ODESA NATIONAL MEDICAL UNIVERSITY

Department of Organization and Economics of Pharmacy

PHARMACEUTICAL LAW AND LEGISLATION

A workbook for students training

Odesa, 2022

UDC 615.1.34(075)

This workbook is recommended by the Central Methodic Commission of the Odesa National Medical University
(minute No 1 dated 30.08.2022)

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Pharmaceutical law and legislation: workbook for training students of speciality 226 “Pharmacy, Industrial pharmacy”/ L. Unhurian, V. Protsenko, O. Bieliaieva, I. Vyshnytska, O. Stepanova. Odesa : ONMedU, 2022. 39 p.

The workbook is intended for training students of speciality 8226 “Pharmacy, Industrial pharmacy” while studying of Pharmaceutical law and legislation discipline. It contains purpose, theoretical questions and practical tasks.

The workbook is recommended for students of pharmaceutical higher schools and pharmaceutical faculties of higher educational institutions of the III-IV accreditation levels.

THEME 1. PHARMACEUTICAL LAW AND PHARMACEUTICAL LEGISLATION. NORMATIVE AND LEGAL REGULATION OF PHARMACEUTICAL ACTIVITY.

Purpose: to study definitions of law, the law system, the legislation system; pharmaceutical law; pharmaceutical legislation; norm of the law; legal act; legal relationship; offense and legal liability.

Theoretical questions:

1. Compare the law system and the legislation system.
2. National legal systems and the international law.
3. Regulatory legal acts as the sources of the law.
4. Classification criteria and characteristics of the normative legal acts.
5. The structure of the legislation system in pharmacy.
6. The hierarchy of normative legal acts in the pharmaceutical branch by legal force.
7. The definition, concept of an offense and its structure.
8. Types of offenses.
9. The concept, features and bases of legal responsibility.
10. Types of legal responsibility.

Practical part:

Task 1. Give the definition of “law” and “legislation”

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Task 2. Define differences between the law system and legislative system according to the following list of characteristics. Place the answer in the table 1.1.

Table 1.1

Characteristics	*Law System*	*Legislative System*
1	2	3
Laws and other normative legal acts (President, Government), that ordered in a certain way		+
Norms, rules of conduct, that established and identified by the State		
The inside of the law – the content		
The outside of the law – the form		
Norms branches of law – the material for a separate branch of law		
The logical distribution of legal norms by industry, institutions of law		
The presence the horizontal structure (on branches)		
The presence horizontal and vertical (hierarchical) structure		
The main element – rules of law		
The main element – an article of the Law		
The presence in the structural elements (NLA) section titles, preambles, common definitions		
The absence the exterior details of structural elements of (names sections, articles, chapters)		
The totality of the NLA		
The totality of legal rules		

Task 3. Name the main legal systems of the world and fill the table 1.2 with their characteristics.

Table 1.2

Characteristics	*Type of the legal systems*		
	Roman-German (Continental; Civil Law)		
The main source of law	*legal document (Statutes/legislation)*		
The lawmaking bodies	*public authorities, except court*		

Understanding of the rule of law	*mandatory rules of behavior*		
System of law	*principles are codified into a referable system which serves as the primary source of law – codified laws; hierarchical*		
Countries (examples)	*France, Germany, Spain, Ukraine, Iraq,Turkey, Egypt, Lebanon etc*		

Task 4. Match normative legal acts with bodies of their formation.

Normative legal acts:	*Source:*	
A. Law	1.	President
B. Decree	2.	Government
C. Resolution	3.	Parliament
D. Order	4.	Regional State Administration
E. Disposition	5.	Ministry

ANSWERS:

A.	**B.**	**C.**	**D.**	**E.**

Task 5. Select the correct combination from the list of names and functions of state bodies and write in table 1.3.

Functions:

Executive functions represent the state in relations with other countries (receives the credentials of foreign ambassadors, signs laws, issues acts, gives state awards, etc.);

Supervises the execution and compliance with laws and other normative acts;

Perform operational work on state management of public processes, provide stability, public relations that inviolability enshrined in the state;

Development and adoption of laws (normative acts having the highest legal force);

Performed jurisdictional activity, decide specific legal case: the penalties for violations, legal disputes, conflicts between different subjects (economic, labor, family, administrative, etc.).

Table 1.3

#	The names of public authorities:	Functions:
1.	Cour	
2.	Monarch	
3.	Parliament	
4.	Office of Public Prosecutor	
5.	Government	
6.	President	
7.	Special Supervisory Authorities (public service).	

Task 6. Complete the table 1.4 with the main sources of the pharmaceutical legislation, their hierarchical level and the legal effect.

Legal act:

- The Constitution of Ukraine
- Codes of Ukraine;
- The laws of Ukraine;
- other legal acts of the Verkhovna Rada (parliament)
- Decrees of the President
- Resolution of the government (CMU)
- Orders of the ministries and agencies
- Legal act of the local executive authorities

State registration:

- Uniform State Register of Legal Acts
- Ministry of Justice of Ukraine
- Department of Justice in regions and districts

Publication:

- Publication in the official printed sources in 15 days after adoption
- Published in specialized publications
- Mass media of the local authorities

The period of entry into power:

- In 10 days after the publication if otherwise is not specified by the legal act
- After publication
- In 10 days after registration

Table 1.4

Hierarchy levels	Legal act	State registration	Publication	The period of entry into power
Higher level				
Level I				
Level II				
Level III				
Level IV				

Self-assessment of knowledge:

1. Give the definition of "law", "legal system" and "legislation".
2. Formulate the main principles and the sources of the law.
3. Give the characteristics of different types of the legal systems.
4. Explain the hierarchical structure of the pharmaceutical legislation.
5. Describe the structure of legislation in the European Union legal field.
6. Describe the main types of offenses.
7. Identify and define the main elements of the offense.
8. Define the legal responsibility, specify its types.

THEME 2. PERMISSION SYSTEM IN THE FIELD OF THE ECONOMIC ACTIVITY. THE LEGISLATIVE FOUNDATION OF THE STATE SURVEILLANCE (CONTROL).

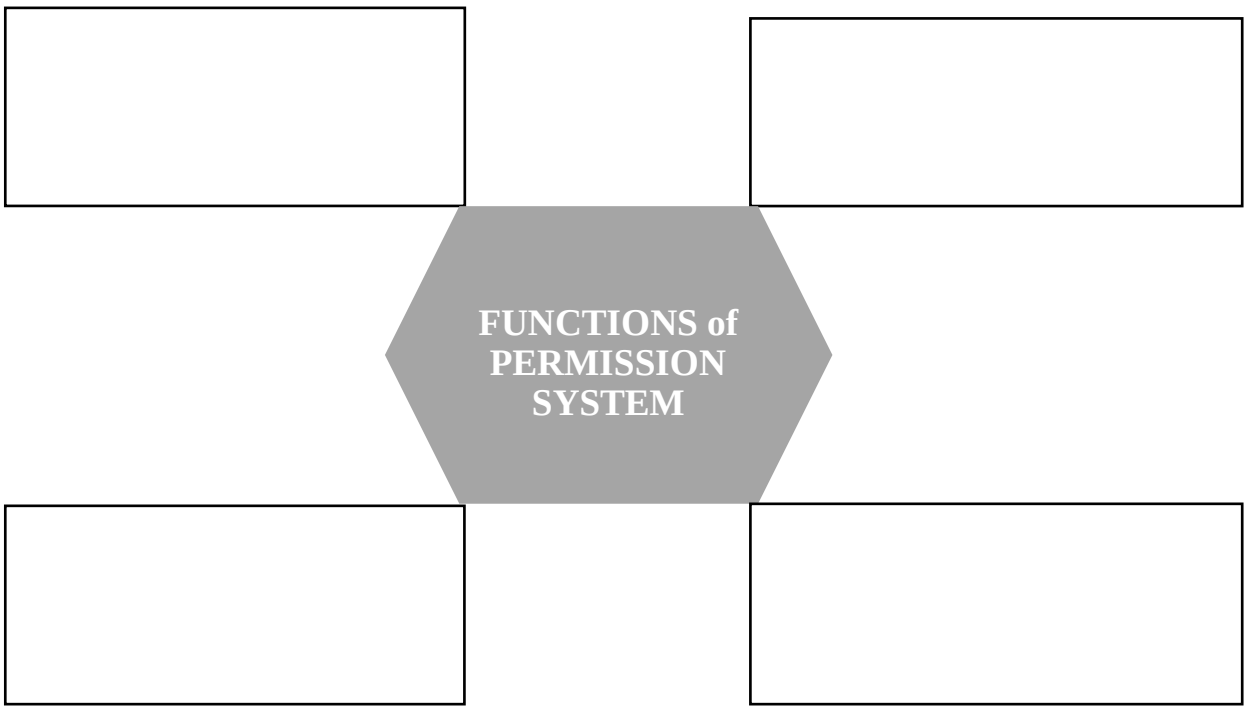
Purpose: to study permission system in the field of the economic activity, authorization document; business entity; license, licensee, licensing authority; state surveillance, inspection, the main tasks of State Service of Ukraine on medicines and drugs control.

Theoretical questions:

1. The basic concepts of permission system of Ukraine in the field of the economic activity.
2. Functions and principles of permission system in the field of the economic activity.
3. Licensing as a main part of the control and permission system in the pharmaceutical field.
4. The basic principles of the state policy in licensing.
5. Responsibility for offenses related with turnover of medicines and other medical products.

Practical part:

Task 1. Describe functions of permission system (scheme 2.1):



Scheme 2.1 The main functions of permission system

Task 2. Choose correct terms for their definitions (table 2.1):

Table 2.1

Terms	Definitions
	a permission, conclusion, decision, approval, certificate, other document, including in the electronic form, that must be issued by a regulatory authority to the business entity in the case of granting the rights in course of certain types of the economic activity
	a business entity with the license for a definite type of the economic activity
	the basic mechanisms of the government control for the activity of the legal and natural persons directed to the concordance of interests of business entities and society as a whole
	a document issued by licensing authority for the right to implement a definite type of the economic activity by an economic entity
	legal acts of Government, provisions which establish an exhaustive list of requirements are mandatory for the licensee and an exhaustive list of documents attached to the application for a license

Terms: A license, a licensee, licensing conditions (provisions), licensing

Task 3. Write the types of the pharmaceutical activity subjected to licensing in your country and in Ukraine. Are they the same?

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Task 4. Complete the table 2.2 with requirements according to the licensing conditions and documents for obtaining a license for different type of pharmaceutical activity in Ukraine.

Table 2.2

	Compounding of medicines	*Production of medicines*	*Wholesale*	*Retail sale*	*Import of medicines*
Requirements for business entity					
Required documents					

Task 5. The main directions of the state surveillance (table 2.3).

Table 2.3

The main directions of the state surveillance

Task 6. Describe responsibility for offenses related with turnover of medicines and other medical products

Self-control of knowledge:

1. Define the principles of the regulatory activity.
2. Explain the main directions of the state policy in the field of medicines turnover regulation.
3. Define the terms “licensing”, “licensee”, “license”.
4. Indicate the types of the pharmaceutical activity subjected to licensing.
5. Describe the procedure for licensing of the pharmaceutical activity by the retail sale of medicines.
6. Describe the grounds for the license cancellation.
7. Define the concept of “the state surveillance”.
8. Indicate the grounds for conducting scheduled and unscheduled inspections of business entities.
9. Describe the procedure for selecting drug samples for laboratory testing.
10. The offenses related with turnover of medicines and medical products.
11. Kinds of responsibility for turnover of medicines and medical products violations.

THEME 3. MECHANISM OF THE STATE REGISTRATION AND MARKET AUTHORIZATION OF NEW MEDICINES FOR USE IN UKRAINE. INTELLECTUAL PROPERTY RIGHTS IN HEALTH CARE.

Purpose: to study stages and characteristics of state registration of medicines; registration certificate; intellectual property rights in health care system, objects of copyright, invention, protection of rights.

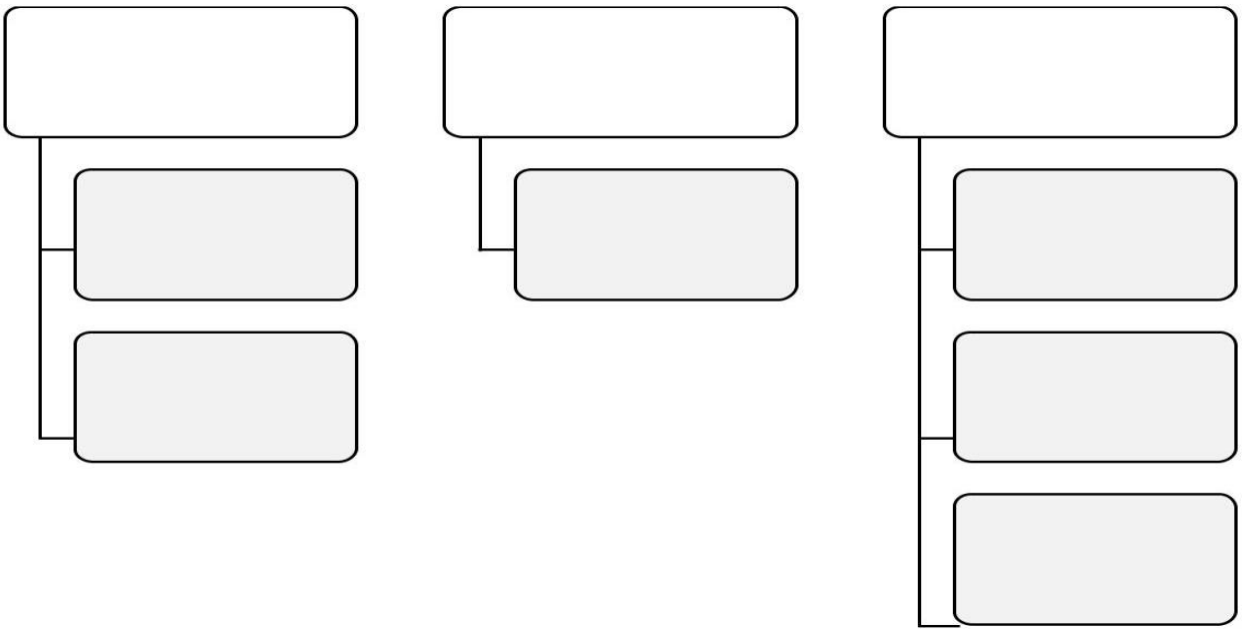
Theoretical questions:

1. Registration of medicines as a mechanism of the pharmaceutical market authorization. The procedure for the expert examination of drugs submitted for the state registration (re-registration).
2. The order of keeping the State Register of Medicinal Products of Ukraine.
3. The concept of intellectual property in healthcare.
4. Objects of the intellectual property law: marks for goods and services, patented inventions, industrial samples, objects of copyright.
5. Legal mechanisms for the protection of intellectual property rights.

Practical part:

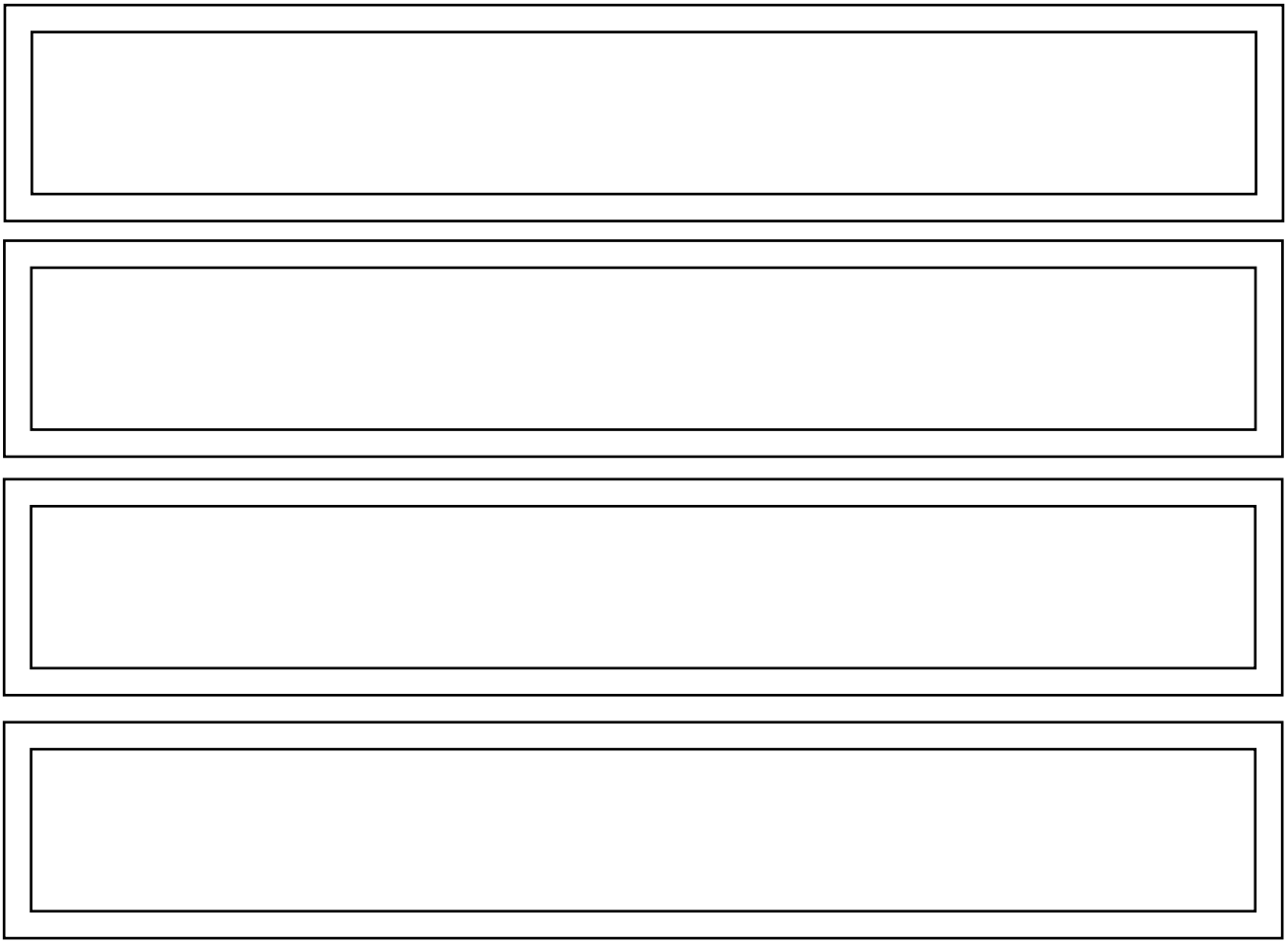
Task 1. Describe medications, which are the subject to state registration, complete the scheme 3.1.

Medications, subject to state registration



Task 2. Describe subjects of interaction in the process of state registration of medicines, complete the scheme 3.2.

Scheme 3.2 State Expert Center



Task 3. Name the main stages of the procedure for the expert examination of medicines submitted for the state registration, describe them (table 3.1).

Table 3.1

#	Stage	Explanation

Task 4. Indicate the name of the organization that carries out the drug registration procedure in USA market, in Ukraine and in your country.

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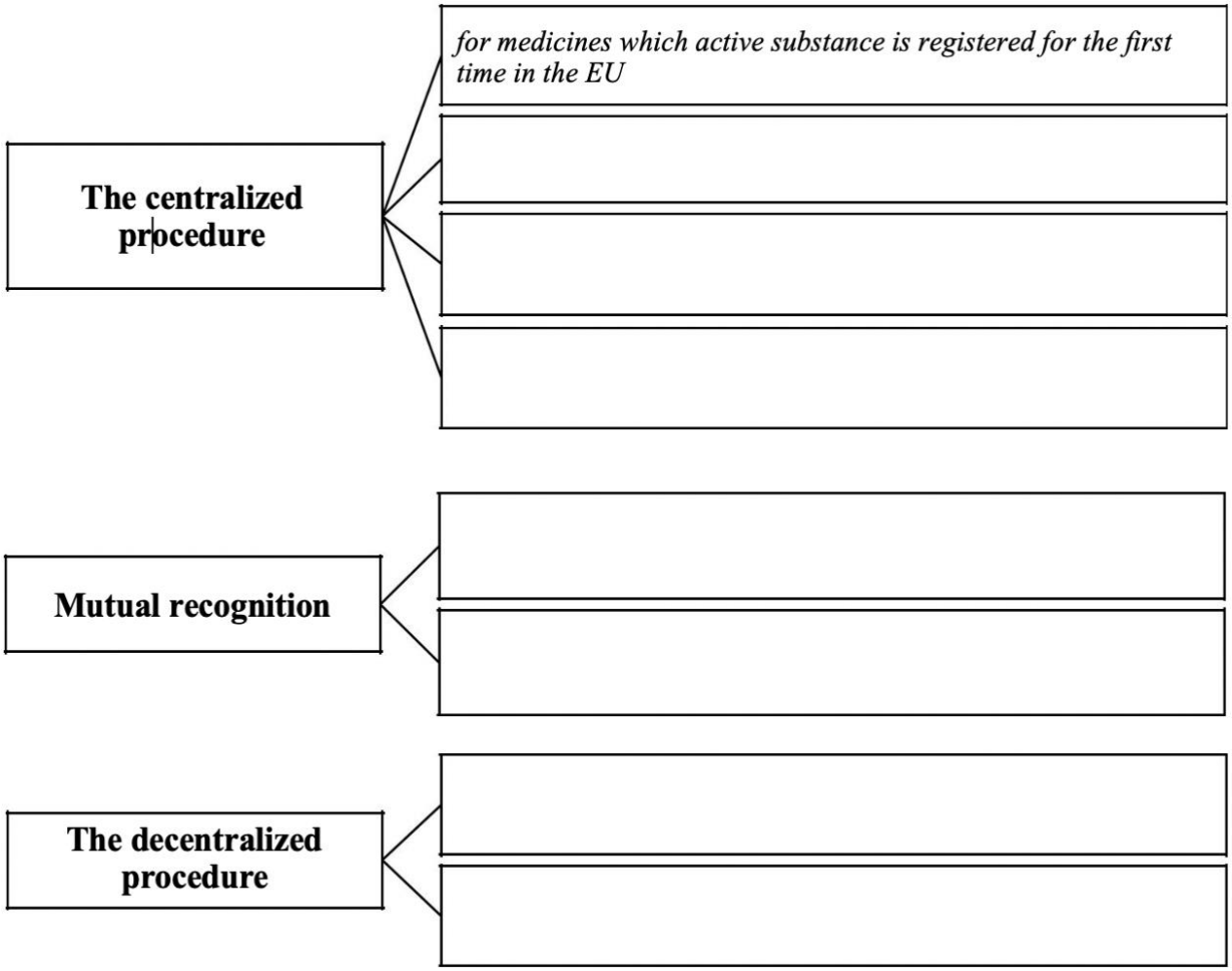
Task 5. Describe procedures by which medicines can receive marketing authorization in the EU countries.



Task 6. From the list of intellectual property objects in the pharmaceutical industry select the right for each classification (table 3.2).

Table 3.2

Objects of intellectual property law	**Copyrights**	**Inventions**	**Utility models (usefulmodels)**	**Industrial designs**	**Commercial designations**
active pharmaceutical ingredient					
dosage forms (capsule; packaging)					
company names					
drug label projects					
finished product manufacturing equipment					
manufacturers logo					
method of producing an active substance					
new medical use of the product					
pharmaceutical composition					
projects of instruction for medical use					
pharmaceutical excipient					
report about development of analytical procedures for quality control of substances and finished pharmaceutical product					
trade name of medicines					
reports on the preclinical and clinical study of drugs					

Self-control of knowledge:

1. Describe the procedure for accessing a drug to the pharmaceutical market in Ukraine and other countries.
2. Explain the stages of the state expert examination of the drug registration materials.
3. Formulate the concept of the intellectual property in healthcare.
4. Describe the main objects of the intellectual property.
5. Characterize the components of the intellectual property rights.
6. Indicate the categories of inventions.
7. Give a comparative description of two forms of protection of intellectual property.

THEME 4. STANDARDIZATION AND CERTIFICATION OF THE PHARMACEUTICAL ACTIVITY. THE DRUG QUALITY ASSURANCE SYSTEM

Purpose: to study processes of standardization and certification in pharmaceutical field; certificate of conformity; quality system; advertising and promotion of medicines.

Theoretical questions

1. Standardization in pharmacy.
2. Classify standardization.
3. Types of standards.
4. Certification in the pharmaceutical activity as a guarantee of quality.
5. Legal and regulatory framework of the drug quality assurance system.
6. The state control over drug promotion at the market.
7. Advertising of drugs.

Practical part:

Task 1. Match the terms and definitions given in the table 4.1:

Table 4.1

Terms	*Definitions*
1.	set of organizational measures to be taken in order to guarantee compliance with quality drugs their assignment, including ensure that drugs are developed and studied with regard GLP/GMP requirements
2.	a set of properties that give consumers the ability to meet drugs in accordance with its purpose and correspond to the requirements established by legislation
3.	procedure whereby an independent third face provides the individual guarantee that the product is in the form of a good or service, process or structure of the organization to meet the requirements
4.	work on establishment rules, regulations and specifications for common and repeated use in the existing or potential problems in order to achieve the optimum degree of order in the sphere of development, production, quality control, registration and sale of drugs

5.	document issued by the producer about accordance of a series of drugs with the requirements established during its registration
6.	document with information about samples tested drugs with the results of laboratory tests and the conclusion of compliance to acting Ukraine and issued analyzing laboratory medicine quality subordinate or authorized by state administration of Ukraine on medicinal products
7.	a certain amount of product discharged from a certain amount of raw materials in a single production cycle or homogenized during about the the production and preparation process in accordance with normative documentation

Terms: Conclusion of quality, Series of drug, Quality of drug, The quality certificate manufacturer, Certification, Standardization, Quality assurance

Task 2. Explain the basic requirements for drug quality (table 4.2)

Table 4.2

The basic requirements for drug quality				
↓	↓	↓	↓	↓
Safety	Compatibility	Reliability	Discrepancy	Conformity

Task 3. Characterize components of the certification system (table 4.3)

Table 4.3

The name of the procedure	The procedure content	Document

Task 4.There is advertisement of Panadol on TV, the warning text: "Self-medication may be harmful to your health", occupying near 5% of the area. Was this advertisement made according to the rules?

Argue your answer and write the list of mandatory requirements for filling an information message that should be put forward to the content of publicity advertising of drugs, medical products, methods of prevention, diagnosis, treatment and rehabilitation, which advertising is not prohibited.

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Self-control of knowledge:

1. Give the definition of the concept of "standardization" and name the historical background for its emergence.
2. Describe the legal and regulatory framework of standardization, name the objects of standardization.
3. Give the essence of the standard, present the classification.
4. Describe the role of the pharmacopoeia as a quality standard for drugs.
5. Name the international standards of the pharmaceutical activity and their degree of harmonization with national standards.
6. What is the role and goal of the PIC/S?
7. Give the list of ISO standards and call the organization that develops these standards.
8. Give the definition of "certification" concept and name its components in relation to drugs.
9. Which bodies are involved in the certification of pharmaceutical companies in Ukraine?
10. Describe certification of the quality systems in enterprises. What advantages does it provide?
11. What documents regulate the quality assurance of medicines in Ukraine?
12. Give the definition of the concepts of "quality" and "quality system".
13. Formulate the basic requirements for quality of drugs.

THEME 5. REGULATORY AND LEGAL SUPPORT FOR TURNOVER OF VARIOUS NOMENCLATURE AND LEGAL AND CLASSIFICATION-LEGAL MEDICINE GROUPS

Purpose: to study classification-legal group of drugs; poisonous and potent medicines; psychotropic substances; narcotic drugs; precursors; analogs of narcotic drugs and psychotropic substances; nomenclature and legal group of drugs.

Theoretical questions:

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

Practical part:

Task 1. Match the terms and definitions given in the table 5.1:

Table 5.1

#	Terms	Definitions
1.		natural or synthetic substances, drugs, natural materials included in the list of narcotic drugs, psychotropic substances and precursors, and that affects the functioning of the central nervous system, leading to a change in mental status.
2.		group that indicates the form of drugs realization (prescription and OTC)
3.		legislative requirements, regulatory and methodological documents for legal nomenclature and legal classification characterization of drugs.
4.		group, which indicates the safety profile of the effects of drugs on the body of the patient (potent, poisonous, narcotic drugs, psychotropic substances, precursors, etc.).
5.		substances used for the production, manufacture of narcotic drugs, psychotropic substances included in the List of narcotic drugs, psychotropic substances and precursors.
6.		natural or synthetic substances, drugs, plants, psychoactive drugs, which upon administration to a human influence on his psyche and behavior, change the emotional condition, will, mind, and included in the List of narcotic drugs, psychotropic substances and precursors.

Terms:

Classification legal group, Nomenclature legal group, Control regime, Narcotic drugs, Precursors, Psychotropic substances

Task 2. Describe (table 5.2) Normative and legal regulation of the narcotic drugs, psychotropic substances and precursors turnover at the international level:

- UN Single Convention «On Narcotic Drugs» (New York), March 30, 1961 https://www.unodc.org/pdf/convention_1961_en.pdf

- Convention on Psychotropic Substances, 1971 https://www.unodc.org/pdf/convention_1971_en.pdf

- United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988 https://www.unodc.org/pdf/convention_1988_en.pdf

Table 5.2

Year of adoption	*Name of the Convention*	*The main results*
1961	UN Single Convention «On Narcotic Drugs» (New York), March 30, 1961	
1971	Convention on Psychotropic Substances	
1988	United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances	

Task 3. Give classification of narcotic drugs, psychotropic substances and precursors (table 5.2) according to The Single Convention on Narcotic Drugs (UN, 1961)
http://www.emcdda.europa.eu/system/files/attachments/10448/convention_1961_en.pdf

Table 5.2

List of drugs	*Measures of control and restrictions*
Schedule I	
Schedule II	
Schedule III	
Schedule IV	

Task 4. Give classification of narcotic drugs, psychotropic substances and precursors Compare criteria for classifying medicines into the category of prescription and non- prescription, using the provisions of Directive 2001/83/EC of the European

Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (Article 70-72) and fill in results in table 5.3.

Table 5.3

Criteria	Group of medicines	
	a medicine is a subject to medical prescription	a medicine is not a subject to medical prescription
Medicines and its ingredients don't cause direct or indirect damage to health of the consumer		+
Medicines are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health	+	
Medicines are intended mainly for outpatients (using in ambulatory)		
Medicines are normally prescribed by a doctor to be administered parenterally		
Medicines present a danger either directly or indirectly, even when used correctly, if utilized without medical supervision		
Medicines don't contain substances or preparations thereof, the activity and/or adverse reactions of which require further investigation		
Medicines are likely, if incorrectly used, to present a substantial risk of medicinal abuse, to lead to addiction or be misused for illegal purposes		
Medicines are used in the treatment of conditions which must be diagnosed in a hospital environment or in institutions with adequate diagnostic facilities, although administration and follow-up may be carried out elsewhere		
Medicines, because of its pharmaceutical characteristics or novelty or in the interests of public health, are reserved for treatments which can only be followed in a hospital environment.		
Medicine contains, in a non-exempt quantity, a substance classified as a narcotic or a psychotropic substance within the meaning of the international conventions in force, such as the United Nations Conventions of 1961 and 1971.		

Task 5. Analyze the list of medicines in Table 5.4 and determine the form of prescription on the basis of Directive 2001/83 / EC of the European Parliament and of the Council "On the Community code relating to medicinal products for human use" https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:en:PDF

Table 5.4

Brand Names of the Medicines	Dosage Forms	INN	Prescription / non-prescription
SOMAXON, (Mili Healthcare, United Kingdom)	solution for injection 500 mg 2 ml, 5 amp.	Citicolinum	
ACC®200, (Sandoz, Germany)	powder 200 mg	Acetylcysteinum	
PEROXYGEL, (GEMI, Poland)	gel 3% 40 G	Hydrogenii peroxidum	
ACIDUM ASCORBI-NICUM-DARNITSA, (Darnitsa, Ukraine)	solution for injection 100 mg 2 ml, 10 amp.	Acidum ascorbicum	
DEPO-PROVERA, (Pfizer Inc., USA)	injectable susp. 400 mg/ml	Medroxyprogesterone acetate	
OTRIVIN®, (Novartis Consumer Health SA, Switzerland)	0.1% nasal spray 10 ml	Xylometazolinum	
DEPODUR, (Pacira Pharma-ceuticals, USA)	oral tablet 5 mg № 50	Morphinum	
RELIUM (Polfa, Poland)	oral tablet 5 mg № 20	Diazepamum	
RETINOLI ACETAS (Vitamin, Ukraine)	oil sol., dermal, 10 ml, № 1	Retinolum	

Self-control of knowledge:

1. Name the regulatory lists of medicines, substituate their significance for the healthcare industry and pharmacy.
2. Indicate the categories of prescription drugs.
3. Indicate which state bodies have the right to monitor compliance with the rules for dispensing medicines from pharmacies and their structural units.
4. Identify and characterize the type of the legal responsibility that occurs when selling drugs from a pharmacy without a prescription in cases prohibited by the law.

THEME 6. LEGAL ASPECTS OF THE FOREIGN ECONOMIC ACTIVITY AND REGULATION OF EXPORT AND IMPORT OF MEDICINAL PRODUCTS.

Purpose: to study foreign economic activity and contract; methods of managing the foreign economic activity; duty, customs tariff of Ukraine; international regulatory organizations; import of drugs and medical products, general license, the state registration of imported medicines.

Theoretical questions

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

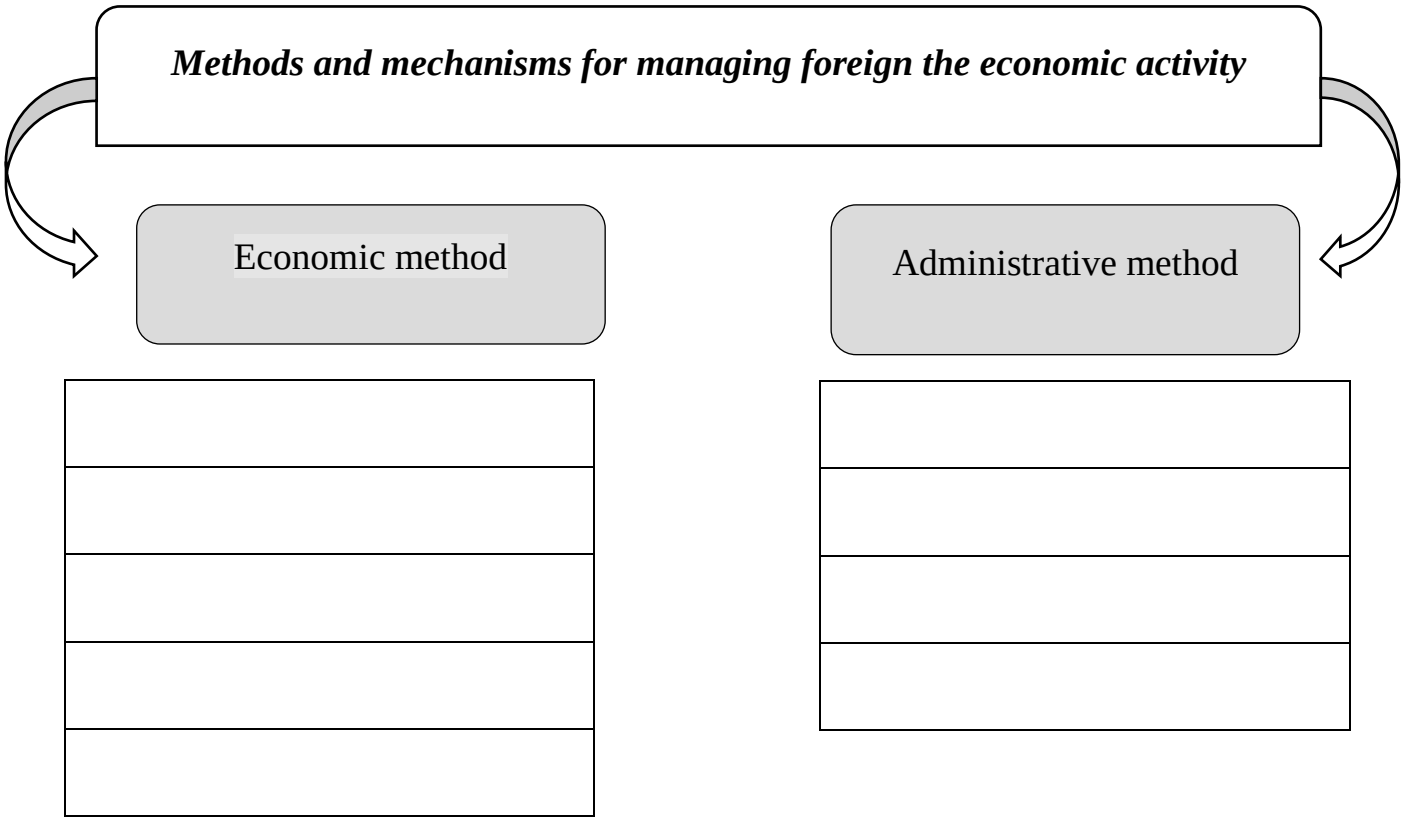
Practical part:

Task 1. Describe the basic principles of the foreign economic activity (FEA) and their content. Complete table 6.1.

Table 6.1

Principles	*Content*
Sovereignty in implementation of the FEA	
Freedom of the foreign economic entrepreneurship	
Legal Equality	
Supremacy of the statute law	
Protection of interests of subjects of the FEA	
Equivalence of exchange, prohibition of dumping when importing and exporting goods	

Task 2. Explain methods and mechanisms for managing foreign the economic activity (scheme 6.1)



Scheme 6.1 Methods and mechanisms for managing foreign the economic activity

Task 3. Export and import operations in the international market are regulated by organizations that promote international cooperation, define the principles of world trade, regulate the monetary and financial relations. Match the major activities of international trade with the names of the regulatory organizations **(**World trade, monetary and financial organizations). Complete table 6.2.

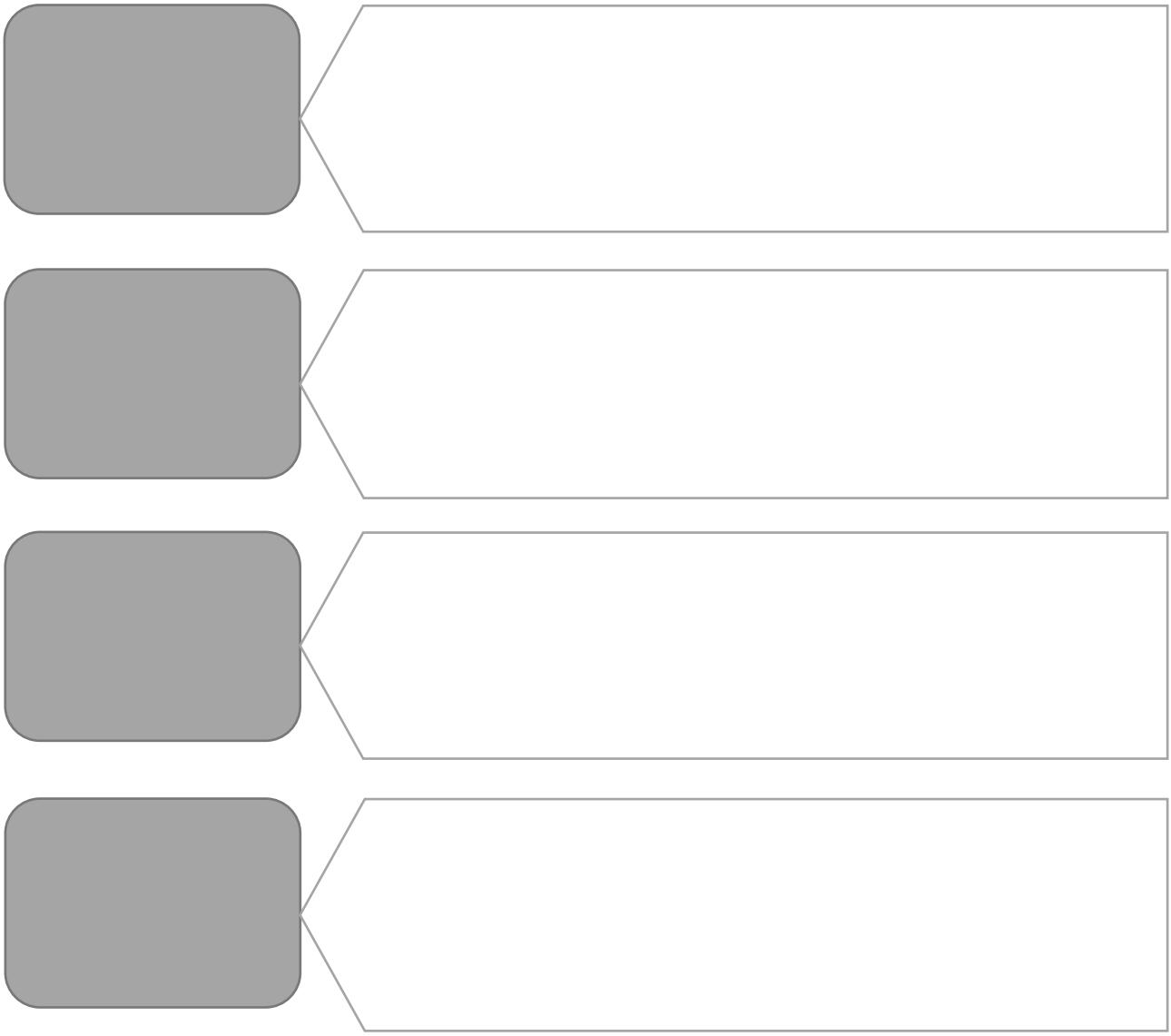
Table 6.2

International organizations	Activities
	the only global international organization dealing with the rules of trade between nations. The goal is to help producers of goods and services, exporters, and importers conduct their business. It is an organization for trade opening. It is a forum for governments to negotiate trade agreements. It is a place for them to settle trade disputes. It operates a system of trade rules.
	a non-binding, informal co-operative arrangement between Regulatory Authorities in the field of GMP of medicinal products for human or veterinary use

	an international organization headquartered in Washington, D.C., of 189 countries working to foster global monetary cooperation, secure financial stability, facilitate international trade, promote high employment and sustainable economic growth, and reduce poverty around the world
	an international financial institution that provides loans to developing countries for capital programs. It comprises two institutions: the International Bank for Reconstruction and Development (IBRD), and the International Development Association (IDA)

International organizations: The World Bank, International Monetary Fund (IMF), World Trade Organization (WTO), Pharmaceutical Inspection Cooperation Scheme (PIC/S)

Task 4. Characterize the main stages of the procedure for legalization of drugs imported into Ukraine (scheme 6.2).



Task 5. Citizen of Morocco are going to come to Ukraine for study in ONMedU. Does he need to registrate medicines that he uses to prevent his allergy, medicines are not produced in Ukraine? Explain what are cases in which import of unregistered drugs is envisaged on the territory of Ukraine.

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Self-control of knowledge:

1. Give the definition of the term “foreign economic activity”.
2. Describe the principles of the foreign economic activity.
3. Indicate the types of the foreign economic activity.
4. Explain methods and management tools of the FEA.
5. Give a description of customs and tariff regulation of the FEA.
6. Explain the types of duties and criteria for their classification.
7. Describe the main activities of international organizations that regulate the world trade, monetary and financial relations.
8. Describe the main principles of the WTO.
9. Give a description of the main stages for obtaining a license to carry out the economic activity for importing drugs in Ukraine.
10. Describe the conditions for conducting a laboratory analysis of the imported drug batch.
11. Indicate the cases, in which import of unregistered drugs into Ukraine is allowed.

THEME 7. THE LEGAL AND REGULATORY FRAMEWORK OF ECONOMIC ACCESSIBILITY OF PHARMACEUTICAL CARE

Purpose: to study health insurance, reimbursement, the state privilege, public benefits, price and pricing system, types of taxes and its collection, system of taxation, simplified taxation system.

Theoretical questions

1. The concept of health insurance.
2. Reimbursement of the cost of pharmaceutical care as an effective socio-economic mechanism to provide its accessibility to the population.
3. Privilege dispensing of medicines, its legal and regulatory framework.
4. Privilege categories and population groups.
5. The legislative basis of the pharmaceutical pricing.
6. Features of formation of the medicine price.
7. The state regulation of medicine prices.
8. Taxes as an economic, public and legal category.
9. The system of taxation of medicines and medical products.

Practical part:

Task 1. Match the terms with definitions. Complete table 7.1.

Table 7.1

Terms	Definitions
	the complete or partial exemption from the fulfillment of a duty or granting of additional rights to the definite categories of citizens provided by the legislation
	an insured patient pays a definite percentage of the cost of medicines (the specified percentage can be 0%), the compensation funds come directly from the insurance company to a medical or pharmacy institution on the basis of a written agreement (contract) between the insurance fund, medical institution and pharmacy
	a type of obligatory social insurance, which is the system of legal, economic and organizational measures created by the state aimed at ensuring, in the event of an insured event, guarantees for free medical care provided to the insured person at the expense of compulsory health insurance (CHI)
	the complete or partial exemptions of definite categories of citizens from the fulfillment of a duty or granting of additional rights in the event of social risk provided by the law.

	an insured patient pays for the medical services or medicines provided, while receiving an invoice for the amount spent, which is given to the insurance company

Terms:

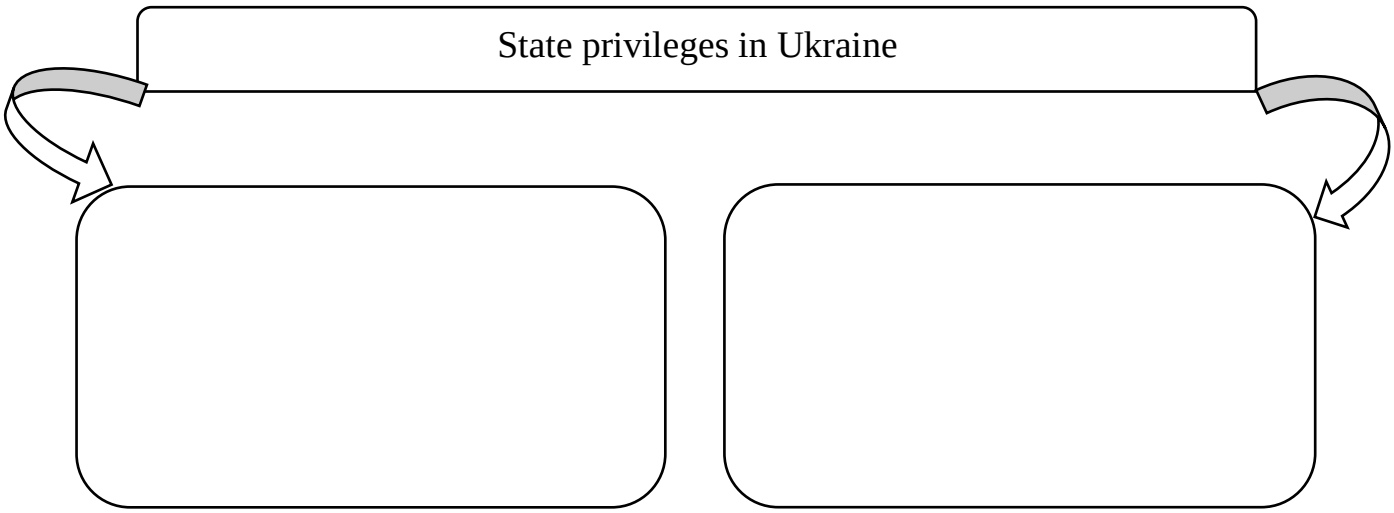
The reimbursement mechanism for insured persons, The reimbursement mechanism for pharmacies and medical institutions, Compulsory health insurance, The state privilege, Social privileges

Task 2. Characterize the main classification criteria and typical conditions for providing reimbursement with examples of countries. Complete table 7.2.

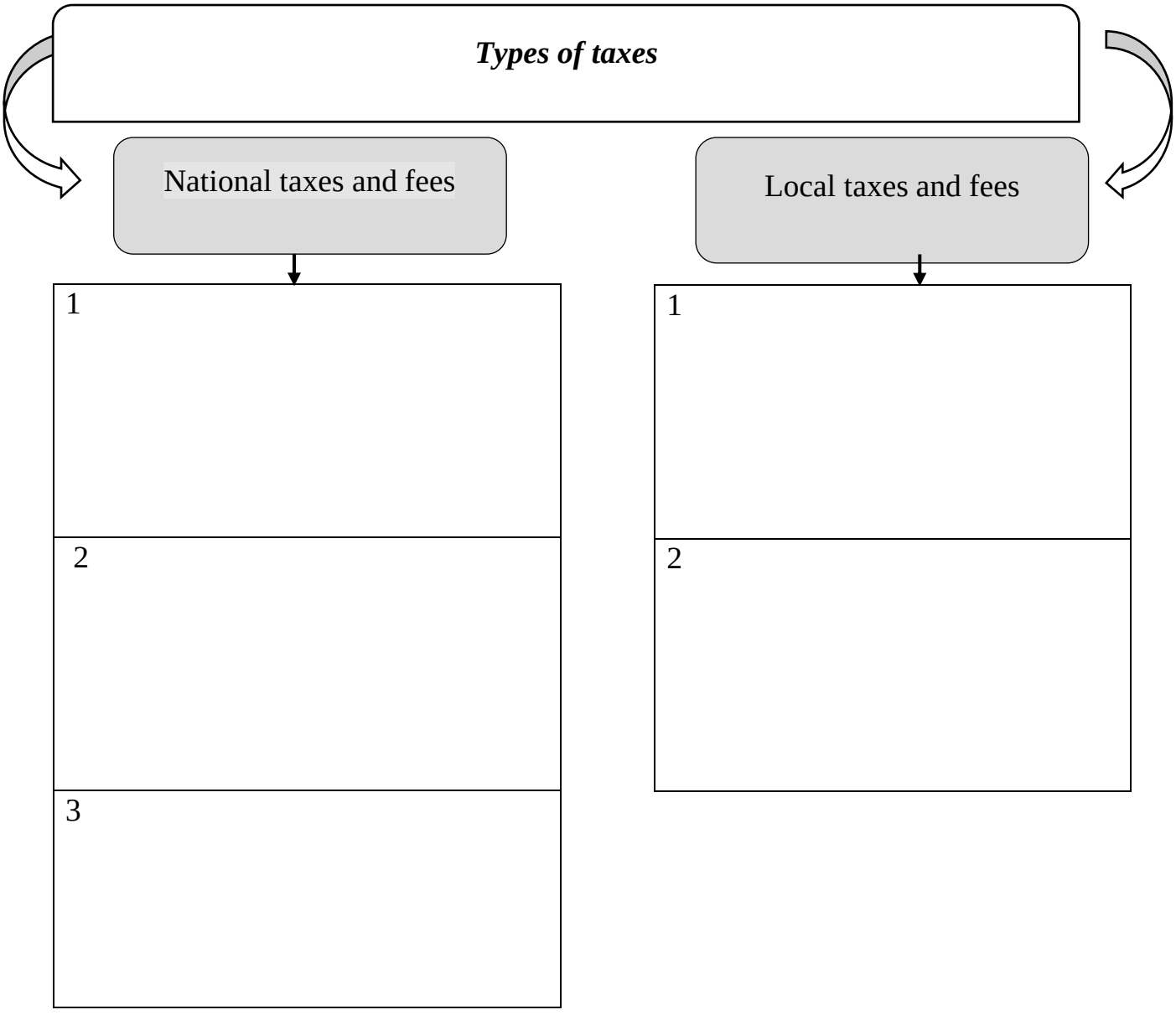
Table 7.2

Criteria of the classification	Terms and Conditions of the compensation	Countries in which the criterion is used
1. The category of patients and the list of diseases, in the treatment of which compensation for the cost of medicines is provided		
2. The type of pharmaceutical care		
3. Price Characteristics		
4. Pharmacothera-peutic characteristics of drugs		

Task 3. Give the classification of the system of the state privileges in Ukraine



Task 4. Classify taxes and fees in Ukraine



Task 5. Explain the main types of legal acts that regulate the pricing system in pharmacy in Ukraine

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Self-control of knowledge:

1. Define the terms “tax”, “collection”, explain their difference.
2. Name the principles of taxation in Ukraine and define their socio-economic content.
3. Specify the main elements of the tax system in Ukraine.
4. Describe the features of taxation in the pharmaceutical sector of the healthcare.
5. Give the classification of taxes depending on the object of taxation.
6. Characterize pricing and the price system in pharmacy.
7. Name the subjects of pharmaceutical pricing and characterize their main socio-economic tasks.
8. Specify the legislative act that defines the basic principles of the pricing policy in Ukraine and regulates the relations arising in the process of formation, establishment and application of prices.
9. List the methods of the state regulation of drug prices in Ukraine and legal acts regulated the use of these methods.
10. Describe the procedure for formation of purchasing and retail prices for medicines purchased at the expense of the population.
11. Indicate the groups of countries in the world depending on the methods of the state price regulation in pharmacy and the reasons that cause this differentiation.

THEME 8. NORMATIVE AND LEGAL ASPECTS OF REGULATION OF THE PHARMACEUTICAL ACTIVITY IN DIFFERENT COUNTRIES.

Purpose: to study gross healthcare system, expenditure on healthcare, system of medical insurance, system of drug pricing, reimbursement of the cost of pharmaceutical care in different countries abroad.

Theoretical questions

1. Characteristics of the modern pharmaceutical legislation in the countries of the Transcaucasian and Central Asian region.
2. The legal and regulatory framework of healthcare and pharmacy in African countries.
3. The pharmaceutical law and legislation in the Middle East countries.
4. The features of the legal and regulatory framework of the pharmaceutical activity in different countries abroad.

Practical part:

Task 1. Compare legal and regulatory framework of healthcare and pharmacy in Ukraine and your country. What are the main differences between them?

Task 2. Prepare presentation about features of the legal and regulatory framework of the pharmaceutical activity in country abroad on your choice. Discuss with your groupmates chosen topics.

Self-control of knowledge:

1. What are the historical and socioeconomic features of formation of healthcare systems in the Transcaucasian and Central Asian regions?
2. Give a comparative description of the modern pharmaceutical legislation of Azerbaijan, Tajikistan and Uzbekistan. Determine the current direction of its improvement.
3. Indicate the main directions of the normative regulation of healthcare and pharmacy in Africa (Morocco, Tunisia, South Africa Republic).
4. Describe the features of the pharmaceutical law and legislation in the countries of the Middle East.
5. Name the main problematic issues of the state regulation of the pharmaceutical activity in the Middle East.
6. Describe the modern provisions of the legal and regulatory framework of the pharmaceutical activity in Poland, Czech Republic, Germany, Austria etc.
7. Name the mechanisms and methods of the state regulation of the pharmaceutical activity in the United States. Describe the main state programs in healthcare.
8. Formulate the main trends in development of the pharmaceutical law and legislation in the international practice.
9. Indicate the factors affective development of the world pharmacy.

Graded test questions

1. The law system and the legislation system. National legal systems and the international law.
2. Regulatory legal acts as the sources of the law. Classification of the normative legal acts.
3. The structure of the legislation system in pharmacy. The hierarchy of normative legal acts in the pharmaceutical branch by legal force.
4. Features of the pharmaceutical legislation in the European Union: the main types of legal acts in the EU legal framework.
5. The concept and types of legal relationships. Legal relationships arising when implementing the pharmaceutical activities.
6. The concept of an offense and its structure. Types of offenses .
7. The concept, features and bases of the legal responsibility. Types of the legal responsibility.
8. The permission system of Ukraine in the field of the economic activity sphere: basic concepts, structure, functions and principles.
9. Licensing as a component of the control and permission system in the field of the economic activity. The basic principles of the state policy in licensing .
10. Legislative framework of state surveillance (control) in the sphere of turnover of medicine and medical products.
11. The procedure for selecting drug samples for laboratory testing of their quality.
12. Responsibility for offenses related with turnover of medicines and other medical products.
13. Registration of medicines as a mechanism of the pharmaceutical market authorization. The procedure for the expert examination of drugs submitted for the state registration (re-registration).
14. The order of keeping the State Register of Medicinal Products of Ukraine.
15. The concept of intellectual property in healthcare.
16. Objects of the intellectual property law: marks for goods and services, patented inventions, industrial samples, objects of copyright.
17. Legal mechanisms for protection of the intellectual property rights.
18. Standardization and certification in pharmacy.
19. Certification in the pharmaceutical activities as a guarantee of quality.
20. Legal and regulatory framework of the drug quality assurance system.
21. The State control over drug promotion at the market. Advertising of the drugs.
22. Nomenclature and legal and classification-legal groups of medicines. Regulatory lists of medicines.
23. The State regulation and control of the turnover of narcotic drugs, psychotropic substances, precursors in healthcare and pharmacy institutions.
24. Responsibility for violation of legislation in the sphere of circulation of nomenclature and legal and classification-legal groups of medicines.
25. The concept of the foreign economic activity. Instruments for regulating foreign economic activity.

26. International organizations regulating the world trade, monetary and financial relations.
27. The legal and regulatory framework of the import of pharmaceutical products to the territory of Ukraine.
28. The concept of health insurance. Reimbursement of the cost of pharmaceutical care as an effective socio-economic mechanism to provide its accessibility to the population.
29. Privilege dispensing of medicines, its legal and regulatory framework. Privilege categories and population groups.
30. The legislative basis of the pharmaceutical pricing. Features of the formation of the drug price. The state regulation of drug prices.
31. Taxes as an economic, social and legal category. The system of taxation of medicines and medical products.
32. Characteristics of the modern pharmaceutical legislation in the post-Soviet countries of the Transcaucasian and Central Asian region.
33. The legal and regulatory framework of healthcare and pharmacy in African countries.
34. The pharmaceutical law and legislation in the Middle East countries.
35. The features of the legal and regulatory framework of the pharmaceutical activity in different countries abroad.

List of practical skills, the mastery of which is monitored during differentiated assessment

– systematization of normative legal acts; documentation of the process of obtaining a license for retail and wholesale sale of drugs;
– regulatory and legal support for monitoring compliance with the requirements of the sanitary regime for pharmacies and their structural subdivisions;
– use of the algorithm for conducting incoming quality control of drugs and medical devices;
– formation of the staff of the pharmacy establishment in accordance with the qualification requirements for personnel engaged in the production (in the conditions of the pharmacy) and retail trade of drugs;
– use of various sources and forms of transmission of pharmaceutical information;
– dispensing OTC-medicines, providing advice on rational use and proper storage of medicines;
– pharmaceutical examination of prescriptions received from the population in accordance with legislation;
– organizing and conducting incoming quality control of medicinal products;
– to analyze the formation of drug prices, including taking into account the state regulation of drug prices;
– formation of retail prices for medicines and medical products;
– documentation of the process of state supervision (control) in the field of pharmaceutical activity on various issues;
– qualify offenses in pharmaceutical activity; choose responsibility for violations of legislation at various stages of circulation of medicinal products.

Recommended literature

Basic

1. Pharmaceutical Law and Legislation : the textbook for applicants for higher education / A.A. Kotvitskaya, I.V. Kubarieva, A.V. Volkova et al. Kharkiv : NUPh : Golden Pages, 2019. 204 p.
2. Pharmaceutical law and legislation: texts of lectures for students of the specialty 226 “Pharmacy. Industrial pharmacy "/ Unhurian L.M., Vyshnytska I.V., Bielyaieva O.I. etc.; ed. L. Unhurian. Odessa: ONMedU, 2020. 98 p.

Additional

1. Comorbidities as factors influencing choice of drug in arterial hypertension therapy / Vyshnytska Iryna, Unhurian Liana, Bieliaieva Oksana, Pietkova Iryna. Medical theory: collective monograph / Bulavenko Olga, Muntian Olga, Muntian Maksym, Yarovenko Anatolii, etc. International Science Group. Boston: Primedia eLaunch, 2020. P. 68-76. Available at: DOI: 10.46299 / isg.2020.MONO.MED.II
2. Implementation of Standards of Good Pharmacy Practice in the World: A Review / Liana Unhurian, Oksana Bielyaieva, Irina Vyshnytska, Natalia Suschuk, Irina Petkova // Asian Journal of Pharmaceutics. Jan-Mar 2018 (Suppl). 12 (1). - R. 42-46.
3. J. Herring Medical Law and Ethics: sixth edition, Oxford university press, 2016. 710 p.
4. Pharmacy Laws and rules: Washington State Department of Health, 2017. 845 p.

Electronic resources:

1. Base of standards of medical care in Ukraine. Internet resource - http://www.moz.gov.ua/ua/portal/standards.html
2. Directive 2011/83 / EC of the European parliament and of the Council of 6 November2011 «On the Community coderelating to medicinal products for human use» [Electronic resource]. – Access mode: http://ec.europa.eu/health/files/eudralex/vol-1/dir_2001_83/2001_83_ec_en.pdf
3. State Register of Medicines of Ukraine: website. URL: http://drlz.com.ua/
4. Pharmacy weekly: website. URL: https://www.apteka.ua/.
5. Legislation of Ukraine: website. URL: http://zakon.rada.gov.ua/laws
6. Normative-directive documents of the Ministry of Health of Ukraine: website. URL: http: // mozdocs.kiev.ua
7. Drug Search Base: Website. URL: https://tabletki.ua/.
8. Drug Search Base: Website. URL: http://likicontrol.com.ua/.
9. Medscape Search Base: Website. URL: https://www.medscape.com/pharmacists.
10. Regulatory framework of NTA Ukraine: website. URL: https://www.hta.ua
11. Compendium online: website. URL: https://compendium.com.ua/
12. National library of medicine. URL: https://pubmed.ncbi.nlm.nih.gov
13. FDA. URL: Access: https://www.fda.gov
14. WHO. URL: https://www.who.int