllabus compiler	Ass-prof. Raisa ZHARLINSKA

1. Status and structure of the discipline

Discipline status	Mandatory
Discipline code in EPP/discipline place in EPP	OK 45, a component of the cycle of professional training disciplines
Course / semester	3rd year (V semester)
The amount of discipline (the total number of hours / number of credits ECTS)	75 hours /2,5 ECTS credits
The structure of the discipline	Lectures - 10 hours Practical classes - 32 hours Independent work - 33 hours In general: classroom classes – 56%, independent work outside the classroom – 44%.
Language of study	English
Form of study	Full-time (when implementing quarantine measures - remote full-time)

2. Description of the discipline

Short annotation of the course, relevance. "Pharmaceutical Law and Legislation" as an educational discipline studies the regulatory legal framework of modern pharmacy, national legislation regulating pharmaceutical activity, and contributes to the acquisition by future specialists of the pharmaceutical industry of professional knowledge and skills to solve both legal and economic tasks in the field of pharmaceutical activity market.

According to the curriculum, the study of pharmaceutical law and legislation is carried out in the 3rd year of study, and includes lectures and conducting practical classes on the main issues of regulatory and legal regulation of pharmaceutical activity in Ukraine.

The lectures on pharmaceutical law and legislation highlight the problematic issues of the general theory of law adapted to pharmaceutical practice, understanding the specifics of regulatory regulation of pharmaceutical activity in Ukraine, the application of the regulatory legal framework for the regulation of economic activity in the field of pharmaceutical activity and circulation of medicinal products, organization and implementation of state supervision (control) measures. liability for violation of current legislation

The educational process is organized according to the credit-module system. The volume of students' academic load is described in ECTS credits - credits that are credited to students upon successful assimilation of the module (credit).

The discipline program is structured into one module, which includes three content modules. The credit-transfer system of the organization of the educational process encourages students to study systematically during the academic year.

The tasks of studying the discipline "Pharmaceutical Law and Legislation" are to learn the main issues of the general theory of law, adapted to pharmaceutical practice, which are considered when studying the discipline, to understand the specifics of the regulatory and legal regulation of pharmaceutical activity in Ukraine, to apply the regulatory and legal framework for the regulation of economic activity in the field pharmaceutical activity and drug circulation, organization and implementation of state supervision (control) measures. Responsibility for violations of current legislation, development of legal awareness and respect for the law throughout the entire professional activity.

Prerequisites – The discipline "Pharmaceutical law and legislation" is based on students' study of economic theory, information technologies in pharmacy, ethics and deontology in pharmacy, organization and economy of pharmacy, pharmacology. Pharmaceutical law and legislation reveals the content and norms of pharmaceutical law, which provide for integration with other disciplines and the formation of a correct understanding and practical application of knowledge from

pharmaceutical legislation in the process of further education and professional activity.

The purpose of the course and its significance for professional activities. The purpose of the course is to study the legal basis of pharmaceutical activity. The purpose of teaching the discipline is the formation of theoretical foundations of law and pharmaceutical legislation in future specialists; acquisition of systemic legal knowledge regarding the regulation of pharmaceutical activity and the circulation of medicinal products, as well as the formation of professionally important skills regarding reasoned adoption of valid and reasoned decisions to ensure the effective functioning of pharmaceutical provision of the population.

Postrequisites - The discipline is the basis for studying pharmaceutical management and marketing, pharmacy organization and economy, pharmaceutical and medical commodity science, occupational health and safety in the industry, quality system in pharmacy, standardization of medicinal products, social pharmacy, international marketing in pharmacy, intellectual property, social interaction, the basics of insurance medicine, the development of medicinal products, working 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.

3. Learning outcomes.

After successful study of the discipline the applicant will be able to:

to know: basic concepts and categories of pharmaceutical law and pharmaceutical legislation and features of regulatory and legal regulation of pharmaceutical activity in Ukraine and abroad; basic concepts of legal responsibility, its principles and functions, to understand the types of legal responsibility according to the branch structure of law; organizational and legal forms of pharmaceutical activity and their content, types of pharmaceutical organizations and their characteristics as subjects of the pharmaceutical market; the main elements of the system of legal relations of environmental safety in different types of pharmaceutical activity, the forms of work and the content of the main measures of state sanitary-epidemiological supervision in Ukraine, the types of responsibility provided for by the legislation of Ukraine for committing environmental offenses; the main sources of labor law, the procedure for concluding an employment contract, forms and the procedure for payment of labor at pharmaceutical enterprises and organizations; basic concepts and structure of legal relations in health care and the pharmaceutical sector, legal status, as well as forms of social and legal protection of medical and pharmaceutical workers, rights and obligations of patients in accordance with the legislation of Ukraine; regulatory and legal aspects of conducting commercial activities in the field of wholesale and retail sale of medicinal products in Ukraine, concepts and directions of activity in the field of distribution of medicinal products in accordance with the provisions of the guideline on the proper practice of distribution of medicinal products; the main legal aspects of the activities of medical representatives in Ukraine and abroad, the main criteria for conducting advertising campaigns regarding pharmaceutical activities in Ukraine; peculiarities of the circulation of various nomenclature-legal and classification-legal groups of medicinal products, to determine the procedure for carrying out activities related to the circulation of narcotic drugs, psychotropic substances and precursors in health care institutions and the peculiarities of state control over compliance with the legislation regarding their circulation; new organizational forms of activity of pharmacies in view of the international experience of their operation, the main aspects of legal regulation of pharmaceutical activity in the countries of the world;

be able to: to analyze domestic legislation that regulates the procedure for conducting state control over the promotion of drugs on the market, to determine the grounds and main stages of planned and unscheduled inspections, the limits of responsibility for violations of the legislation on medicinal products; to analyze the forms and methods of state regulation of pharmaceutical activity in the aspect of ensuring the physical and economic availability of pharmaceuticals in foreign countries; distinguish the concepts and types of working time and rest of employees, which are regulated by Ukrainian legislation; use normative legal acts in the process of carrying out professional activities; exercise control over the price discipline of pharmaceutical establishments; distinguish the concepts and types of crimes against public health in the case of professional pharmaceutical activity;

to solve independently: questions about the consequences of professional activity.

4. Content and logistic of the discipline

Module 1	9th semester 75 hours/2,5 credits	Lectures No. 1, 4, 6,14, 15 Practical lessons No. 1-15, 17 Topics for self-study No. 16
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The discipline includes 17 topics in one module.

Module 1

Topic 1. General theory of the state and law: basic concepts and categories. Sources of law. Branches and institutes of law. Offense.

Topic 2. Pharmaceutical law and pharmaceutical legislation: concepts and main categories.

Topic 3. Pharmaceutical activity: concept and content. Public policy and public administration in the field of health care and pharmacy.

Topic 4. Basics of economic activity and insurance in the field of health care. Concepts and types of medical care. Medical and pharmaceutical service as an object of legal relations. Agreement on the provision of medical (pharmaceutical) services: concepts, types and content.

Topic 5. State regulation of pharmaceutical activity in Ukraine. Regulation of drug circulation. Licensing of pharmaceutical activity.

Topic 6. Preclinical study and clinical trials of drugs. The mechanism of state registration and admission of new drugs for use in Ukraine. Basics of intellectual property law. Intellectual property in the field of health care and pharmaceutical activity.

Topic 7. Quality assurance system of pharmaceuticals. Regulatory and legal regulation of quality assurance in health care institutions.

Topic 8. Standardization and certification in pharmaceutical activity. State control over the promotion (promotion) of drugs on the market. Drug advertisement.

Topic 9. Taxes as an economic, social and legal category. The system of taxation of LZ and VMP. Legislative bases of pharmaceutical pricing. Peculiarities of formation and regulation of drug prices.

Topic 10. Environmental law and pharmaceutical activity.

Topic 11. Legal aspects of foreign economic activity and customs regulation. State control of the quality of LZ and VMP imported into the customs territory of Ukraine

Topic 12. State regulation and control of circulation of narcotic drugs, psychotropic substances, precursors in health care institutions.

Topic 13. Legal status of subjects of pharmaceutical activity. Certification of pharmacists.

Topic 14. Legal regulation of the work of pharmaceutical workers.

Topic 15. Legal responsibility of pharmaceutical workers for offenses in the field of professional activity

Topic 16. Pharmaceutical legislation in the system of social protection law.

Topic 17. Differential calculation.

Types of education according to the curriculum are: a) lectures, b) practical classes, c) independent work of students, d) consultations.

The topics of the lecture course reveal the problematic issues of the relevant sections of pharmaceutical law.

Practical classes involve theoretical substantiation of the main issues of the topic and the acquisition of the following practical skills:

1) filling out samples of regulatory documentation;

2) mastery of practical skills for independent solution of typical tasks with competent use of legal terminological apparatus and sources of pharmaceutical law and legislation.

In practical classes, students solve professionally oriented situational problems and test problems.

The student's independent work involves preparation for practical classes and development of practical skills, study of topics for independent work outside the classroom, preparation of

presentations, tables, study of scientific literature and writing reviews on given topics for individual work. Control of mastering topics of independent work outside the classroom is carried out at intermediate control classes and final control of the discipline.

Thematic plans of lectures, calendar plans of practical classes, thematic plan of independent work outside the classroom, scope and directions of individual work are published on the website of the department.

Route of obtaining materials: Department of Forensic Medicine and Law/Student/Full-time study/Pharmacy/ 3rd year/Educational and methodological materials/ or via the link <https://www.vnmu.edu.ua/> Department of Forensic Medicine and Law58. Access to the materials is carried out from the student's corporate account s000XXX@vnmu.edu.ua.

5. Forms and methods of monitoring academic performance

Current control in practical studies	Methods: oral or written survey, testing, solving situational problems
Final control of the discipline - module	Methods: oral survey (according to the regulations on the organization of the educational process at National Pirogov Memorial Medical University, Vinnytsya (link https://www.vnmu.edu.ua/General information/Basic documents)
Learning success diagnostic tools	Theoretical questions, practically-oriented situational tasks, practical tasks

6. Assessment criteria

Knowledge assessment is carried out in accordance with the Regulations of the Academic process in National Pirogov Memorial Medical University, Vinnytsya (link <https://www.vnmu.edu.ua/General information>)

Continuous assessment	On a four point system of traditional assessments: 5 «excellent», 4 «good», 3 «satisfactory», 2 «unsatisfactory»
Control of practical skills	According to the four-point system of traditional assessments
Final control of the discipline	Final credit grade: 71-80 points - "excellent" 61-70 points - "good" 50-60 points - "satisfactory" Less than 50 points - "unsatisfactory" / did not pass
Discipline assessments:	Current academic assessment - from 72 to 120 points (conversion of the average traditional assessment of practical class on a 120-point scale): 60% of the grade for the discipline Final control - from 50 to 80 points: 40% of the grade for the discipline Individual work - from 1 to 12 points From 122 to 200 points in total.

Discipline Score Scale: National and ECTS

The sum of grades for all types of educational activities	Score ECTS	Score on a national scale	
		For exam, course project (work), practice	for credit test
180-200	A	Excellent	Credited
170-179,9	B		

160-169,9	C	Good	
141-159,9	D	Satisfactory	
122-140,99	E	Satisfactory	
60-121,99	FX	unsatisfactory with the possibility of reassembly	is not credited with the possibility of reassembling
0-59,99	F	unsatisfactory with a mandatory reexamination of discipline	is not credited with mandatory reexamination of discipline

Criteria for assessing student knowledge

Assessment of oral / written response during the current control

The grade "excellent" is awarded to a student who has deeply and comprehensively mastered the theoretical material and teaches it competently and logically. He can freely use Latin terminology, clearly answers non-standard questions on the topic of the lesson, knows how to connect the material of this topic with previously studied sections, which indicates mastery of the recommended literature and the ability to analyze the studied material, and also clearly demonstrates the value of the acquired theoretical knowledge for practical of medicine

The grade "good" is awarded to a student who knows and has a good command of the theoretical material, teaches it competently, does not allow inaccuracies in the answer, knows how to reveal the topic from the standpoint of its medical significance and practical application, but at the same time the answers do not go beyond the textbook and methodical recommendations.

The grade "satisfactory" is assigned to a student who knows the basic concepts and definitions of the studied topic, but makes significant inaccuracies or has difficulties in formulating an answer, does not understand the medical aspects of the topic, cannot connect theoretical material with practice.

An "unsatisfactory" grade is given to a student who does not know the theoretical foundations of the topic, makes gross mistakes when answering, does not understand basic concepts and definitions, and cannot explain the meaning of theoretical material for practical medicine.

Assessment of the solution of typical situational problems

The grade of "**excellent**" is awarded to a student who answered all the questions of the situational problem correctly, in full, substantiated his answer to the question in the situational problem to a sufficient extent, logically and consistently.

A grade of "**good**" is given to a student who answered all the questions of the situational problem in full, but was unable to justify his answer sufficiently.

A grade of "**satisfactory**" is given to a student who answered part of the questions of the situational problem in full, but was unable to justify his answer to a sufficient extent.

The grade of "**unsatisfactory**" is given to a student who did not answer the question of the situational problem and could not justify his answer.

Evaluation of the oral answer during the final control (differential test)

The grade "excellent" is given to the student who correctly answers all questions, during the answer reveals comprehensive and deep knowledge of a program material, closely connects theoretical concepts with practice, expresses own reasonable thoughts concerning the decision of concrete organizational and medical situations, in rendering medical care. When solving a situational problem, he not only gets the right result, but also knows how to interpret it correctly.

The grade "good" is deserved by the student who at the answer shows full knowledge of a program material, correctly uses theoretical positions at the decision of a situational problem.

A student who shows knowledge of the basic program material, but has not mastered its details, admits inaccuracies, insufficiently correct formulations, and violates the sequence in the presentation of program material deserves a grade of "satisfactory". Experiencing difficulties in performing situational tasks.

A grade of "unsatisfactory" is given to a student who does not master certain parts of the program

material, is not able to solve a situational problem on his own and make fundamental conclusions and generalizations.

The calculation of individual points

The calculation of individual points is carried out on the basis of the Regulations on the organization of the educational process at National Pirogov Memorial Medical University, Vinnytsya (Vinnytsya, 2022). (link <https://www.vnmdu.edu.ua/generalinformation/main-documents>) - 12 points, which are added to the assessment of the discipline - are added for prizes at inter university competitions in the discipline and interuniversity and international (foreign) scientific conferences with the availability of printed work. - 11-10 points - are added for prizes at intra-university competitions and scientific conferences with the presence of printed work. - 10 points - are given to the assessment of the discipline for participation (if took part, but did not receive a prize) in inter university competitions in the discipline and interuniversity and international (foreign) scientific conferences with the availability of printed work. - 8 points - are added to the assessment of the discipline for participation (if took part, but did not receive a prize) in intra-university competitions, scientific conferences of the institution with the presence of printed work. - up to 6 points - are added to the assessment of the discipline for the manufacture of diagrams, tables, multimedia and videos at the department - taking into account the importance of the work performed.

7. Policy of discipline / course

The student has the right to receive high-quality educational services, access to contemporary scientific and educational information, qualified tutoring during the study of discipline and mastering practical skills. The policy of the department during the providing of educational services is a student- centered, based on normative documents of the Ministry of Education and the Ministry of Health of Ukraine, the Statute of the University and the Procedure for the Providing of Educational Services regulated by the main principles of the organization of the educational process in National Pirogov Memorial Medical University, Vinnytsya and the principles of academic integrity (link <https://www.vnmdu.edu.ua/Generalinformation>).

Adherence to the rules of National Pirogov Memorial Medical University, Vinnytsya, safety techniques in practical classes.

Observance of the rules of the National Pirogov Memorial Medical University, Vinnytsya regulations, safety precautions at practical classes. Instruction on biosafety, safety of handling chemical reagents and burners is conducted at the first practical lesson by the teacher. The instructed students are registered in the Safety Instruction Journal. A student who has not been instructed is not allowed to perform practical work.

Requirements for preparation for practical classes.

The student should be prepared for a practical lesson, testing tasks for the current topic should be solved in a workbook, diagrams and tables are filled.

A student should come to class on time, without delay. A student who is more than 10 minutes late is not allowed to the practical class and must work it in the prescribed manner.

In practical classes, the student must have a work uniform (medical gown, hat). Students who do not have a work uniform are not allowed to practice in a forensic office.

The student must follow the rules of safety in practical rooms and at the department of forensic medicine office.

When discussing theoretical issues, students should demonstrate tolerance, courtesy and respect for their colleagues and the teacher; when performing practical tasks, the workplace should be kept in order and be cleaned after performing practical work.

Usage of mobile phones and other electronic devices.

The use of mobile phones and other electronic devices in the classroom is allowed by the teacher.

Academic integrity. When studying the discipline, the student must be guided by the Code of Academic Integrity and Corporate Ethics of National Pirogov Memorial Medical University, Vinnytsya (link : <https://www.vnmdu.edu.ua/Generalinformation/> Code of Academic Integrity).. In case of violation of the norms of academic integrity during the current and final controls student receives a grade of "2" and

must work it out to his teacher in the prescribed manner within two weeks after receiving an unsatisfactory assessment).

Missed classes. Missed classes are working out in the manner prescribed by Regulations of the Academic process in National Pirogov Memorial Medical University, Vinnytsya (link [https://www.vnmu.edu.ua/General information](https://www.vnmu.edu.ua/General%20information)) at the time of work out schedule (published on the website of the department [https://www.vnmu.edu.ua/ Department of Forensic medicine and law #58](https://www.vnmu.edu.ua/Department%20of%20Forensic%20medicine%20and%20law%20#58)) to the teacher on duty. To work out missed lesson student must provide a completed workbook protocol on the relevant topic, take a test and answer questions in writing or orally to the topic of the lesson. The reworking of missed lectures is carried out after providing a thesis of lecture material, or writing an abstract, or preparing own presentation on the topic of missed lecture.

The procedure for admission to the discipline final control is given in the Regulation of the Academic process in National Pirogov Memorial Medical University, Vinnytsya (link [https://www.vnmu.edu.ua/General information](https://www.vnmu.edu.ua/General%20information)). Students who do not have missed practical classes and lectures and received an average traditional grade of at least "3" are allowed final control.

Additional points. Individual points in the discipline that student can receive for individual work, is determined by the results of his individual work according to Regulation of the Academic process in National Pirogov Memorial Medical University, Vinnytsya (link [https://www.vnmu.edu.ua/General information](https://www.vnmu.edu.ua/General%20information)) and policy of the course.

Conflict resolution. In case of misunderstandings and complaints to the teacher because of the quality of educational services, knowledge assessment and other conflict situations, student should submit his / her claims to the teacher. If the issue is not resolved, the student has a right to apply to the head of the department according to Complaints Consideration Procedure ([https://www.vnmu.edu.ua/ General information / Basic documents](https://www.vnmu.edu.ua/General%20information/Basic%20documents)).

Politics in terms of remote learning. Distance learning regulated by the Regulations of the elements of remote learning in National Pirogov Memorial Medical University, Vinnytsya ([https://www.vnmu.edu.ua/ General information](https://www.vnmu.edu.ua/General%20information)). The main training platforms for studying are Microsoft Team and Google Meets. Practical classes and lectures, exercises and consultations during distance learning is published on the website of the department ([https://www.vnmu.edu.ua/ Department of Forensic medicine and law / Student](https://www.vnmu.edu.ua/Department%20of%20Forensic%20medicine%20and%20law/Student) or [https://www.vnmu.edu.ua/Department of Forensic medicine and law / News](https://www.vnmu.edu.ua/Department%20of%20Forensic%20medicine%20and%20law/News)).

Feedback from teachers is via messengers (Microsoft Teams) or e-mail (at the teacher's choice) during working hours.

8. Educational resources.

Educational and methodological support of the discipline is published on the website of the department ([https://www.vnmu.edu.ua/ Department of Forensic medicine and law/ To students](https://www.vnmu.edu.ua/Department%20of%20Forensic%20medicine%20and%20law/To%20students)). Consultations are hold twice a week according to the schedule.

Recommended reading:

1) Main literature.

1. Constitution of Ukraine [Electronic resource]: Law of Ukraine dated June 28, 1996 No. 254k/96-VR (amended and supplemented) / Verkhovna Rada of Ukraine. Access mode: <http://zakon0.rada.gov.ua/laws/show/254%D0%BA/96%D0%B2%D1%80>
2. Code of Labor Laws of Ukraine [Electronic resource]: Law of Ukraine, Code of 10.12.1971 No. 322-VIII (amended and supplemented) / Verkhovna Rada of the Ukrainian SSR .-Access mode: <http://zakon5.rada.gov.ua/laws/show/322-08>
3. Civil Code of Ukraine [Electronic resource]: Law of Ukraine, Code dated 16.01.2003 No. 435-IV (amended and supplemented) / Verkhovna Rada of Ukraine. – Mode access: <http://zakon5.rada.gov.ua/laws/show/435-15>
4. Criminal Code of Ukraine [Electronic resource]: Law of Ukraine, Code of April 5, 2001 No.

- 2341-III (amended and supplemented) / Verkhovna Rada of Ukraine. - Access mode: <http://zakon3.rada.gov.ua/laws/show/2341-14>
5. Code of Ukraine on administrative offenses [Electronic resource]: Law of Ukraine, Code dated 07.12.1984 No. 8073-X (amended and supplemented) / Verkhovna Rada of the Ukrainian SSR. - Access mode: <http://zakon3.rada.gov.ua/laws/show/80731-10>
 6. Economic Code of Ukraine [Electronic resource]: Law of Ukraine, Code dated 16.01.2003 No. 436-IV (amended and supplemented) Verkhovna Rada of Ukraine. - Access mode: <http://zakon5.rada.gov.ua/laws/show/436-15>
 7. About licensing of economic activities [Electronic resource]: Law of Ukraine dated March 2, 2015 No. 222-VIII (amended and supplemented) / Verkhovna Rada of Ukraine. - Access mode: <http://zakon2.rada.gov.ua/laws/show/222-19>
 8. Fundamentals of Ukrainian legislation on health care [Electronic resource]: Law of Ukraine dated November 19, 1992 No. 2801-XII (amended and supplemented) / Verkhovna Council of Ukraine. - Access mode: <http://zakon5.rada.gov.ua/laws/show/2801-12129>
 9. About medicinal products [Electronic resource]: Law of Ukraine dated 04.04.1996 No. 123/96-BP (amended and supplemented) / Verkhovna Rada of Ukraine. - Access mode: <http://zakon3.rada.gov.ua/laws/show/123/96-%D0%B2%D1%80>
 10. On measures to counter the illegal circulation of narcotics, psychotropic substances and precursors and their abuse [Electronic resource]: Law of Ukraine dated February 15, 1995 No. 62/95-VR (amended and supplemented) / Verkhovna Rada of Ukraine. - Access mode: <http://zakon0.rada.gov.ua/laws/show/62/95-%D0%B2%D1%80>
 11. On narcotic drugs, psychotropic substances and precursors [Electronic resource]: Law of Ukraine dated February 15, 1995 No. 60/95-VR (amended and supplemented) / Verkhovna Rada of Ukraine. - Access mode: <http://zakon3.rada.gov.ua/laws/show/60/95-%D0%B2%D1%80>
 12. On making changes to the Law of Ukraine "On drug trafficking in Ukraine means, psychotropic substances, their analogues and precursors" [Electronic resource]: Law of Ukraine dated 07/08/1999 No. 863-XIV (amended and supplemented) / Verkhovna Council of Ukraine. - Access mode: <http://zakon2.rada.gov.ua/laws/show/863-14>
 13. About the main principles of state supervision (control) in the economic sphere activities [Electronic resource]: Law of Ukraine dated 04/05/2007 No. 877-V (with amendments and additions) / Verkhovna Rada of Ukraine. - Access mode: <http://zakon2.rada.gov.ua/laws/show/877-16>
 14. On the appeal of citizens [Electronic resource]: Law of Ukraine no 02.10.1996 No. 393/96-VR (amended and supplemented) / Verkhovna Rada of Ukraine. - Mode access: <http://zakon3.rada.gov.ua/laws/show/393/96-%D0%B2%D1%80>
 15. About advertising [Electronic resource]: Law of Ukraine dated July 3, 1996 No. 270/96-BP (amended and supplemented) / Verkhovna Rada of Ukraine. - Access mode: <http://zakon5.rada.gov.ua/laws/show/270/96-%D0%B2%D1%80130>
 16. On the protection of consumer rights [Electronic resource]: Law of Ukraine no 12.05.1991 No. 1023-XII (amended and supplemented) / Verkhovna Rada of the Ukrainian SSR. - Mode access: <http://zakon0.rada.gov.ua/laws/show/1023-12>

2) Supplementary reading

1. Oxford Textbook of Global Public Health, 6 edition. Edited by Roges Detels, Martin Gulliford, Quarraisha Abdool Karim and Chorh Chuan Tan. Oxford University Press, 2023. 1728 p.
2. About the Commissioner for Human Rights of the Verkhovna Rada of Ukraine [Electronic resource]: Law of Ukraine dated 23.12.1997 No. 776/97-VR (as amended and add.) / Verkhovna Rada of Ukraine. - Access mode: <http://zakon2.rada.gov.ua/laws/show/776/97-%D0%B2%D1%80>
3. About trade unions, their rights and guarantees of activity [Electronic resource]: Law of Ukraine dated 15.09.1999 No. 1045-XIV (amended and supplemented) / Verkhovna Rada of Ukraine. - Access mode: <http://zakon2.rada.gov.ua/laws/show/1045-14>
4. About the Prosecutor's Office [Electronic resource]: Law of Ukraine dated 14.10.2014 No. 1697-VII (amended and supplemented) / Verkhovna Rada of Ukraine. - Access mode:

<http://zakon5.rada.gov.ua/laws/show/1697-18>

5. About the judicial system and the status of judges [Electronic resource]: Law of Ukraine no 02.06.2016 No. 1402-VIII (amended and supplemented) / Verkhovna Rada of Ukraine. - Mode access: <http://zakon5.rada.gov.ua/laws/show/1402-19>

6. About the Security Service of Ukraine [Electronic resource]: Law of Ukraine no 25.03.1992 No. 2229-XII (amended and supplemented) / Verkhovna Rada of Ukraine. - Mode access: <http://zakon5.rada.gov.ua/laws/show/2229-12>

7. About the National Police [Electronic resource]: Law of Ukraine dated 02.07.2015 No. 580-VIII (amended and supplemented) / Verkhovna Rada of Ukraine. - Mode access: <http://zakon3.rada.gov.ua/laws/show/580-19>

Electronic resources:

1. E-mail address of the university website: <http://vnmu.edu.ua>
2. E-mail address of the website of the university library: <http://library.vnmu.edu.ua>
3. Presentations of lectures and other methodological materials from the discipline "Medical Law of Ukraine" on Google - disk of the website of the department: URL: <http://forensic.vnmu.edu.ua/>
4. <http://www.moz.gov.ua><http://www.moz.gov.ua/> – the official website of the Ministry of Health of Ukraine
5. <http://www.diklz.gov.ua> – the official website of the State Service of Ukraine for Medicinal Products and Drug Control
6. <http://www.rada.gov.ua>. – the official website of the Verkhovna Rada of Ukraine
7. <http://www.kmu.gov.ua> – the official website of the Cabinet of Ministers of Ukraine
8. <http://www.who.int> is the official website of the World Health Organization.
9. <http://www.diklz.gov.ua> – the official website of the State Service of Ukraine for Medicinal Products and Drug Control
10. <http://nuph.edu.ua> – the official website of the National Pharmaceutical University
11. <http://fp.com.ua> – website of the magazine "Pharmacist Praktik"
12. <http://www.provisor.com.ua> – the official website of the magazine "Provisor"
13. <https://www.uniprot.org/>
14. <https://www.forens-med.ru/>
15. <https://www.aic.gov.au/>

9. The timetable and distribution of groups with assigned teachers are published on the web page of the department (<https://www.vnmu.edu.ua/> Department of Forensic medicine and law/ To students).

The syllabus of the discipline "Pharmaceutical law and legislation" was discussed and approved at the meeting of the department Forensic medicine and law (record № 1, dated "30" 08 2024)

Responsible for the academic discipline

(signature)

Ass-prof. Raisa ZHARLINSKA

Head of the department

(signature)

Ass-prof. Valery GUNAS