

Federal State Budgetary Educational Institution of Higher Education
"Privolzhsky Research Medical University"
Ministry of Health of the Russian Federation



APPROVED

Vice-Rector for Academic Affairs

E.S. Bogomolova

31 August 2021

WORKING PROGRAM

Name of the academic discipline: **LEGAL ASPECTS OF ORGANIZATION OF PHARMACEUTICAL ACTIVITIES (ADDITIONAL COURSE)**

Specialty: **33.05.01 PHARMACY**

Qualification: **PHARMACIST**

Department: **MANAGEMENT AND ECONOMICS OF PHARMACY AND PHARMACEUTICAL TECHNOLOGY**

Mode of study: **FULL-TIME**

Labor intensity of the academic discipline: **72 academic hours**

Nizhny Novgorod
2021

The working program has been developed in accordance with the Federal State Educational Standard for the specialty 33.05.01 PHARMACY, approved by Order by Order of the Ministry of Science and Higher Education of the Russian Federation No. 219 of March 27, 2018.


Developers of the working program:

Maxim Alekseevich Mishchenko, PhD in pharmaceutical sciences, associate professor of the Department of management and economics of pharmacy and pharmaceutical technology.

The program was reviewed and approved at the department meeting (protocol No. 9 of 29.04.2022).

Acting head of the Department,
PhD in pharmaceutical sciences

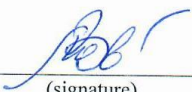
29.04.2021



(signature) I.V. Spitskaya

AGREED
Head of the EMA

01.06.2021



(signature) L.V. Lovtsova

1. The purpose and objectives of mastering the academic discipline "Legal aspects of organization of pharmaceutical activities" (hereinafter – the discipline).

1.1. The purpose of mastering the discipline – participation in forming the following competencies:

- professional competencies (PC-10 (10.1, 10.2)).

1.2. Objectives of the discipline:

1. Formation of basic, fundamental pharmaceutical knowledge in the specialty 33.05.01 Pharmacy.

2. Training of a specialist with analytical thinking, well versed in control and permitting, organizational and managerial activities in the field of circulation of medicines, with in-depth knowledge of related disciplines.

3. Formation of skills in mastering the latest technologies and techniques in the field of their professional interests.

1.3. Requirements to the deliverables of mastering the discipline

As a result of completing the discipline, the student should

Know:

- the structure of the modern health care system of the Russian Federation, the basics of the legislation of the Russian Federation on the protection of public health, the main regulatory and legal documents regulating relations in the field of circulation of medicines;

- legal status of pharmaceutical entities: individual entrepreneurs and legal entities, types of legal entities;

- regulatory framework for the creation, reorganization and liquidation of individual entrepreneurs and legal entities engaged in pharmaceutical activities;

- regulatory framework for the creation, reorganization and liquidation of corporations engaged in pharmaceutical activities and other activities related to the circulation of medicines;

- norms of legislation relating to state control and supervision in the field of pharmaceutical activities and other activities related to the circulation of medicines;

- procedure and requirements for the implementation of pharmaceutical activities.

- legal regime of property of subjects of pharmaceutical activity;

- the procedure for recognizing the insolvency (bankruptcy) of pharmaceutical entities;

- fundamentals of antimonopoly regulation of pharmaceutical activities and other activities related to the circulation of medicines and medical devices;

- methods of legal protection of the rights and legitimate interests of subjects of pharmaceutical activity;

- fundamentals of regulation of pharmaceutical activities and other activities related to the circulation of medicines and medical devices within the EAEU;

- modern information technologies for solving problems of professional activity.

Be able to:

- organize the creation, reorganization, liquidation of pharmaceutical entities;

- carry out types of work or services constituting pharmaceutical activities, and activities in the field of circulation of medicines in compliance with the requirements of the legislation of the Russian Federation in the field of health protection;

- use modern information technologies in solving problems of professional activity.

Possess:

- regulatory and legal documentation regulating the procedure for the creation, reorganization, liquidation of pharmaceutical entities;

- regulatory documentation regulating the procedure for carrying out pharmaceutical activities and activities in the field of circulation of medicines

– regulatory and legal reference systems, as well as professional databases for solving problems of professional activity.

2. Position of the academic discipline in the structure of the General Educational Program of Higher Education (GEP HE) of the organization.

2.1. The discipline refers to additional disciplines.
The discipline is taught in the 8 semester/4 year of study.

2.2. The following knowledge, skills and abilities formed by previous academic disciplines are required for mastering the discipline:

- law;
- introduction to the specialty;
- information support of life cycle of medicines;
- information technologies in pharmacy;
- management and economics of pharmacy;
- pharmaceutical propaedeutic practice.

2.3. Mastering the discipline is required for forming the following knowledge, skills and abilities for subsequent academic disciplines:

- legal basis for the pharmacist's activities;
- pharmaceutical management;
- management and economics of pharmacies (practice).

3. Deliverables of mastering the academic discipline and metrics of competence acquisition

Mastering the discipline aims at acquiring the following professional competencies (PC):

№	Competence code	The content of the competence (or its part)	Code and name of the competence acquisition metric	As a result of mastering the discipline, the students should:		
				know	be able to	possess
1.	PC-10	Able to carry out measures to control (supervise) the activities of legal entities and individuals licensed for pharmaceutical activities, to comply with mandatory requirements	<p>PC-10.1. Supervises the activities of legal entities and individuals who have licenses for pharmaceutical activity</p> <p>PC-10.2. Monitors the procedure established by law regarding the compliance of available medicines for medical use, instructions and data on its safety and effectiveness</p>	<ul style="list-style-type: none"> – the structure of the modern health care system of the Russian Federation, the basics of the legislation of the Russian Federation on the protection of public health, the main regulatory and legal documents regulating relations in the field of circulation of medicines; – legal status of pharmaceutical entities: individual entrepreneurs and legal entities, types of legal entities; – regulatory framework for the creation, reorganization and liquidation of individual entrepreneurs and legal entities engaged in pharmaceutical activities; – regulatory framework for the creation, reorganization and liquidation of corporations engaged in pharmaceutical activities and other activities related to the circulation of medicines; – norms of legislation relating to state control and supervision in the field of pharmaceutical activities and other activities related to the circulation of medicines; – procedure and requirements for the implementation of pharmaceutical activities. – legal regime of property of subjects of pharmaceutical activity; – the procedure for recognizing the insolvency (bankruptcy) of pharmaceutical entities; – fundamentals of antimonopoly regulation of pharmaceutical activities and other activities related to the circulation of medicines and medical devices; – methods of legal protection of the rights and legitimate interests of subjects of pharmaceutical activity; – fundamentals of regulation of pharmaceutical activities and other activities related to the circulation of medicines and medical devices within the EAEU; – modern information technologies for solving problems of professional activity. 	<ul style="list-style-type: none"> – organize the creation, reorganization, liquidation of pharmaceutical entities; – carry out types of work or services constituting pharmaceutical activities, and activities in the field of circulation of medicines in compliance with the requirements of the legislation of the Russian Federation in the field of health protection; – use modern information technologies in solving problems of professional activity. 	<ul style="list-style-type: none"> – regulatory and legal documentation regulating the procedure for the creation, reorganization, liquidation of pharmaceutical entities; – regulatory documentation regulating the procedure for carrying out pharmaceutical activities and activities in the field of circulation of medicines – regulatory and legal reference systems, as well as professional databases for solving problems of professional activity

4. Sections of the academic discipline and competencies that are formed when mastering them.

№	Competence code	Section name of the discipline	The content of the section in teaching units
1.	PC-10	Legal aspects of organization of pharmaceutical activities	<p>State regulation of pharmaceutical activity as an element of the system of public health protection in pharmaceutical activities. Legal status of subjects of pharmaceutical activity.</p> <p>The procedure for the creation, reorganization and liquidation of pharmaceutical entities.</p> <p>Corporations in pharmaceutical activities and other activities related to the circulation of medicines and medical devices.</p> <p>Licensing of pharmaceutical activities.</p> <p>The general legal regime of the property of subjects of pharmaceutical activity.</p> <p>Insolvency (bankruptcy) of pharmaceutical entities.</p> <p>Antimonopoly regulation of pharmaceutical activities and other activities related to the circulation of medicines and medical devices.</p> <p>Protection of the rights and legitimate interests of subjects of pharmaceutical activity (jurisdictional and non-jurisdictional forms).</p> <p>Regulation of pharmaceutical activities and other activities related to the circulation of medicines and medical devices within the EAEU.</p>

5. Volume of the academic discipline and types of academic work.

Type of educational work	Labor intensity		Labor intensity in semesters (AH)
	volume in credit units (CU)	volume in academic hours (AH)	
			8
Classroom work, including	1,22	44	44
Lectures (L)	0,28	10	10
Laboratory practicum (LP)*	Laboratory practicums are not stipulated		
Practicals (P)	0,94	34	34
Seminars (S)	Seminars are not stipulated		
Student's individual work (SIW)	0,78	28	28
Mid-term assessment: credit			
TOTAL LABOR INTENSITY	2	72	72

6. Content of the academic discipline.

6.1 Sections of the discipline and types of academic work.

№	Semester	Name of the section of the academic discipline	Types of academic work* (in AH)					total
			L	LP	P	S	SIW	
1	8	Legal aspects of organization of pharmaceutical activities	10		34		28	72
		TOTAL:	10		34		28	72

* - L – lectures; LP – laboratory practicum; P – practicals; S – seminars; SIW – student’s individual work.

6.2. Thematic schedule of educational work types:

6.2.1 Thematic schedule of lectures

№	Name of lecture topics	Volume in AH
		8
1.	Legal status of subjects of pharmaceutical activity. The procedure for the creation, reorganization and liquidation of pharmaceutical entities.	2
2.	Corporations in pharmaceutical activities and other activities related to the circulation of medicines and medical devices.	2
3.	The general legal regime of the property of subjects of pharmaceutical activity.	1
4.	Insolvency (bankruptcy) of pharmaceutical entities.	2
5.	Antimonopoly regulation of pharmaceutical activities and other activities related to the circulation of medicines and medical devices.	2
6.	Regulation of pharmaceutical activities and other activities related to the circulation of medicines and medical devices within the EAEU.	1
TOTAL (total - 10 AH)		10

6.2.2. The thematic plan of laboratory practicums

Laboratory practicums are not stipulated.

6.2.3. Thematic plan of practicals

№	Name of the topics of practicals	Volume in AH
		8
1.	State regulation of pharmaceutical activity as an element of the system of public health protection in pharmaceutical activities. Legal status of subjects of pharmaceutical activity. Types of legal entities.	4
2.	The procedure for the creation, reorganization and liquidation of pharmaceutical entities.	4
3.	Corporations in pharmaceutical activities and other activities related to the circulation of medicines and medical devices.	4
4.	Licensing of pharmaceutical activities.	4
5.	The general legal regime of the property of subjects of pharmaceutical activity.	4
6.	Insolvency (bankruptcy) of pharmaceutical entities.	4
7.	Antimonopoly regulation of pharmaceutical activities and other activities related to the circulation of medicines and medical devices.	3
8.	Protection of the rights and legitimate interests of subjects of pharmaceutical activity (jurisdictional and non-jurisdictional forms).	4
9.	Regulation of pharmaceutical activities and other activities related to the circulation of medicines and medical devices within the EAEU. Credit.	3
TOTAL (total - 34 AH)		34

6.2.4. Thematic plan of seminars

Seminars are not stipulated.

6.2.5. Types and topics of student's individual work (SIW)

№	Types and topics of SIW	Volume in AH
		8
1	Work with literary and other sources of information on the section under study	12
2	Performance of tasks in the form of preparation of reports, speeches	8
3	Work with electronic educational resources	8
	TOTAL (total - 28 AH)	28

7. Educational, methodological and informational support for mastering the academic discipline (printed, electronic publications, the Internet and other network resources)

7.1. Key literature references

№	Name according to bibliographic requirements	Number of copies	
		at the department	in the library
1	The system of legislative regulation of circulation of medicines: Textbook / M.A. Mishchenko, E.V. Shalenkova, A.A. Ponomareva, N.N. Chesnokova, S.V. Kononova. – Nizhny Novgorod, 2021. – 77 p.	electronic resource	
2	Fundamentals of state legislation on manufacturing of medicines: Textbook / M.M.A. Mishchenko, E.V. Shalenkova, A.A. Ponomareva, N.N. Chesnokova, S.V. Kononova. – Nizhny Novgorod, 2021. – 56 p.	electronic resource	
3	Fundamentals of state legislation on pharmaceutical activities: Textbook / M.A. Mishchenko, E.V. Shalenkova, A.A. Ponomareva, N.N. Chesnokova, S.V. Kononova. – Nizhny Novgorod, 2021. – 50 p.	electronic resource	
4	The concept of good practices in the pharmaceutical regulatory system: Textbook / M.A. Mishchenko, E.V. Shalenkova, A.A. Ponomareva, N.N. Chesnokova, S.V. Kononova. – Nizhny Novgorod, 2021. – 57 p.	electronic resource	
5	Fundamentals of pharmaceutical economics: Textbook / M.A. Mishchenko, E.V. Shalenkova, A.A. Ponomareva, N.N. Chesnokova, S.V. Kononova. – Nizhny Novgorod, 2021. – 125 p.	electronic resource	
6	Prices and pricing in the pharmaceutical market: Textbook / M.A. Mishchenko, E.V. Shalenkova, A.A. Ponomareva, N.N. Chesnokova, S.V. Kononova. – Nizhny Novgorod, 2021. – 77 p.	electronic resource	
7	Product policy of a pharmaceutical organization: Textbook / M.A. Mishchenko, E.V. Shalenkova, A.A. Ponomareva, N.N. Chesnokova, S.V. Kononova. – Nizhny Novgorod, 2021. – 90 p.	electronic resource	

7.2. Further reading

№	Name according to bibliographic requirements	Number of copies
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		at the department	in the library
1	The medicine lifecycle concept: Textbook / M.A. Mishchenko, S.V. Kononova, A.A Ponomareva. – Nizhny Novgorod, 2020. – 80 p.	electronic resource	
2	Information technologies in the medicine lifecycle management: Textbook / M.A. Mishchenko, S.V. Kononova, A.A Ponomareva. – Nizhny Novgorod, 2020. – 99 p.	electronic resource	
3	Evaluating the quality of pharmaceutical information: Textbook / M.A. Mishchenko, S.V. Kononova, A.A Ponomareva. – Nizhny Novgorod, 2020. – 98 p.	electronic resource	
4	Analysis and processing of pharmaceutical information: Textbook / M.A. Mishchenko, S.V. Kononova, A.A Ponomareva. – Nizhny Novgorod, 2020. – 95 p.	electronic resource	
5	Post-marketing evaluation of medicinal products – pharmacoepidemiology: Textbook / M.A. Mishchenko, S.V. Kononova, A.A Ponomareva. – Nizhny Novgorod, 2020. – 53 p.	electronic resource	
6	Post-marketing evaluation of the medicinal products – pharmacoconomics: Textbook / M.A. Mishchenko, S.V. Kononova, A.A Ponomareva. – Nizhny Novgorod, 2020. – 107 p.	electronic resource	
7	Post-marketing evaluation of medicinal products – pharmacovigilance: Textbook / M.A. Mishchenko, S.V. Kononova, A.A Ponomareva. – Nizhny Novgorod, 2020. – 70 p.	electronic resource	
8	Fundamentals of the state regulation of pharmaceutical information that is advertising: Textbook / M.A. Mishchenko, S.V. Kononova, A.A Ponomareva. – Nizhny Novgorod, 2020. – 109 p.	electronic resource	

7.3. Electronic educational resources for teaching academic subjects

7.3.1. Internal Electronic Library System of the University (IELSU)

№	Name of the electronic resource	Brief description (content)	Access conditions	Number of users
1	Internal electronic library system (IELS) http://nbk.pimunn.net/MegaPro/Web	Works of university teaching staff: textbooks, manuals, collections of tasks, teaching aids, laboratory works, monographs, collections of scientific works, scientific articles, dissertations, abstracts of dissertations, patents	From any computer and mobile device with individual login and password. Access mode: http://nbk.pimunn.net/MegaPro/Web	Not limited

7.3.2. Electronic educational resources acquired by the University

<i>№</i>	<i>Name of the electronic resource</i>	<i>Brief description (content)</i>	<i>Access conditions</i>	<i>Number of users</i>
1	Electronic legal reference system "Consultant Plus" (contract for free) http://www.consultant.ru	Regulatory documents regulating the activities of medical and pharmaceutical institutions From the scientific library computers	Access mode: http://www.consultant.ru/	Not limited Term of validity: Unlimited

7.3.3 Open access resources

<i>№</i>	<i>Name of the electronic resource</i>	<i>Brief description (content)</i>	<i>Access conditions</i>
1	PubMed https://www.ncbi.nlm.nih.gov/pubmed	US National Library of Medicine search engine for Medline, PreMedline databases	From any computer and mobile device. Access mode: https://www.ncbi.nlm.nih.gov/pubmed Not limited
2	Scopus database www.scopus.com	International abstract database of scientific citation From university computers, from any computer by individual login and password	Access mode: www.scopus.com Not limited
3	Web of Science Core Collection https://www.webofscience.com	International abstract database of scientific citation. From university computers, from any computer by individual login and password.	Access mode: https://www.webofscience.com Not limited

8. Material and technical support for mastering an academic discipline

8.1. List of premises for classroom activities for the discipline

1. Classes for lectures and practical classes, equipped with multimedia and other means of training, allowing the use of simulation technologies, with standard sets of professional models (sets of protocols of clinical trials, formulary lists of LPU, price lists of distribution companies, sets of quality of life questionnaires), allowing students to master the skills and abilities, provided by professional activity, individually.

2. Simulation center "Educational pharmacy", equipped with simulation technics, which imitates the activity of pharmacy and its subdivisions (acceptance of goods, storage of goods, dispensing, pharmaceutical expertise of receipt) in the amount that allows students to master skills, provided by professional activity individually.

3. Rooms for students' independent work, equipped with computers with the ability to connect to the Internet and access to the electronic information and educational environment of the University.

8.2. List of equipment for classroom activities for the discipline

1. Multimedia complex (laptop, projector, screen, TV)
2. Computer class (15 computers) with installed applications and Internet access.

8.3. List of software

1. Online event platform "Webinar"

2. Yandex Browser
3. Reference system "Consultant Plus"

10. List of changes to the working program (to be filled out by the template)

Federal State Budgetary Educational Institution of Higher Education
 "Privolzhsky Research Medical University"
 Ministry of Health of the Russian Federation
 (FSBEI HE "PRMU" of the Ministry of Health of Russia)

Department of
Name of the department

CHANGE REGISTRATION SHEET

working program for the academic discipline
NAME OF THE ACADEMIC DISCIPLINE

Field of study / specialty / scientific specialty: _____
(code, name)

Training profile: _____
(name) - for master's degree programs

Mode of study: _____
full-time/mixed attendance mode/extramural

Position	Number and name of the program section	Contents of the changes made	Effective date of the changes	Contributor's signature
1				

Approved at the department meeting
 Protocol No. _____ of _____ 20__

Head of the Department _____ / _____
department name, academic title *signature* *print name*