



## CALENDAR-THEMATIC PLAN OF LECTURES

### Pharmaceutical Law and Legislation for 3 course

(the name of educational component)

In specialty 226 Pharmacy, industry pharmacy ФМ21\*(4,10Д)АНГЛ-01

(code and specialty name)

(group code)

(autumn semester 2023\2024)

№	Date	Lesson Name	Volume in hours	Lecturer
<b>MODULE 1. Pharmaceutical law and legislation</b>				
1.	05.09.2022	Pharmaceutical law and pharmaceutical legislation. Normative and legal regulation of pharmaceutical activity	2	Volkova A. V.
2.	12.09.2022	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	Volkova A. V.
3.	19.09.2022	Mechanism of the state registration and market authorization of new medicines for use in Ukraine. Intellectual property rights in health care	2	Volkova A. V.
4.	26.09.2022	Standardization and certification of the pharmaceutical activity. The drug quality assurance system	2	Volkova A. V.
5.	03.10.2022	Regulatory and legal support for turnover of various nomenclature and legal and classification-legal drug groups	2	Volkova A. V.
6.	10.10.2022	Legal aspects of the foreign economic activity and regulation of export and import of medicinal products	2	Volkova A. V.
7.	17.10.2022	The legal and regulatory framework of economic accessibility of pharmaceutical care	2	Volkova A. V.
8.	24.10.2022	Normative and legal aspects of the regulation of pharmaceutical activity in different countries.	2	Volkova A. V.
<b>Total:</b>			16	

Note: the lecture takes place at \_\_\_\_\_ in the classroom No \_\_\_\_\_

( day of the week) (time)

(classroom number)

Head of the Department,

Associated Professor

\_\_\_\_\_

Alina VOLKOVA



## CALENDAR-THEMATIC PLAN OF PRACTICAL LESSONS

**in Pharmaceutical law and legislation for 3 course**

(the name of educational component)

In speciality 226 Pharmacy, industry pharmacy ФМ21 (4,10Д) АНГЛ-01

(code and specialty name)

(group code)

(autumn semester 2023\2024)

№	Date	Lesson Name	Volume in hours Type of activity	Knowledge Assessment System, points	
				min	max
<b>CONTENT MODULE 1. Theoretical foundations of law, pharmaceutical law system and the system of pharmaceutical legislation. The legal basis of pharmaceutical companies.</b>					
1.	11.09.2023	Pharmaceutical law and pharmaceutical legislation. Normative and legal regulation of pharmaceutical activity.	4	5,5	9
2.	18.09.2023	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	5,5	9
3.	25.09.2023	Mechanism of the state registration and market authorization of new medicines for use in Ukraine. Intellectual property rights in health care.	4	5,5	9
4.	02.10.2023	Standardization and certification of the pharmaceutical activity. The drug quality assurance system	2	5,5	9
5.		<i>The final test of CM 1 assimilation</i>	2	8	14
<b>Total from CM 1:</b>				<b>30</b>	<b>50</b>
<b>CONTENT MODULE 2. The legal basis of pharmaceutical companies. Regulatory and legal support development, production and quality control of drugs</b>					
6.	9.10.2023	Regulatory and legal support for turnover of various nomenclature and legal and classification-legal drug groups	2	5,5	9
7.		Legal aspects of the foreign economic activity and regulation of export and import of medicinal products	2	5,5	9
8.	16.10.2023	The legal and regulatory framework of economic accessibility of pharmaceutical care	2	5,5	9
9.		Normative and legal aspects of regulation of pharmaceutical activity indifferent countries.	2	5,5	9
10.	23.10.2023	<i>The final test of CM 2 assimilation</i>	2	8	14
<b>Total from CM 2:</b>				<b>30</b>	<b>50</b>
	23.10.2023	<b>Semester credit of the module: "Pharmaceutical law and legislation"</b>	1		
<b>THE WHOLE AMOUNT OF HOURS FOR THE MODULE 1</b>			<b>27</b>	<b>60</b>	<b>100</b>

Head of the Department,  
Associated Professor

  
(signature)

Alina VOLKOVA