MINISTRY OF HEALTH OF UKRAINE
NATIONAL UNIVERSITY OF PHARMACY
Faculty of Pharmacy Department of Social Pharmacy

PHARMACEUTICAL LAW AND LEGISLATION

(name of academic educational component)

WORKING PROGRAM
of educational component

training for second (master's) level
(Higher Educational Level Name)

field of knowledge 22 Health care
(Code and Knowledge Field Name)

in specialty 226 Pharmacy, industrial pharmacy
(Code and Specialty Name)

of educational program Pharmacy
(Educational Program Name)

specialization _____
(Specialization Name)

2022 year

Work program of a course Pharmaceutical Law and Legislation in specialty 226 Pharmacy, Industrial Pharmacy of educationalprogram Pharmacy specialization____for applicants for higher education 3 year of study.

Educational course team:

KOTVITSKA Alla, professor of the Social Pharmacy department, Doctor ofPharmacy, Professor;
VOLKOVA Alina, head of the Social Pharmacy department, Ph.D., AssociateProfessor;
KUBARIEVA Inna, Associate Professor of the Social Pharmacy department, Ph.D.,Associate Professor;
KORZH Yuliya, Associate professor of the Social Pharmacy department, Ph.D.,Associate Professor;
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SURIKOVA Iryna, assistant of the Social Pharmacy department, Ph.D.

Work program has been considered and approved at the Social Pharmacy Department Meeting
Record from "29" August 2022 year №1

Head of the Department _____ assoc.prof. Alina VOLKOVA
(signature) (name and surname)

Work program has been considered and approved at meeting of the profile Methodical Commission on economicand managerial disciplines
Record from «30» August 2022 year № 1

Head of Specialized Committee _____ prof. Alla NEMCHENKO

1. Description of the educational component

The language of the study: English

Status of the educational component*:* obligatory

Prerequisites for studying the educational component:

- the course is based on the study of "Introduction to the specialty with introductory practice";
- the course is the basis for the study of “Organization and economics of pharmacy”, “Pharmaceutical marketing and management”, “Pharmaceutical commodity science”, “Social pharmacy”, which involvesthe integration of teaching with the above educational components to form the skills to apply knowledge in the processof further training and in professional activities;
- laying the foundation for students to study systematic analysis of pharmaceutical institutions, provides for the application of the acquired knowledge in the process of further training and in professional activities.

The purpose statement of studying the course «Pharmaceutical law and legislation » is the legislationof Ukraine and other countries of the world, as well as theoretical and applied aspects of the legal regulation of the pharmaceutical sector of health.

Information content of the educational component. 3 ECTS credit 90 hours are assigned to the study of the educational component.

2. Objectives and tasks of the course

The purpose of teaching the educational component «Pharmaceutical law and legislation » is to study the role andplace 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.

The **main tasks** of the educational component "Pharmaceutical law and legislation" is the assimilation of the main issues of general theory adapted to the pharmaceutical practice, which are considered in the study:

- acquisition of systemic knowledge of the legal basis of the organization of health care in the countries of the world and in Ukraine;
- acquisition of systematic knowledge on the systematization of normative-legal acts;
- understanding of organizational and legal forms of pharmaceutical activity;
- assimilation of the main issues of state policy and mechanisms of state regulation of health care andcirculation of medicines;
- understanding of the legal responsibility of pharmaceutical workers for professional and official offenses;
- assimilation of knowledge on the issues of environmental offenses in the implementation of pharmaceutical activities;
- acquisition of knowledge on the legislative basis of state supervision in the field of circulation of medicines and medical devices.

3. Competence and planned educational outcomes

The course «Pharmaceutical law and legislation » provides acquisition of competencies by applicants for higher education**:**

- *integral* ***:***

Ability to solve typical and complex specialized tasks and critically comprehend and solve the practical problems in the professional pharmaceutical and/or research and innovation activity using provisions, theories and methods of the fundamental, chemical, technological, biomedical, socio-economic science; integrate knowledge and solve complex issues, formulate judgments in the presence of incomplete or limited information, clearly and unambiguously to convey their conclusions and use their knowledge, reasonably substantiating them, to professional and non-professional audience.

- *general :*

G1. 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.

- *specialized (professional, subject):*

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

Integrative final program learning outcomes (PLO), the formation of which is facilitated by the educational component:

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.

As a result of studying the course, students will be able to

know:

- the main sources of the law, the peculiarities of different legal systems, the concept of law, the differences between the system of law and legislation;
- the basic concepts and categories of pharmaceutical law and pharmaceutical legislation and features ofthe legal regulation of pharmaceutical activity in Ukraine and abroad;
- the legislative basis of the system of state supervision in the sphere of turnover of medicines, the powersof officials, to determine the grounds and the main stages of scheduled and unscheduled inspections;
- the basic concepts of legal responsibility, its principles and functions, to understand the types of legalresponsibility;
- organizational-legal forms of pharmaceutical activities and their content, types of pharmaceutical organizations and their characteristics as the subjects of the pharmaceutical market;
- the basic concepts of the licensing system in the sphere of entrepreneurial activity, the principles of state policy in the sphere of licensing, the peculiarities of the normative-legal regulation of licensing of pharmaceutical activity;
- the international standards of pharmaceutical activities and learn the features of building a quality assurance system in pharmacies and pharmaceutical wholesalers, to know the regulatory framework governing the circulation and quality control of medicines in health care institutions;
- the basic elements of the system of legal relations of ecological safety in different kinds of pharmaceutical activity, forms of work and the content of the main activities of the state sanitary-epidemiological, types of responsibility provided by the legislation of Ukraine for environmental

offenses;

- normative legal aspects of trade activities in the sphere of wholesale and retail sale of medicines in Ukraine;
- basic legal aspects of the activity of medical representatives in Ukraine and abroad; basic criteria for advertising campaigns on pharmaceuticals;
- peculiarities of circulation of different nomenclatural and classification-legal groups of medicines, theprocedure for carrying out activities related to circulation of narcotics, psychotropic substances and precursors in health care institutions and peculiarities of state control over compliance with legislationon their circulation
- the concept and principles of foreign economic activity and customs regulation; learn the features of state control of medicines and medical devices imported into the customs territory of Ukraine;
- basic principles of pharmaceutical pricing policy in Ukraine;
- basic regulatory socio-economic lists of medicines that determine the name of the drug prices of whichare subject to state regulation;
- the main elements of the tax system of Ukraine and peculiarities of taxation of pharmaceuticalcompanies;

to be able to:

- analyze and professionally apply pharmaceutical legislation and regulatory documents on pharmaceutical activities, form conclusions;

possess:

- skills in processing regulatory legal acts, be able to identify problems and prospects of rulemaking oncurrent issues in health care and pharmacy.

4. The educational component structure

Names of content mod-ules and topics	The amount of hours				
	full time study				
	the whole amou nt	including			
		l	p.c.	sem.	self-study
Content module 1. Theoretical foundations of law, pharmaceutical law system and the system ofpharmaceutical legislation. The legal basis of pharmaceutical companies					
Topic 1. Pharmaceutical law and pharmaceutical legislation. Normative andlegal regulation of pharmaceutical activity.	10	2	4	-	4
Topic 2. Permission system in the field of economic activity. The legislative foundation of the state surveillance (control) in the sphere ofturnover of medicine and medical products.	12	2	4	-	6
Topic 3. Mechanism of the state registration and market authorizationof new medicines for use in Ukraine. Intellectual property rights in health care.	12	2	4	-	6
Topic 4. Standardization and certification of the pharmaceutical activity.The drug quality assurance system.	8	2	2	-	4
Final test of CM 1 assimilation	6	-	2	-	4
The whole amount of hours for the content module 1	**48**	**8**	**16**	**-**	**24**
Content module 2. The legal basis of pharmaceutical companies. Regulatory and legal support development, production and quality control of drugs.					
Topic 5. Regulatory and legal support for turnover of various nomenclature and legal and classification-legal drug groups.	8	2	2	-	4
Topic 6. Legal aspects of the foreign economic activity and regulationof export and import of medicinal products.	8	2	2	-	4

Topic 7. The legal and regulatory framework of economic accessibility of pharmaceutical care.	9	2	2	-	5
Topic 8. Normative and legal aspects of regulation of the pharmaceuticalactivity in different countries	9	2	2	-	5
Final test of CM 2 assimilation	7	-	2	-	5
The whole amount of hours for the content module 2	**41**	**8**	**10**	**-**	**23**
Semester credit	**1**	**-**	**1**	**-**	
The whole amount of hours for the course	**90**	**16**	**27**	**-**	**47**

5. Contents 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 regulationof pharmaceutical activity.

The law system and the legislation system. National legal systems and international law. Regulatory legal acts as the sources of the law. Classification of the normative legal acts. The structure of the legislation system in pharmacy. The hierarchy of normative legal acts in the pharmaceutical branch by legal force. Features of the pharmaceutical legislation in the European Union: the main types of legal acts in the EU legal framework. The concept and types of legal relationships. Legal relationships arise whenimplementing pharmaceutical activities. The concept of an offense and its structure. Types of offenses.The concept, features and bases of legal responsibility. Types of legal responsibility.

Topic 2. Permission system in the field of economic activity. The legislative foundation of the state surveillance (control) in the sphere of turnover of medicine and medical products.

The permission system of Ukraine in the field of the economic activity sphere: basic concepts, structure, functions and principles. Licensing as a component of the control and permission system in the field of economic activity. The basic principles of the state policy in licensing.

Legislative framework of state surveillance (control) in the sphere of turnover of medicine and medical products. The procedure for selecting drug samples for laboratory testing of their quality. Responsibility for offenses related with the turnover of medicines and other 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.

Registration of medicines as a mechanism of the pharmaceutical market authorization. The procedure for the expert examination of drugs submitted for state registration (re-registration). The order of keeping the State Register of Medicinal Products of Ukraine.

The concept of intellectual property in healthcare. Objects of the intellectual property law: marks for goods and services, patented inventions, industrial samples, and objects of copyright. Legal mechanisms forthe protection of intellectual property rights.

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

Standardization and certification in pharmacy. Certification in the pharmaceutical activity as a guarantee of quality. Legal and regulatory framework of the drug quality assurance system. The state control over drug promotion at the market. Advertising of drugs.

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

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

Nomenclature and legal and classification-legal groups of medicines. Regulatory lists of medicines.The state regulation and control of the turnover of narcotic drugs, psychotropic substances, precursors in healthcare and pharmacy institutions. Responsibility for violation of legislation in the sphere of circulationof nomenclature and legal and classification-legal groups of medicines.

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

The concept of foreign economic activity. Instruments for regulating foreign economic activity. International organizations regulating the world trade, monetary and financial relations. The legal and regulatory framework of the import of pharmaceutical products to the territory of Ukraine.

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

The concept of health insurance. Reimbursement of the cost of pharmaceutical care as an effectivesocio-economic mechanism to provide its accessibility to the population. Privilege dispensing of medicines, its legal and regulatory framework. Privilege categories and population groups. The legislative basis of thepharmaceutical pricing. Features of formation of the medicine price. The state regulation of medicine prices. Taxes as an economic, public and legal category. The system of taxation of medicines and medicalproducts.

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

Characteristics of the modern pharmaceutical legislation in the post-Soviet countries of the Transcaucasian and Central Asian region. The legal and regulatory framework of healthcare and pharmacyin African countries. The pharmaceutical law and legislation in the Middle East countries. The features of the legal and regulatory framework of the pharmaceutical activity in different countries abroad.

6. Topics of lectures

№	Name of topic	The amount of hours
1.	Topic 1. Pharmaceutical law and pharmaceutical legislation. Normative and legal regulationof pharmaceutical activity.	2
2.	Topic 2. Permission system in the field of economic activity. The legislative foundation of the state surveillance (control) in the sphere of turnover of medicine and medical products.	2
3.	Topic 3. Mechanism of the state registration and market authorization of new medicinesfor use in Ukraine. Intellectual property rights in health care.	2
4.	Topic 4. Standardization and certification of the pharmaceutical activity. the drug qualityassurance system.	2
5.	Topic 5. Regulatory and legal support for turnover of various nomenclature and legal andclassification-legal drug groups	2
6.	Topic 6. Legal aspects of the foreign economic activity and regulation of export and import of medicinal products.	2
7.	Topic 7. The legal and regulatory framework of economic accessibility of pharmaceuticalcare.	2
8.	Topic 8. Normative and legal aspects of regulation of pharmaceutical activity in different countries	2
	The whole amount of hours	**16**

7. Topics of seminars

Not provided for in the working curriculum

8. Topics of practical lessons

№	Name of topic	The amount of hours
1.	Topic 1. Pharmaceutical law and pharmaceutical legislation. Normative and legal regulationof pharmaceutical activity.	4
2.	Topic 2. Permission system in the field of economic activity. The legislative foundation of the state surveillance (control) in the sphere of turnover of medicine and medical products.	4
3.	Topic 3. Mechanism of the state registration and market authorization of new medicines foruse in Ukraine. Intellectual property rights in health care.	4

4.	Topic 4. Standardization and certification of the pharmaceutical activity. The drug quality assurance system.	2
5.	*The final test of CM 1 assimilation*	2
6.	Topic 5. Regulatory and legal support for turnover of various nomenclature and legal andclassification-legal drug groups	2
7.	Topic 6. Legal aspects of the foreign economic activity and regulation of export and import of medicinal products	2
8.	Topic 7. The legal and regulatory framework of economic accessibility of pharmaceutical care	2
9.	Topic 8. Normative and legal aspects of regulation of pharmaceutical activity indifferent countries.	2
10.	*The final test of CM 2 assimilation*	2
11.	**Semester credit**	1
	The whole amount of hours	**27**

9. Topics of laboratorial lessons

Not provided for in the working curriculum

10.Self-study work

№	Name of topic	The amount of hours
1	Topic 1. Pharmaceutical law and pharmaceutical legislation. Normative and legal regulation of pharmaceutical activity.	4
2	Topic 2. Permission system in the field of economic activity. The legislative foundation of the state surveillance (control) in the sphere of turnover of medicine andmedical products.	6
3	Topic 3. Mechanism of the state registration and market authorization of new medicinesfor use in Ukraine. Intellectual property rights in health care.	6
4	*Preparing for to final test of CM 1 assimilation*	4
5	Topic 4. Standardization and certification of the pharmaceutical activity. The drug quality assurance system.	4
6	Topic 5. Regulatory and legal support for turnover of various nomenclature and legal and classification-legal drug groups	4
7	Topic 6. Legal aspects of the foreign economic activity and regulation of export and import of medicinal products	4
8	Topic 7. The legal and regulatory framework of economic accessibility of pharmaceutical care	5
9	Topic 8. Normative and legal aspects of regulation of pharmaceutical activity in different countries.	5
10	*Preparing to final test of CM 2 assimilation*	5
	The whole amount of hours	**47**

Tasks for self-study work

Preparation of abstracts, presentations, essays, work with educational and methodical literature,lecture notes, Internet - resources.

Execution of tasks in accordance with the topics of the educational component:

1. Describe the features of the pharmaceutical legislation in the European Union.
2. Name the main types of legal acts in the EU legal framework.
3. Describe the concept and types of legal relationships.
4. Define legal relationships arising when implementing the pharmaceutical activities.
5. Describe types of offenses.
6. Define the concept, features and bases of legal responsibility.
7. Name types of legal responsibility.
8. Describe the basic principles of the state policy in licensing.
9. Name legislative acts of state surveillance (control) in the sphere of turnover of medical

products.

10. Name types of responsibility for offenses related with turnover of medicines and other medicalproducts.
11. Provide a description of the concept of intellectual property in healthcare.
12. Describe legal mechanisms for the protection of intellectual property rights.
13. Name legal and regulatory documents of the drug quality assurance system.
14. Describe the state control over drug promotion at the market.
15. Name regulatory lists of medicines.
16. Characterize responsibility for violation of legislation in the sphere of circulation of nomenclatureand legal and classification-legal groups of medicines.
17. Name instruments for regulating foreign economic activity.
18. Characterize the rules of the import of pharmaceutical products to the territory of Ukraine.
19. Describe the state regulation of medicine prices.
20. Prepare the report of the features of the legal and regulatory framework of the pharmaceuticalactivity in different countries abroad to choose from.

11. Criteria and evaluation order of educational outcomes

During the study of the educational component, all types of student activities are subject to control: current (at each lesson and when performing tasks for independent work of students), content modules (checking the mastery of content modules).

Current control is carried out at each practical lesson in accordance with the specific objectives of the topic, during the individual work of the teacher with the student for those topics that the student developsindependently.

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	T4	Control of CM 1	T5	T6	T7	T8	Control ofCM 2
5,5–9	5,5–9	5,5–9	5,5–9	8–14	5,5–9	5,5–9	5,5–9	5,5–9	8–14
50					50				
100									

T1, T2 ... T8 – Topics

The current control of content modules (CM1, CM2) totals **a maximum of 100 scores, a minimumof 60 scores**.

Incentive (additional) points: performance of an individual task, participation in competitions, contests, student scientific conferences, active participation in lectures, etc. – up to **10** scores**.**

The overall rating of the module (educational component) **does not exceed 100** scores.

The module is considered completed if the applicant has scored **from 60 to 100** scores**.**

Assessment of current learning activities is carried out at each practical lesson in the form of controlof theoretical knowledge, practical skills and abilities.

The control of content modules (CM) is carried out in the last practical classes of studying the topics of content modules. Only those applicants for higher education who have performed all types of work provided for in the curriculum (missed seminars, lectures, etc.) are allowed to control the CM. The structureof the ticket CM 1 and CM 2: 14 test questions. The sum of points for the study of theCM is the sum of points received by the student during the study of all topics of the content module.

Assessment of current learning activities (conducted at each practical lesson) control of theoretical knowledge, practical skills and abilities. At mastering of each theme of the content module

1 for current educational activity to students points for all kinds of activity which at the end of studying of the content module are summed up are exposed.

The following scoring system is used for each topic of content module 1 (minimum number of points for one topic 5,5 points, maximum – 9 points):

Assessment of practical skills - students are given from 0 to 4 points:			
Type of task being assessed	**System evaluation knowledge, points**		**Evaluation criteria**
Practical (situational) task	**from 0 to 5,0**	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.
Assessment of theoretical knowledge, 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)	**from 0 to 5,0**	5,0	is given to student 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 reproduction, 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 tickets: 14 test questions of different types. Each correct answer is scored 1 point. The sum of points for control CM1 is a maximum of **14** points. Control CM1 is considered credited if the applicant has obtained at least **8** points.

Grade A, B, C, D, E is given only to students who have enrolled in all modules of the educational component. The number of points that the student scored in the educational component is defined as the arithmetic mean of the number of points from the modules of the course.

COURSE EVALUATION SCALE

The sum of points for alltypes of educational activities	ScoreECTS	Score on a national scale
90 – 100	**A**	Excellent
82-89	**B**	Good
74-81	**C**	
64-73	**D**	Satisfactory
60-63	**E**	
35-59	**FX**	Unsatisfactory with the possibility ofreassembly

0-34	**F**	Unsatisfactory with compulsory re-study ofthe educational component

12. Forms of progress and final tests of academic academies

Semester control is carried out in the form of a semester credit.

13. Methodological support

1. Syllabus of the course.
2. Working program of the course.
3. Schedules of lectures and practical classes.
4. Methodical materials of computer presentations of lectures.
5. Methodical recommendations for practical classes.
6. The list of theoretical questions to the content modules.
7. Pack of tickets for control of content modules with standards of answers.
8. Methodical materials for independent work of students, which are posted on the website of the Center for Distance Learning Technologies of NUPh.

14. Reading suggestions

The main reading suggestions

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

1. Convention on Contracts for the International sale of goods, Vienna, 1980.
2. Council of Europe Convention on Counterfeiting of Medical Products and Similar Crimes involvingThreats to Public Health of 07.06.2012.
3. Directive 2011/83 / EC of the European parliament and of the Council of 6 November 2011 «Onthe Community coderelating to medicinal products for human use»
4. Fassett, W. E. Washington Pharmacy Law: A User's Guide 2011 / W. E. Fassett. – Spokane, 2011. – 446 p.
5. Gordon, E. Wingfield Dale and Appelbe's Pharmacy Law and Ethics / E. Gordon, J. Appelbe. – 9thed. – London : Pharmaceutical Press, 2009. – 553 p.
6. Guidance Documents for Drug Applications [Electronic resource]. – Access mode: https://www.fda.gov/Drugs/DevelopmentApproval Process/ucm090361.htm (Date of access: 18.08.2020).
7. International pharmacy : Official journal of FIP. – 2000. – Vol. 12, № 8. – 30 p.
8. International pharmacy : Official journal of FIP. – 2001. – Vol. 12, № 5. – 32 p.
9. Kelly, W. N. Pharmacy. What It Is and How It Works / W. N. Kelly. – NY: CRC Press, 2012. – 417p.
10. Lexicon of alcohol and drug terms. – WHO Library Cataloguing in Publication Data, 1994
11. Organization of pharmaceutical providing of the population : textbook for university students / A. S. Nemchenko, I. V. Zhirova, V. N. Nazarkina, A. L. Panfilova, V. N. Chernuha, M. V. Podgaynaya, Y. L. Zaitseva. – Kh. : NUPh, 2014. – 268 p.
12. Resolution on the use of the WHO Certification System (WHO Assembly, May, 1992. WHA 45/29)
13. The main documents of the World Health Organization / WHO. – Geneva, 2003. – 261 p.
14. The main documents of the World Health Organization. – Geneva, 2003. – 261 p.
15. The Pharmacy Law. Excerpts from the Business and Professions Code. Board of Pharmacy

Regulations. - http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf.
16. 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.
17. UN Convention «Against illicit trafficking in narcotic drugs and psychotropic substances» (Vienna), 1988.
18. UN Convention «On Psychotropic Substances» (Vienna), February 21, 1971.
19. UN Single Convention «On Narcotic Drugs» (New York), March 30, 1961 (as amended in accordance with the 1972 Protocol)
20. William E. Fassett Washington Pharmacy Law: A User's Guide 2011 Edition. – 2011 – 446 p.

16. Electronic resources

1. Державний Експертний Центр Міністерства охорони здоров'я України. Офіційний сайт. [Електронний ресурс]. – Режим доступу: http://www.dec.gov.ua/
2. Міністерство охорони здоров'я України. Офіційний сайт. [Електронний ресурс]. – Режим доступу: http://www.moz.gov.ua
3. Належна аптечна практика: Стандарти якості аптечних послуг (Спільна настанова МФФ/ВООЗ з НАП). [Електронний ресурс]. – Режим доступу: http://zakon3.rada.gov.ua/laws/show/897_009
4. Наукова бібліотека НФаУ. [Електронний ресурс]. – Режим доступу:: http://dspace.ukrfa.kharkov.ua; http://lib.nuph.edu.ua
5. European Convention on Human Rights. Council of Europe. Rome, 04.12.1950 [Electronic resource]. – Mode of access: http://www.echr.coe.int/Documents/Convention_ENG.pdf.
6. European Social Charte. Council of Europe. Turin, 18.10.1961 [Electronic resource]. – Mode ofaccess: http://www.equalrightstrust.org/content/european-social-charter-1961.
7. National Drug Policy. – 2003. - http://apps.who.int/medicinedocs/ documents/s16450e/s16450e.pdf
8. World Health Organization. Official website. [Electronic resource]. – Access mode: https://www.who.int/home
9. WHO model list of essential medicines - 21st list, 2019. [Electronic resource]. – Access mode:https://www.who.int/publications/i/item/WHOMVPEMPIAU2019.06
10. WHO Model List of Essential Medicines for Children - 7th list, 2019. [Electronic resource]. –Access mode: https://www.who.int/publications/i/item/WHOMVPEMPIAU201907
11. WHO Collaborating Centre for Drug Statistics Methodology. ATC/DDD Index 2020. [Electronic resource]. – Access mode:https://www.whocc.no/atc_ddd_index/
12. The WHO Programme for International Drug Monitoring [Electronic resource]. – Access mode: https://www.who-umc.org/global-pharmacovigilance/who-programme-for-international-drug-monitoring/