SOCIAL PHARMACY

TRAINING MANUAL

THE MINISTRY OF HEALTH OF UKRAINE
NATIONAL UNIVERSITY OF PHARMACY
Department of Social pharmacy

SOCIAL PHARMACY

Training manual for classroom work for students of the Faculty for Foreign Citizens' Education

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The training manual for classroom work is intended for use in practical classes in the course "Social Pharmacy" by students in the specialty 226 Pharmacy, industrial pharmacy of the Faculty for Foreign Citizens' Education.

The publication contains a list of theoretical questions for each topic in accordance with the content of the curriculum of the discipline, practical and situational tasks to be performed in the classroom, a list of recommended literature.

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CONTENT

INTRODUCTION

Comprehensive health care reform processes are taking place through conceptual change and the introduction of new forms of medical and pharmaceutical care. Today, pharmacy is defined as an independent social institution with a multilevel structure, whose main task is to preserve and improve the health of the population by providing highly qualified pharmaceutical care, which led to a new scientific and practice-oriented concept – social pharmacy.

The subject of study of social pharmacy is the health of citizens, the study of dependence on the impact of a complex of social, psychological, environmental factors. Social pharmacy combines pharmacy with economics, law, sociology, political science, psychology, computer science, management, demography and statistics and other sciences, characterizes the health of the population, the effectiveness of the health care system and pharmaceutical supply. Social pharmacy can be considered as an interdisciplinary and interdisciplinary science that combines basic, clinical and sociological sciences, where the implementation of pharmaceutical professions at the social level, taking into account the impact of legislation on pharmaceutical activities, public health, economy, training and availability of specialists, patient compliance etc.

Social pharmacy as a discipline belongs to the cycle of compulsory disciplines of professionally oriented training of specialists in the specialty 226 Pharmacy, industrial pharmacy and is based on the study of such courses as Ethics and Deontology in Pharmacy, Organization and Economics of Pharmacy, Clinical Pharmacy and integrates with such courses in curriculum of NUPh, as Pharmaceutical law and legislation, Pharmacoeconomics.

The purpose of teaching the discipline "Social Pharmacy" is the formation of systematic knowledge on socio-economic aspects of the organization of pharmaceutical support at the macro and microeconomic levels, as well as the formation of professionally important skills to implement socio-economic mechanisms to ensure access to pharmaceutical care.

The main tasks of studying the discipline "Social Pharmacy" are the formation of students' necessary knowledge, skills and abilities on: theoretical foundations of social policy in providing the population with medicines (drugs) in Ukraine and abroad; use of the legal framework for regulating the social and economic aspects of pharmaceutical activities; conducting a comprehensive analysis of the main socio-economic indicators of the effectiveness of pharmaceutical provision of the population, drawing conclusions and creating forecasts; adherence to the basic principles of pharmaceutical ethics in the conduct of professional activities by specialists in the pharmaceutical sector of health care.

Lesson 1

Topic 1-2: INTERNATIONAL EXPERIENCE IN THE FORMATION AND DEVELOPMENT OF SOCIAL PHARMACY. THE CONCEPT OF SOCIAL PHARMACY AS AN INTEGRAL PART OF A MODERN AND EFFICIENT PHARMACEUTICAL SECTOR OF THE HEALTHCARE INDUSTRY

Purpose: to study current trends in the pharmaceutical sphere and analyze them; know the structure and features of professional activity; know the basic mechanisms of state regulation of pharmaceutical activities; know the principles of organizing pharmaceutical care to the population; know organizational structure of the pharmaceutical system in Ukraine, its goals, objectives and functions; be able to determine the indicators of physical and economic accessibility of pharmaceutical care to the population in the dynamics of the years, on a territorial basis and at the level of the business entity; be able to analyze the impact of key factors on the indicators of physical and economic affordability of pharmaceutical care.

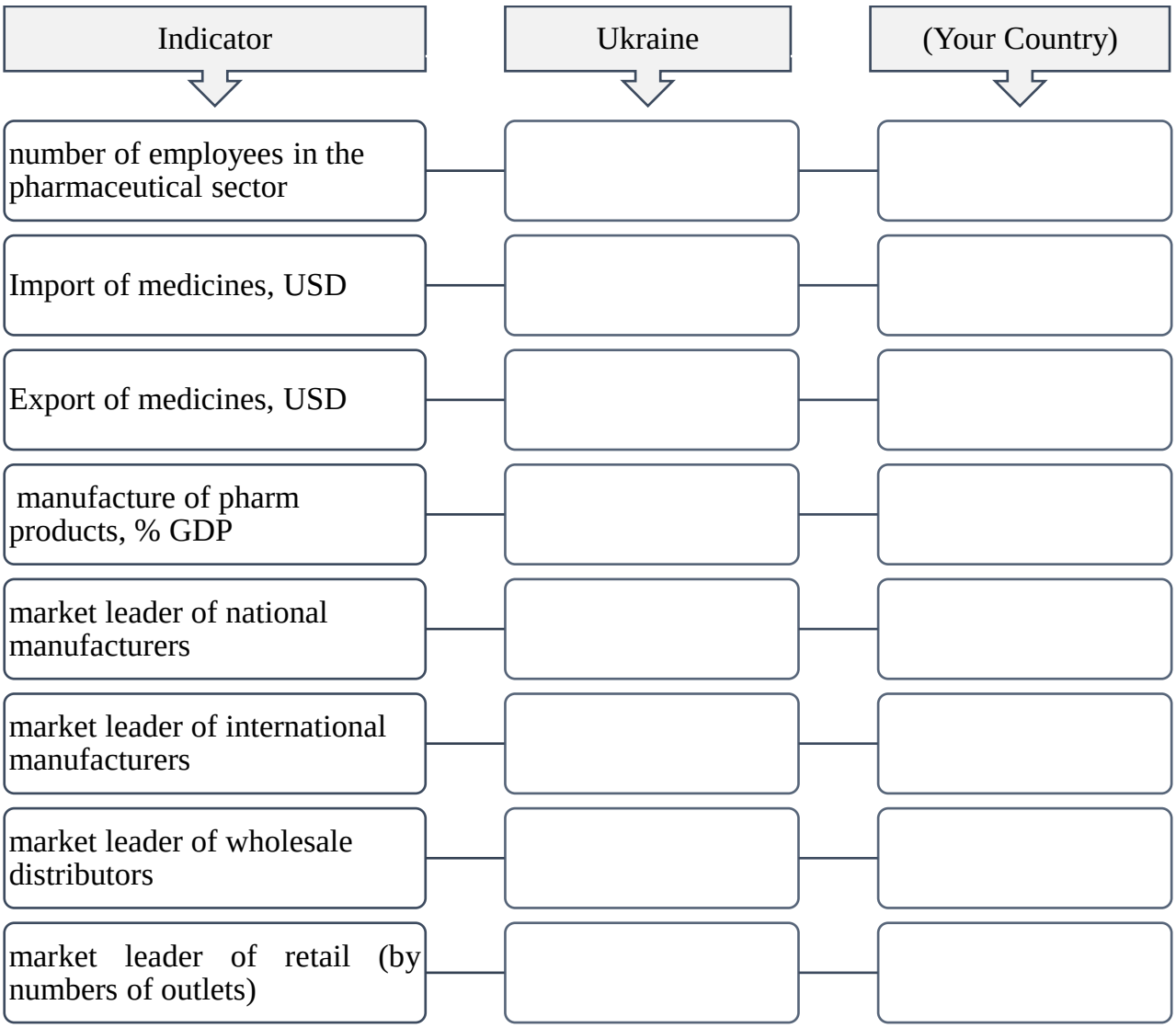
Theoretical questions:

1. Historical aspects of the formation and development of social pharmacy. Social pharmacy in Ukraine: origin, formation and development.
2. Social pharmacy as an interdisciplinary science. The relationship of social pharmacy with other disciplines.
3. Methods and objects of research in social pharmacy
4. The health care system as an important component of the social sphere. Characteristics of the pharmaceutical healthcare sector.
5. Systems of indicators of socially effective pharmaceutical provision

Practical tasks:

Task 1

Please describe the current pharmaceutical healthcare sector by using key indicators and compare obtained results for Ukraine and Your country:



Task 2

Please carry out a retrospective analysis of the development of pharmaceutical sector of healthcare industry in Ukraine. Comparative analysis of the main indicators is carried out by *the growth coefficient (GC), growth rate (GR), increase rate (IR).*

Additional information

Indicator		Calculation formula
GC	=	*index next year ÷ the indicator of the previous year*
GR	=	*the rate the following year ÷ the indicator of the previous year × 100%*
IR	=	*GR – 100%*

Level indicators of pharmaceutical provision of the population in Ukraine

	Indicators	***2015***	***2016***	***2017***	***2018***	***2019***
1	public expenditures on healthcare (% of GDP)	3,7	2,5	2,8	2,6	3,8
2	pharmaceutical market size (pharmacy sales, bln. UAH))	49.2	59.9	72.6	89.0	103.9
3	pharmaceutical market size (pharmacy sales, bln. of units)	1.51	1.59	1.69	1.75	1.7
4	total number of registered medicines	12859	13024	12841	13205	13503
	• number of registered local medicines	3673		3831	4060	4130
	• number of registered imported medicines	9186		9010	9145	9373
5	number of national manufactures	110		115	113	114
6	Production volume, billion UAH		20.1	24.6	34.2	
7	Export of medicines, million USD	155	184	180	216	251
8	Import of medicines, million USD	1367	1607	1767	1947	2143
9	A number of wholesale pharmaceutical enterprises	497		505		425
10	pharmaceutical network structure					
	• number of pharmacies	14625	15325	16118	16256	16457
	• pharmacy branches	4457	4410	4401	4305	4163
	• compounding pharmacies	390		387		325
11	population served by one pharmacy					
12	the number of pharmacies per 1 thousand km^2					
13	per capita consumption of medicinal products, USD	52	54	62	73	

** Population of Ukraine as of 01.07.2020— 41 762 138 people (according to the State statistics service of Ukraine)*

*** The total area of Ukraine is 603.5 thousand square kilometers. km^2 (according to the State service of Ukraine for geodesy, cartography and cadaster).*

	Indicators	***2016 / 2015***			***2017 / 2016***			***2018 / 2017***			***2019 / 2018***		
		GC	***GR***	***IR***	***GC***	***GR***	***IR***	***GC***	***GR***	***IR***	***GC***	***GR***	***IR***
1	public expenditures on healthcare (% of GDP)												
2	pharmaceutical market size (pharmacy sales, bln UAH))												
3	pharmaceutical market size (pharmacy sales, bln of units)												
4	total number of registered medicines												
	• number of registered local medicines												
	• number of registered imported medicines												
5	number of national manufactures												
6	Production volume, billion UAH												
7	Export of medicines, million USD												
8	Import of medicines, million USD												
9	A number of wholesale pharmaceutical enterprises												
10	pharmaceutical network structure												
	• number of pharmacies												
	• pharmacy branches												
	• compounding pharmacies												
11	population served by one pharmacy												
12	the number of pharmacies per 1000 km^2												
13	per capita consumption of medicinal products, USD												

For calculations:

General conclusions _____

Lesson 2

Topic 3: RATIONAL PHARMACOTHERAPY AS THE MAIN ELEMENT OF EFFECTIVE AND SAFE PHARMACEUTICAL CARE

Purpose: to master the theoretical foundations of the rational use of medicines, the organizational structure of the WHO Basic List of Essential Medicines for Adults and Children of the National List of Health Care Products, the peculiarities of the functioning of the system of pharmaceutical support for palliative patients with severe, socially dangerous and rare (orphan) diseases.

Theoretical questions:

1. System of rational use of drugs: principles, goals, objectives, functions, mechanisms of regulation and directions of implementation.
2. Characteristics of the main elements of standardization of medical and pharmaceutical information.
3. Pharmaceutical support for palliative patients. Description of the regulatory framework for the organization and provision of medical and pharmaceutical care to palliative patients in Ukraine and abroad.
4. The main positive features and problematic issues of pharmaceutical support for palliative patients.
5. Pharmaceutical provision of patients with rare (Orphan) diseases.
6. Features of the functioning of the system of pharmaceutical provision for patients in need of social protection.

Practical tasks:

Task 1

Match the term name (1-7) to its meaning (A-C):

Term name		Term meaning	
1	Rational use of medicines	**A**	is that the activities, capabilities and available resources of stakeholders in the Healthcare system are aligned to ensure that patients are able to receive the necessary (essential) medicines at the right time, use them appropriately, for the benefit of patients
2	Industry Standard for Healthcare	**B**	a list of effective, safe, pharmacoeconomically justified medicines necessary to ensure the provision of medical and pharmaceutical care to the population at the expense of state and local budgets.

3	Responsible use medicines	**C**	it is the use of medicines that meet their clinical needs, in doses that suit their individual needs, for a sufficient period of time, at the lowest cost to patients and society. At the same time, medicines must be of adequate quality, physically and economically available to patients and society.
4	Orphan diseases	**D**	a set of measures for the application of a multidisciplinary approach aimed at alleviating the physical and emotional suffering of palliative patients, as well as providing psychosocial and moral support to their family members.
5	Palliative care	**E**	tuberculosis, sexually transmitted infections, AIDS, leprosy.
6	Socially dangerous infectious diseases	**F**	diseases characterized by a severe, chronic course, progressive course, accompanied by the formation of degenerative changes in the body, a decrease in the quality and a reduction in the life expectancy of patients and even pose a threat to their life (diseases are extremely rare - less often than one case per 2000 population of the country).
7	National List of Essential Medicines	**G**	it is a set of norms, rules and regulations, as well as indicators (indicators) of the quality of medical care of the corresponding type, which are developed taking into account the current level of development of medical science and practice.

Answers:

1.	**2.**	**3.**	**4.**	**5.**	**6.**	**7.**

Task 2

Check out the WHO Core List of Essential Medicines (https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines/essential-medicines-lists) and indicate the purpose, structure of the WHO List of Essential Medicines. Show the answer in Fig. 1.

Fig. 1. Organizational structure of the WHO Core List of Essential Medicines

Task 3

Analyze the WHO Core List of Essential Medicines for Adults and Children *(https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines/essential-medicines-lists*). Compare the list of medicines (INN, dosage form) that are used to treat fungal infections in children and adults (6.3 Antifungal medicines). Complete the table 1.

Table 1

WHO lists of essential medicines for adults	WHO lists of essential medicines for children
The Core List:	

The Complementary List:	

Task 4

Describe the components of palliative care. Complete the Fig. 2.

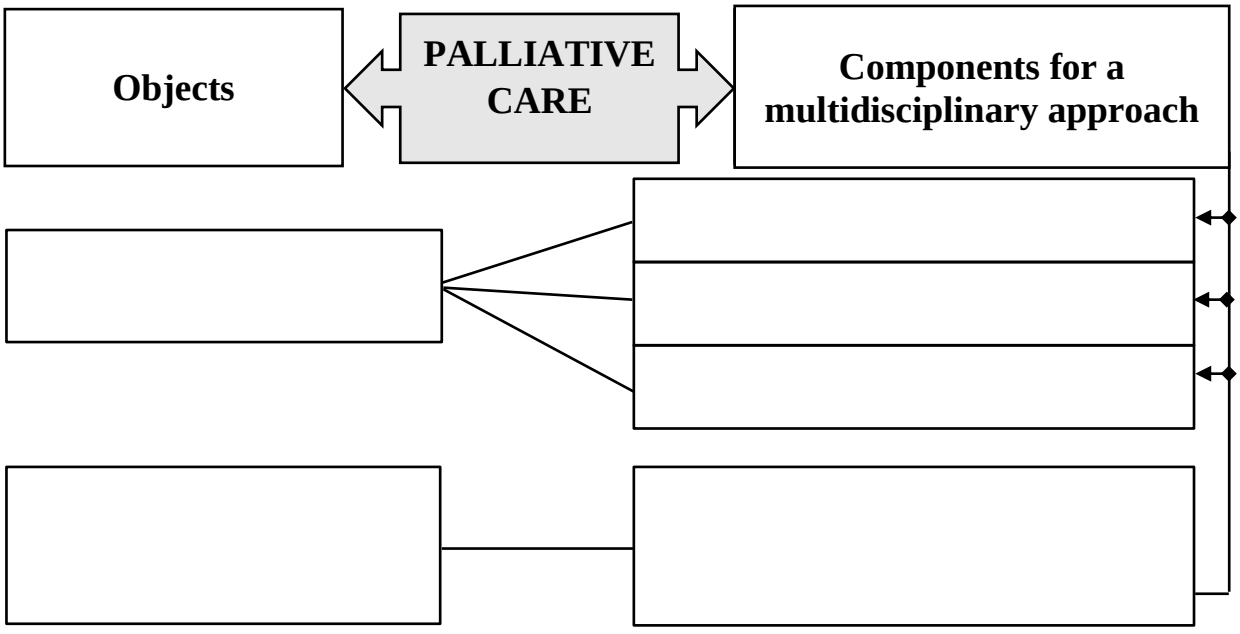


Fig 2. The main components of palliative care

Task 5

Indicate which medicines are recommended for use in palliative care according to the WHO EML (2 Medicines for pain and palliative care) (***https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines/essential-medicines-lists***). Complete the table 2.

Table 2

Indicators	The Core List	The Complementary List
Group		
INN taking into account the form of issue		
Group		
INN taking into account the form of issue		
Group		
INN taking into account the form of issue		

Task 6

Indicate the limits for the classification of diseases as orphan (rare) in different countries of the world. Complete the table 2.

Table

Countries	Limit levels
USA	
European Union	
Australia	
Japan	
Ukraine	

Task 7

Indicate the main criteria for assigning the status of "orphan drugs" to a medicinal product:

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General conclusions: _____
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Lesson 3

Topic 4: PHARMACOEPIDEMIOLOGY AS A COMPONENT OF SOCIAL PHARMACY

Purpose: to analyze the elements of rational use concept of medicines; provide a description of the basic elements of research on medicine consumption, analyze medicine consumption using the methodology of ATC-DDD, which is recommended by the WHO; to assess the conformity of medicines leading in consumption with the epidemiological situation in Ukraine; analyze the information obtained as a result of research, summarize and systematize it for use in professional activities.

Theoretical questions:

1. Fundamentals of pharmacoepidemiology: dynamics, trends.
2. Pharmacoepidemiological studies and indicators.
3. Organization of the system of statistics in health care of Ukraine.
4. Population health and demographic trends in Ukraine.

Practical tasks:

Task 1

Answer the test questions:

1. Choose the basic scientific elements on which the *concept of rational use of medications* is based among the following:

□ Clinical pharmacology
□ Marketing analysis
□ Pharmacoeconomics
□ Pharmacoepidemiology
□ Pharmacotherapy

2. The concept of rational use of medications is based on the use of three basic scientific elements, one of which is pharmacoepidemiology. Choose *a component of pharmacoepidemiology* from the following:

□ Medication safety assessment
□ Estimation of pharmacotherapy costs
□ Assessment of economic affordability of medications
□ Evaluation of medication efficacy
□ Assessment of the physical availability of medications

3. Name the applied science of studying the effectiveness and safety of drug consumption in real conditions (after their entry into the pharmaceutical market) at the level of the population or large groups of people in order to promote their rational use

□ _____

4. Confirmation of the therapeutic efficacy of the drug and detection of its side effects after entering the pharmaceutical market and implementation in general medical practice is the purpose of:

□ Preclinical studies
□ Marketing research
□ Socio-economic research
□ Pharmacoeconomic research
□ Pharmacoepidemiological research

5. *Drug utilization* research, as defined by the WHO, includes the study of sales, distribution, purpose and practice of drug use in society and is one of the areas in pharmacoepidemiology. Name the *main purpose of research on drug consumption*:

□ _____

Task 2

In order to compare data on drug consumption in different countries around the world, a new unit of measurement - DDD (defined daily dose) was developed and a unified classification system – ATC (Anatomical Therapeutic Chemical classification system) was adopted. Determine ATC-codes and DDD for individual drugs using the data of the WHO site – ***https://www.whocc.no/atc_ddd_index/***, add table. 1.

Table 1

ATC codes and DDD for medications

Name of medications (INN)	ATC-code	DDD
Atorvastatin		
Salmeterol		
Perindopril		
Omeprazole		
Imatinib		
Trimetazidine		
Erythropoietin		
Enalapril		
Metoprolol		
Metformin		

Task 3

Answer the test questions:

1. Name the year in which the WHO recommended the ATC / DDD methodology as a standard for the study of drug statistics in international practice:

□ _____

2. With the help of ATC classification it is possible to encode drugs, determine their possible use in therapy, potency and composition. Indicate which products of the pharmacy range are assigned an ATC code:

□ Homeopathic medicine
□ Folk remedies
□ Monocomponent drugs
□ New drug substance that has not passed the registration procedure

3. Define the abbreviation of the universal unit of measurement of drug consumption, which according to the WHO is *«the calculated average maintenance daily dose of drugs used for the main indication in adults»*:

□ ABC
□ ATC
□ DDD
□ GDP
□ OTC

4. Define the characteristics of DDD among the following:

□ Only for drugs that have an ATC code
□ Depends on the price of the drug
□ Depends on the form of the drug
□ Must correspond to the recommended or prescribed daily dose
□ Technical unit of measurement

5. Name the pharmacoepidemiological method that allows you to quantify the volume and structure of drug consumption (by the amount of active substance in certain doses):

□ ABC analysis
□ ATC methodology
□ ATC / DDD methodology
□ DDD-methodology
□ OTC methodology

6. Choose from the following advantages of ATC / DDD methodology:

□ DDD is defined for all drugs

□ DDD is the same for all countries
□ DDD is a standardized unit of measurement for drugs
□ Possibility of comparing drug consumption in health facilities, regions and countries
□ The methodology is suitable for deciding on the effectiveness of drugs or deciding on drug replacement

Task 4

Using the data in table 2, calculate the cost of 1 DDD for the proposed drugs and draw a conclusion.

Table 2

Analysis of the range of statins presented in the retail segment of the Ukrainian pharmaceutical market

№	Trade name, form of production	Manufacturer	Average retail cost of packaging, UAH	Number of DDD per pack.	Cost of 1 DDD
1.	Vazilip, tablets 20 mg № 28	KRKA (Slovenia)	142,1		
2.	Simgal, tablets 20 mg № 28	TEVA (Israel)	81,69		
3.	Vabadin, tablets 20 mg № 28	Menarini International (Luxembourg)	178,08		
4.	Atoris, tablets 20 mg № 30	KRKA (Slovenia)	180,56		
5.	Torvacard, tablets 20 mg № 30	Zentiva (Czech Rep.)	137,31		
6.	Atorvakor tablets 10 mg № 60	Farmak (Ukraine)	110,61		
7.	Crestor, tablets 10 mg № 28	AstraZehera (Great Britain)	411,1		
8.	Rozart, tablets 10 mg № 30	Actavis (Malta)	83,4		
9.	Roxera, tablets 10 mg № 30	KRKA (Slovenia)	199,9		

INFORMATION REFERENCE

INN	Code ATC	DDD (mg)
Simvastatin	C10AA07	30
Atorvastatin	C10AA07	20
Rosuvastatin	C10AA07	10

Calculations:

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Conclusions:

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Task 5

The study of drug consumption significantly contributes to their rational use. The availability of credible information on how drugs are prescribed and used helps to discuss the rational use or search for ways to improve the purpose and use of drugs. Provide a description of the main components of the study of drug consumption, add table 3.

Table 3

Drug consumption research

Components	Characteristics
The structure of use	volume and characteristics of the drugs using, trends in their use and changes in cost over time: • • •

The quality of use	Comparison of actual use with the provisions of national guidelines for the appointment of drugs or local medical formularies by audit: • • • • • •
Determinants of use	• consumer characteristics: • characteristics of the doctor prescribing treatment: • characteristics of drugs:
Results of use	• therapeutic results: • economic results:

** The concept of drug use audit was introduced in 1979 by Crooks as a study of the method of drug use in clinical practice, carried out at intervals sufficient to ensure compliance with generally accepted standards*

Task 6

You have found that the use of amoxicillin, expressed in DDD per 1000 inhabitants, has increased over the last 2 years. What types of actual drug use data will you need to assess the possible causes of this fact?

Answer:

DDD per 1000 inhabitants per day	=	

Hypothesis 1.

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Hypothesis 2.

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Task 7

The use of antidepressants (in DDD per 1000 inhabitants) and their costs have been rising for at least the last 5 years. What types of data will you need to find out the causes of these changes and determine what is behind them - positive or negative treatment results?

Answer:

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Task 8

On the basis of the regional children's infectious clinical hospital, a retrospective analysis of 411 medical records of patients who were treated for acute intestinal infection, namely with a diagnosis of viral diarrhea (enteritis). Conduct frequency analysis of prescriptions for children in accordance with the data of medical cards:

8.1. Calculate the frequency of prescribing drugs under the international non-proprietary name (INN). The results of the analysis are given in table 4.

Table 4

The results of frequency analysis of pharmacotherapy of children with viral diarrhea

№	ATC classification group	Names of drugs for INN	Frequency of assignments of each INN, units	Assignment frequency, %
1.	A07AX03	Nifuroxazide	251	
2.	A07BC05	Dioctahedral smectite	125	
3.	A07CA	Salt mixtures for oral rehydration	169	
4.	A07FA	Lactobacilli, their combinations	78	
5.	A07FA02	Saccharomyces of Bullardi	67	
6.	A07FA05	Products of vital activity of intestinal flora	13	
7.	A07FA49	Spores of Bacillus clausii	2	
8.	A07FA50	Subalin	8	
9.	B05BB01	Electrolytes	28	
10.	B05XA 05	Magnesium sulfate	94	
11.	B05XA03	Sodium chloride	49	
12.	B05XA31	Electrolytes in combination with other drugs	39	
13.	J01DA23	Cefixime	7	
14.	J01DD01	Cefotaxime	65	
15.	J01DD04	Ceftriaxone monotherapy and its combinations	103	
16.	J01DD13	Cefpodoxime	4	
17.	J01DE01	Cefepime hydrochloride	9	
18.	A07FA	Bifidobacterium, enterococci in combination.	214	
19.	A07BC10	Silicon dioxide	161	
20.	A07BC10	Methyl silicic acid hydrogel	26	
21.	B05C X01	Dextrose	94	
22.	B05XA01	Potassium chloride	94	
Total:			**1700**	

8.2. Calculate the average rate of prescriptions of drugs ($\overline{X}$) for the course of treatment of one patient.

Based on the results of calculations of the frequency of prescriptions and the average rate of prescriptions of drugs, justify the rationality of pharmacotherapy of children with viral diarrhea.

Note:

Average frequency assignments drugs for the totality of patients defined by:

$$\overline{X} = \frac{\sum x_n}{n},$$

where x_n – average frequency assignments drugs for the totality of patients;

n – number of medical cards studied.

Calculations:

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Conclusions:

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General conclusions: _____

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Lesson 4

Topic 5: SOCIO-EFFECTIVE MECHANISMS OF PROVIDING THE AVAILABILITY OF PHARMACEUTICAL CARE TO THE POPULATION

Purpose: to know the structure of the availability of pharmaceutical care and the main mechanisms for ensuring the socio-economic accessibility of pharmaceutical care; know the principles of organizing the reimbursement of the cost of pharmaceutical care to the population.

Theoretical questions:

1. The concept of the availability of pharmaceutical care to the population.
2. Indicators of the socio-economic availability of medicines to the population.
3. Modern approaches to the organization of medicine cost reimbursement systems in international practice.
4. The main classification features of modern systems for reimbursing the cost of medicines.
5. General organizational structure of the system of reimbursement and pharmaceutical assistance to the population.
6. The procedure for the provision of humanitarian pharmaceutical aid to the population.

Practical tasks:

Task 1

Match the terms (1-6) with their definitions (A-F):

1.	Reimbursement	**A.**	compensation funds come directly from the insurance company on the basis of an agreement between the insurance fund, medical and pharmacy institution.
2.	Reimbursement subject	**B.**	the process by which the health care system influences the availability of medicines and health services to the population.
3.	Reimbursement object	**C.**	providing the population with free, high-quality and necessary drugs for the provision of affordable medical and pharmaceutical care

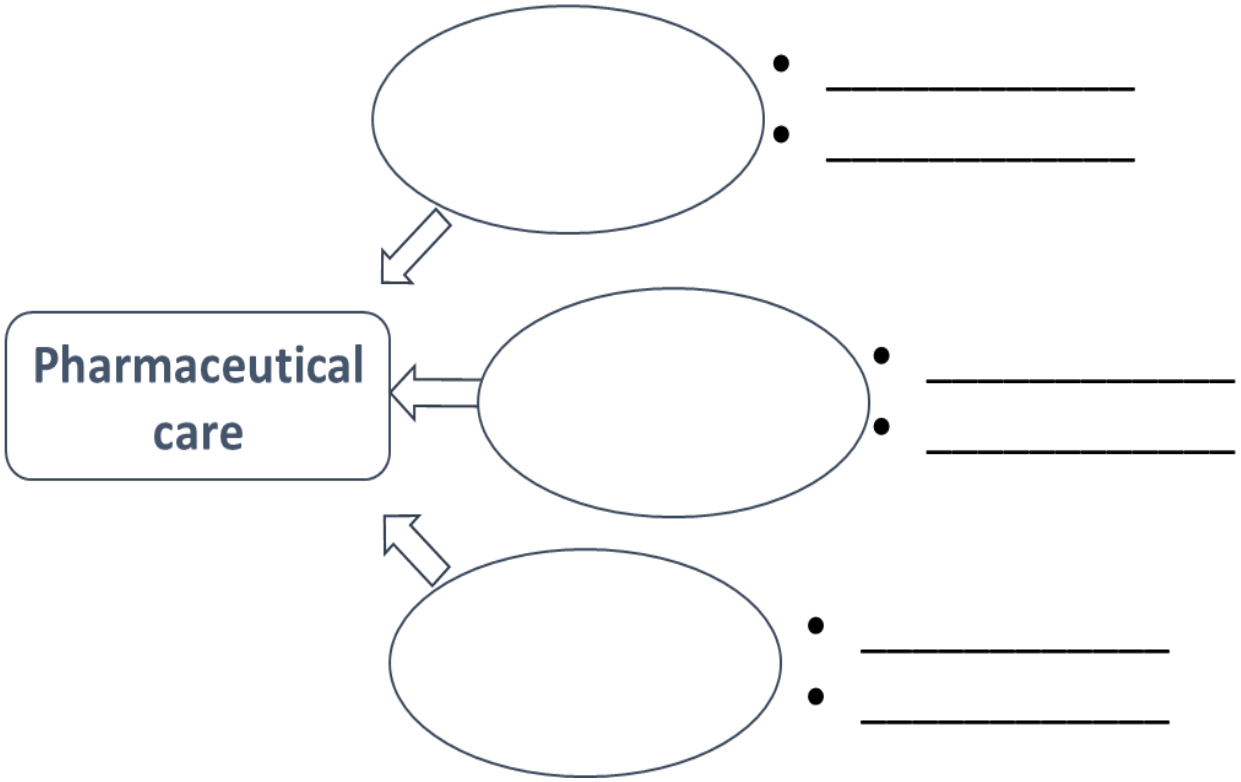
4.	Reimbursement mechanism for pharmacies and medical institutions	**D.**	the insured patient pays for the provided medical services or medicines, while receiving an invoice for the amount spent, which is submitted to the insurance company. In this case, there is no direct connection between the insurance fund and medical and pharmacy institutions.
5.	Reimbursement mechanism for insured persons	**E.**	authorized bodies making compensation payments from certain funding sources
6.	Government procurement of drugs	**F.**	Certain categories of diseases and patients

Answer:

1.	2.	3.	4.	5.	6.

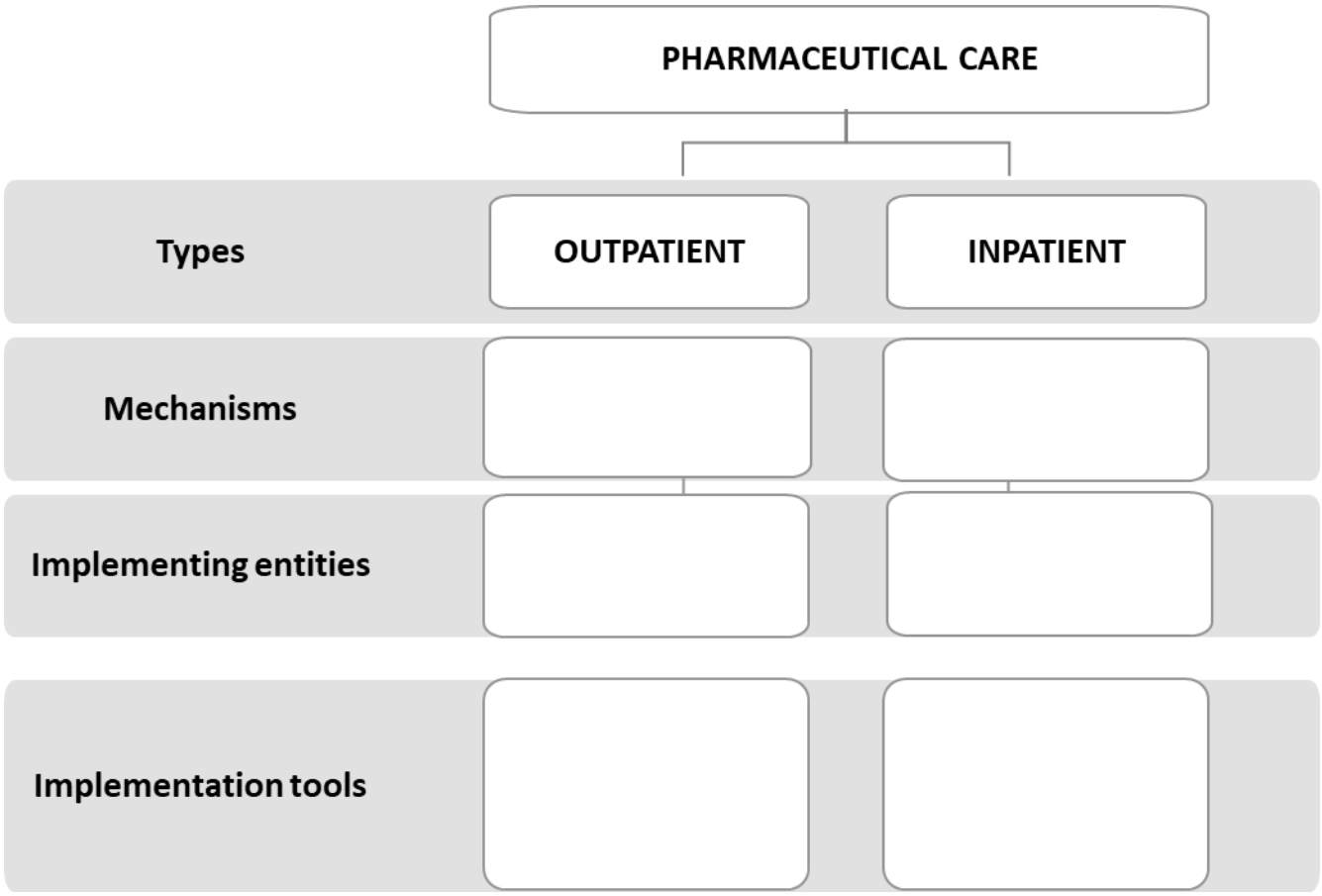
Task 2

Describe the basic principles of providing pharmaceutical care and fill in the scheme.



Task 3

Describe the mechanisms for the implementation of the provision of pharmaceutical care. Complete the fig.



Task 4

Provide a comparative description of approaches to the implementation of medicine reimbursement in international practice. Give a description of medicines that are and are not subject to medicine reimbursement. Complete the table 1.

Table 1

Country	Characteristics of medicines	
	Subject to medicine reimbursement	Not subject to medicine reimbursement
Germany		

Great Britain		
Italy		
Spain		
Ukraine		

Task 5

Calculate the solvency ratio of medicines for the working population and in cases of reimbursement (co-payments of reimbursable medicines), taking into account the data in Table 2.

Additional information:

- The average salary in Ukraine: 11360 UAH or 405 USD
- The solvency adequacy ratio (Ca.s) of medicines is calculated by the formula:

$$\text{Ca. s.} = \frac{\text{P}}{\text{Wa.w.}} * 100\%$$

where Ca.s. – solvency adequacy ratio;

P – average retail price of medicine for a certain period of time;

Wa.w. – average salary for the corresponding period of time

Table 2

Medicine	Average retail price of the medicine, UAH	Co-payments of reimbursable medicines, UAH	Ca.s for the working population, %	Ca.s for the working population, taking into amount of co-payments, %
BECLAZONE-EKO 250 mg 200 doses, Ireland	267	56,31		
BECLOFORT EVOCHALER, 250 mkg 200 doses, France	214	0		
PULMICORT 0.25 No. 40 Sweden	767	102,87		
PULMICORT TURBUHALER 200 mcg 100 doses Sweden	307	206,30		
BUDESONID EASYHALER, Finland	231	27,83		
ASTHALIN, India	61	0		
SALBUTAMOL, France	74	10,60		
SALBUTAMOLUM-NEO, Ukraine	62	0		

For calculations

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Conclusions_____
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Task 6

Calculate the solvency ratio of medicines for the working population and in cases of reimbursement. Complete the Table 3.

Table 3

Medicine	**Retail price, dollars. USD**	**Co-payments of reimbursable medicines, USD**	**Ca. s for the working population, %**	**Ca. s for the working population, taking into amount of co-payments, %**
The average salary in Poland - 1265 USD				
Xarelto, tabl., 10 mg №10	25,66	15,67		
Xarelto, tabl. powl., 20 mg № 30	36,62	15,36		
The average salary in the Czech Republic - 1380 USD				
Xarelto, tabl., 10 mg № 10	31,06	6,80		
Xarelto, tabl. powl., 20 mg №30	80,66	20,46		
The average salary in Germany - 3396 USD				
Xarelto, tabl., 10 mg № 10	47,94	47,94		
Xarelto, tabl. powl., 20 mg №30	117,81	117,81		

For calculations

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Conclusions_____
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General conclusions: _____
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Lesson 5

Topic 6-7: PHARMACEUTICAL CARE QUALITY MANAGEMENT. THE ROLE OF THE PHARMACIST AT THE MODERN STAGE OF PHARMACY DEVELOPMENT

Purpose: know the structure of pharmacovigilance system and effectiveness criteria; distinguish the types of negative consequences of medicine use; know and identify the types of errors associated with medicines during the provision of pharmaceutical care; be able to analyze the prevalence of adverse reactions by category.

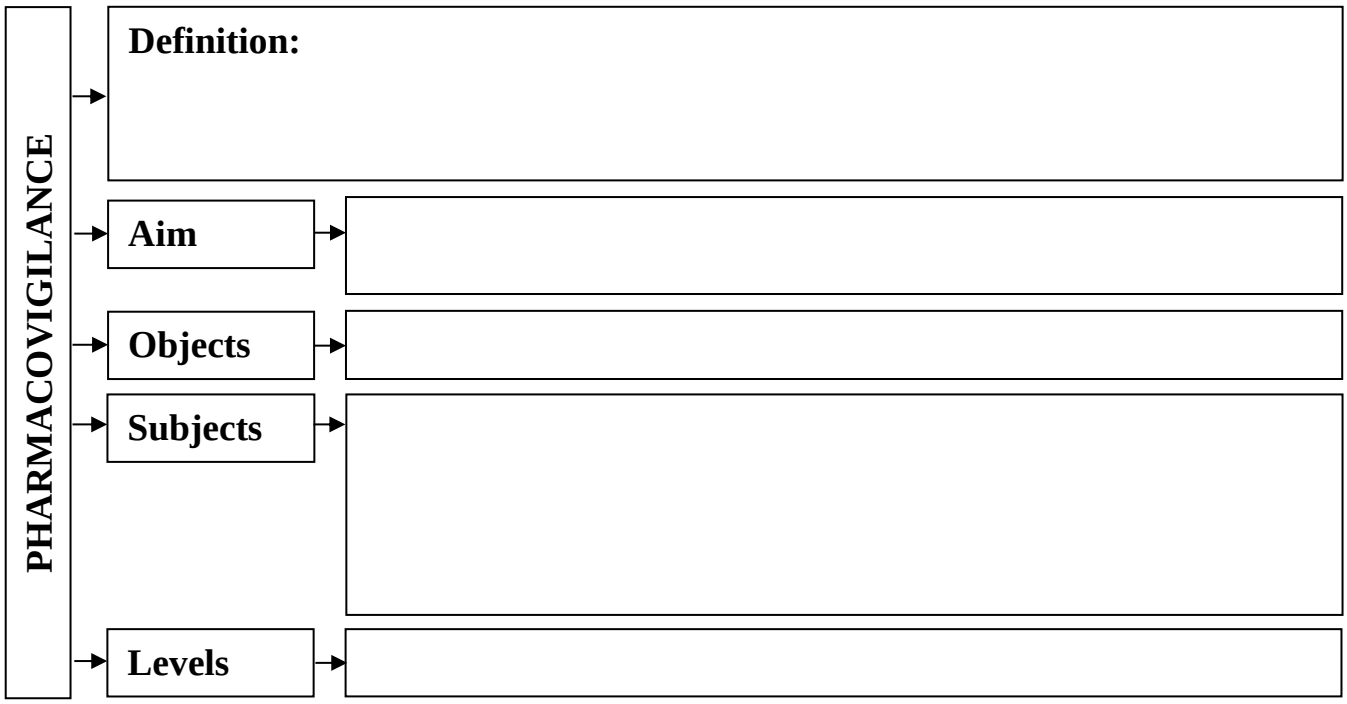
Theoretical questions:

1. Pharmacovigilance system. Modern international trends in ensuring the safety and quality of medicines.
2. Negative consequences of using medicines: types, status, registration, control
3. Medication Errors in Pharmaceutical Care
4. Good Prescription Practice: main provisions, structure, implementation perspectives.
5. Professional Profile in the Pharmaceutical Healthcare Sector
6. Quality standards of pharmaceutical services. (Good pharmacy practice)

Practical tasks:

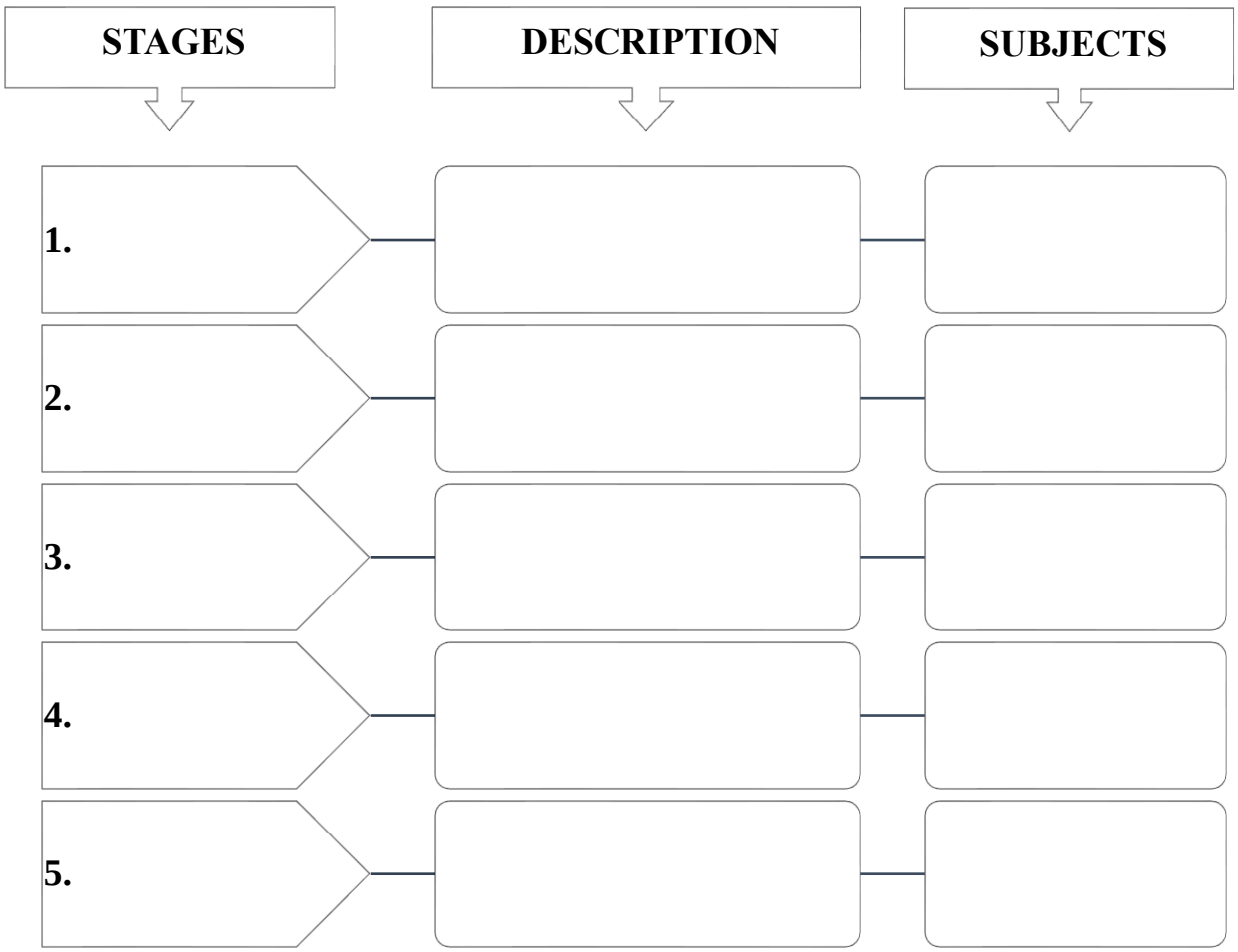
Task 1

Describe the organizational structure of the pharmacovigilance system. Complete the Fig. 1.



Task 2

Describe the structure and main elements of the pharmacovigilance system and fill in the scheme:



Task 3

Find information about the pharmacovigilance authority in your country. For searching you can use interactive map from WHO Collaborating Centre for International Drug Monitoring ***https://www.who-umc.org/global-pharmacovigilance/who-programme-for-international-drug-monitoring/***

Task 4

Match the terms (1-7) with their definitions (A-G):

Type negative consequences of using medicines		**Definition**	
1.	Adverse Event	**A.**	An adverse reaction, the nature or severity of which is not consistent with the applicable product information
2.	Adverse drug reaction (ADR)	**B.**	An event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes
3.	Unexpected Adverse Drug Reaction	**C.**	Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment.
4.	Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR)	**D.**	Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use
5.	Lack of Efficacy	**E.**	Any untoward medical occurrence that at any dose: – results in death, – is life-threatening, – requires inpatient hospitalization or prolongation of existing hospitalization, – results in persistent or significant disability/incapacity, or – is a congenital anomaly/birth defect
6.	Medication Error	**F.**	In the pre-approval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established: all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions.
7.	Drug-related problem	**G.**	The lack of expected or desired effect related to a therapy

Answer:

1.	2.	3.	4.	5.	6.	7.

Task 5

Select one of the proposed medicines or suggest your own and analyze the statistics on adverse reactions reports for it. For analysis, use information from WHO Collaborating Centre for International Drug Monitoring (***http://www.vigiaccess.org/***). Complete the table.

Medicines:

1) Metamizole
2) Drotaverine
3) Ceftriaxone
4) Omeprazole
5) Sildenafil
6) Oseltamivir
7) Pancreatin
8) Ambroxol
9) Xylometazoline
10) Fluconazole
11) Paracetamol
12) Vitamin C
13) Metformin
14) Losartan
15) Enalapril
16) Ibuprofen
17) Bisoprolol

Name of medication	
Total number of records	
Year of first case	
ADR reports per year 2020 2019 2018	
Geographic distribution	
Adverse drug reactions (3 most common)	

Task 6.

In 2019, the Center's database entered 26,370 valid reports of adverse drug reactions. Non-serious adverse reactions amounted to 24184, serious – 2186. Of the total number of adverse reactions – 50735 cases, 49809 were predicted, 93 were unexpected, without indicating the predictability – 833. Calculate:

a) the ratio of the number of unpredictable / predictable adverse reactions (as a percentage and in terms of one unpredictable adverse reaction)

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b) the ratio of the number of serious / non-serious adverse reactions (as a percentage and in terms of one serious adverse reaction)

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Conclusion:_____
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Task 7.

Calculate the prevalence of adverse drug reactions among cases of disease. For calculations use the data given in table. The number of inhabitants of Ukraine as of 1.01.2020 made 41 902 416 people. Make reasoned conclusions about the frequency of adverse reactions.

The ratio of disease prevalence by individual classes with the number of cases of adverse reactions

Name of the disease	Prevalence of diseases on 100 thousand population	Absolute number cases of ADR	Cases of ADR on 100 thousand population	Prevalence of ADR among cases diseases	Group of the frequency of adverse reactions
Some infectious and parasitic diseases	4675	11431			
Diseases of the circulatory system	729	3035			
Diseases of the nervous system	1739	371			
Diseases of the respiratory system	88082	2971			
Diseases of the digestive system	4540	896			
Diseases of the genitourinary system	2458	685			
Neoplasm	330	180			
Mental and behavioral disorders	381	706			
Diseases of the skin and subcutaneous tissue	6533	232			

Criteria for assessing the frequency of adverse reactions:

>10%	-	Very common • *conducting a mandatory drug safety profile;* • *immediate adoption of appropriate regulatory decisions*
1-10%	-	Common (frequent) • *study of the safety profile of drugs* • *providing risk management plans* • *making restrictions / warnings in the instructions for medical use*
0,1-1%	-	Uncommon (infrequent)
0,01-0,1%	-	Rare
< 0,01%	-	Very rare

For calculations

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Conclusion:_____
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Task 8.

During pharmaceutical care, the patient has frequent cases of drug-related errors. Identify the categories of drug-related errors that may occur and different stages:


Errors in the use of drugs during **inpatient treatment**
Errors in **prescribing drugs** and during **self-medication**
Errors during the **release of drugs by a pharmacist**

Task 9.

One of the reasons of drug-related errors cases is the sound-alike of the names of drugs. Analyze the List of Confused Drug Names and select 10 pairs of drugs with sound-alike names (***https://www.ismp.org/recommendations/confused-drug-names-list***). Explain whether this pair can cause a drug-related error by specifying the nonproprietary name (INN) or pharmacotherapeutic group.

	Trade name (nonproprietary name, therapeutic group)	**Confused trade name (nonproprietary name, therapeutic group)**
1.	Luvox (fluvoxamine, antidepressant)	Lasix (furosemide, diuretic)
2.		
3.		
4.		
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10.		

General conclusions: _____

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Lesson 6

Topic 8: MODERN INFORMATION SYSTEMS AND HEALTH INFORMATIZATION

Purpose: To identify the features of the informatization of the pharmaceutical sector in the health system; to study modern health information systems and their analysis; to know the structure and features of the e-health system, its objectives and functions.

Theoretical questions:

1. eHealth system.
2. Electronic document management in health care.
3. Electronic prescription as an element of informatization of the pharmaceutical industry: legal status, level of implementation, prospects for use.
4. Mobile health. Mobile apps for patient care.

Practical tasks:

Task 1.

Match the terms (1-9) with their definitions (A-I):

1.	Health information technology (HIT)	A.	the computer-based electronic generation, filling of a medical prescription, and transmission of prescriptions from doctors to pharmacists
2.	Electronic Health (eHealth)	B.	the ability to seek, find, understand and appraise health information from electronic sources and apply knowledge gained to addressing or solving a health problem
3.	Electronic document	C.	the integration of all information and knowledge sources involved in the delivery of healthcare via information technology-based systems. This includes patients and their records, caregivers and their systems, monitoring devices and sensors, management and administrative functions.
4.	Electronic document flow (EDF)	D.	a document in which information is registered in the form of electronic data, including mandatory details

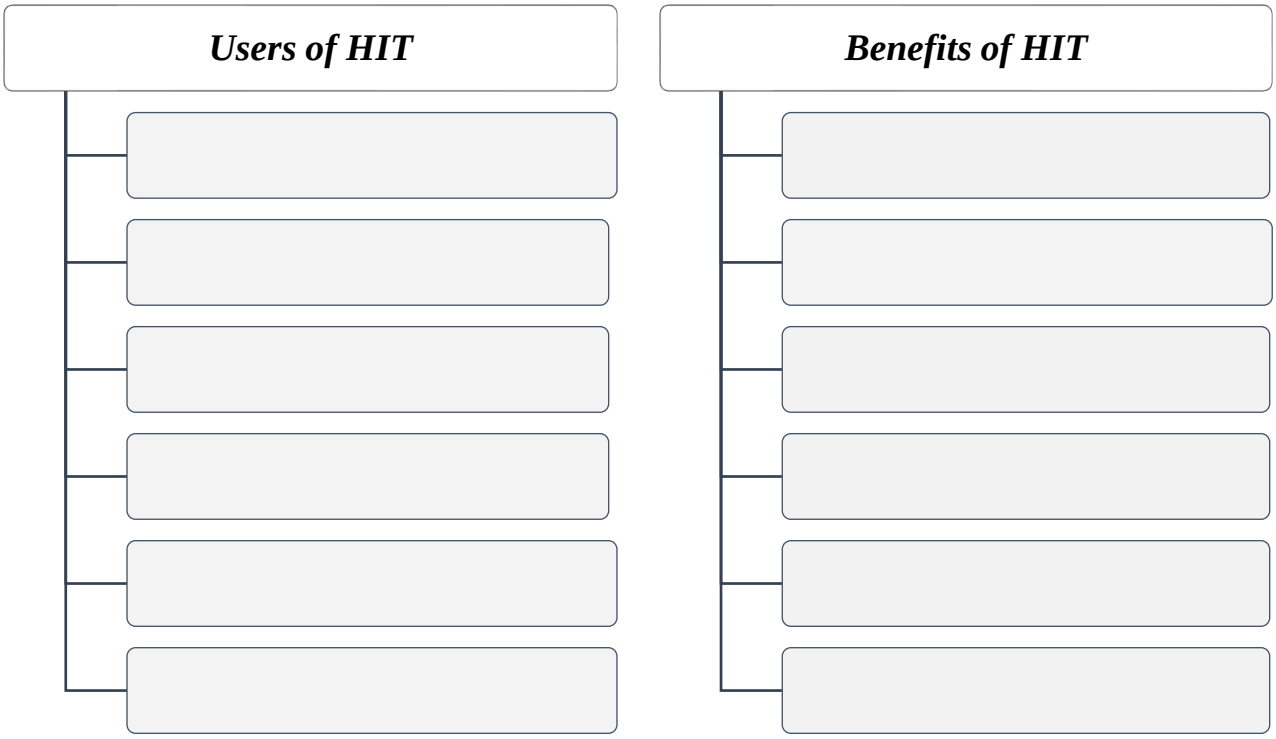
5.	Electronic prescription (E-prescription)	E.	the processing, storage, and exchange of health information in an electronic environment; it's used to improve the quality of health care, prevent medical errors, reduce health care costs, increase administrative efficiencies, decrease paperwork, and expand access to affordable health care
6.	Electronic prescribing (e-prescribing)	F.	a term that refers to the use of mobile devices and information technology for medical purposes, as well as to ensuring a healthy lifestyle
7.	eHealth literacy	G.	physical and psychological diagnosis and treatments at a distance, including telemonitoring of patients' functions
8.	Mobile health (mHealth)	H.	a digital document created by a medical professional appointing a medicinal product and obtained by a medical professional releasing the drug. Defines the requirements for this information object and defines data elements to achieve interoperability
9.	Telemedicine	I.	a set of processes for creating, processing, sending, transmitting, receiving, storing, using and destroying electronic documents, which are carried out using a bona fide check and, if necessary, confirmation of the receipt of such documents

Answer:

1.	2.	3.	4.	5.	6.	7.	8.	9.

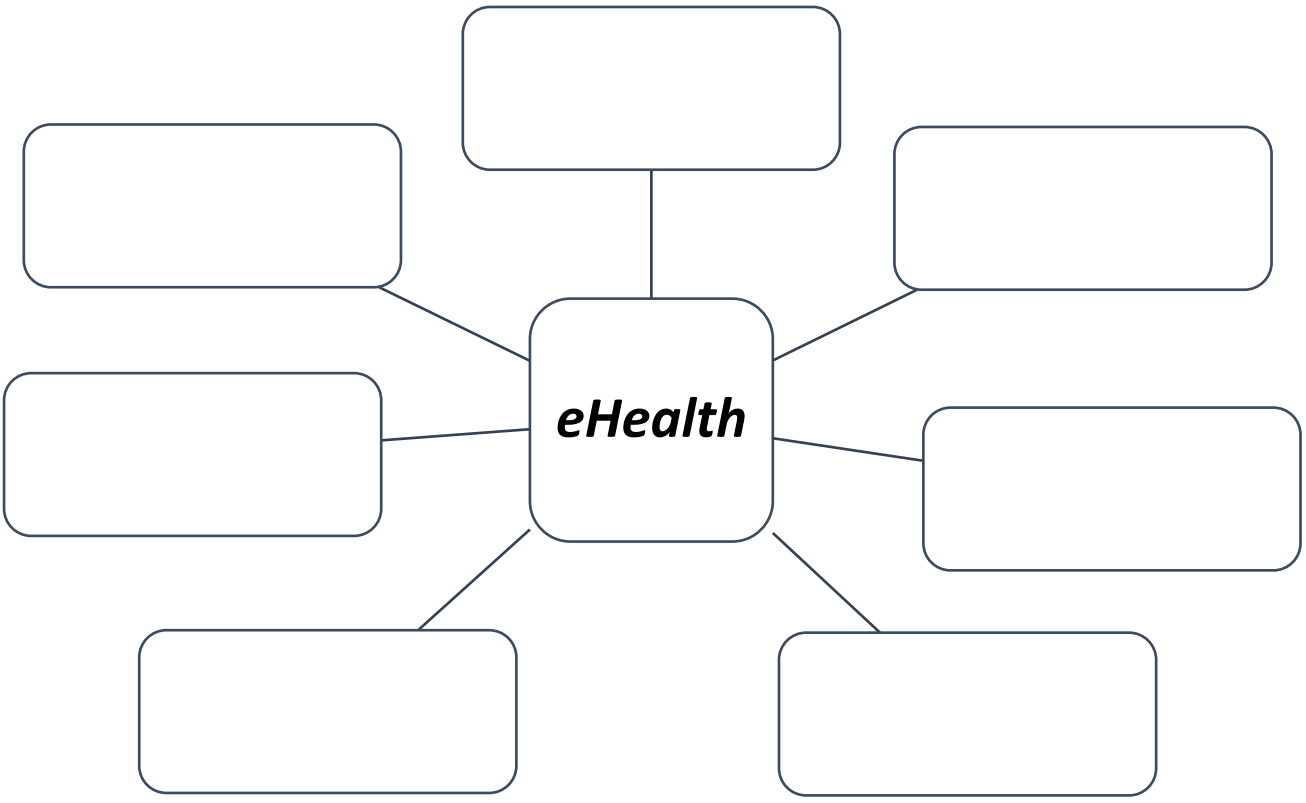
Task 2.

Health information technology (HIT) is transforming the manner and quality in which health care providers administer treatment to their patients. There are numerous benefits for doctors and patients when it comes to adopting HIT infrastructure. Name potential users of HIT and benefits of HIT for them:



Task 3.

Describe the basic elements of eHealth and fill in the scheme:



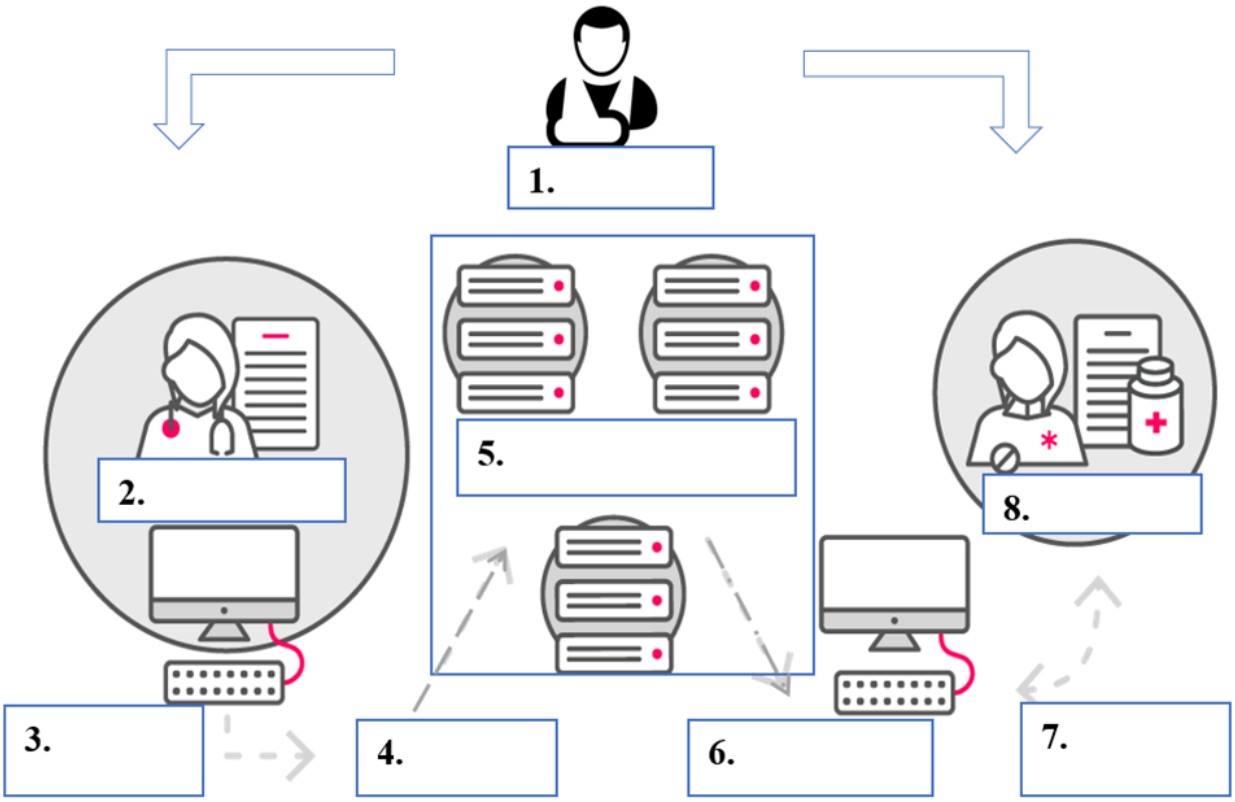
Task 4.

Describe differences between an e-prescription and a paper-prescription:

Electronic prescription	Paper prescription
☐ _____	☐ _____
☐ _____	☐ _____
☐ _____	☐ _____
☐ _____	☐ _____
☐ _____	☐ _____
☐ _____	☐ _____

Task 5.

Complete the scheme of Electronic Transfer of Prescription and name participants and steps of the process:



Task 6.

Analise basic data on pharmacies participating in the government program reimbursement "Affordable Drugs" and provide an overview of electronic prescribing and dispensing under this program.

Additional information:

A. Use the formula for calculating the length of the range (h) for ranking and grouped results of the analysis into three groups (n): high, medium and low:

$$h = \frac{\max - \min}{n},$$

where max – the maximum value of the indicator; min – the minimum value of the indicator; n = 3 (number of levels groups).

B. Use the scale and range length to assign regions to groups:

high		**medium**		**low**	
maximum result	maximum result – h	maximum result – h	maximum result – 2h	maximum result – 2h	minimum result

6.1. Calculate the proportion (%) of pharmacies in administrative divisions of Ukraine that take part in the "Affordable Drugs". Rank the administrative divisions in terms of rate of engagement – high, medium, low involvement in the program reimbursement "Affordable Drugs". Complete the Table 1.

Table 1

Results of the analysis of pharmacies which take part in the "Affordable Drugs" program

Administrative divisions	**Number of pharmacies taking part in the program**	**Total number of pharmacies in the region**	**Part of the participation, %**	**Rate of engagements**
1	**2**	**3**	**4**	**5**
Donetsk Region	373	1016		
Dnipropetrovsk Region	783	1560		
Kiev	568	1563		
Kyiv Region	491	990		
Kharkiv Region	896	1290		
Lviv Region	745	1218		
Odesa Region	383	1431		
Luhansk Region	256	429		
Zaporizhzhia Region	371	860		
Vinnytsia Region	475	825		
Poltava Region	489	751		
Ivano-Frankivsk Region	292	803		
Khmelnytskyi Region	368	801		

1	2	3	4	5
Zakarpattia Region	224	729		
Zhytomyr Region	344	645		
Cherkasy Region	339	756		
Rivne Region	381	561		
Mykolaiv Region	256	596		
Sumy Region	278	545		
Ternopil Region	248	632		
Kherson Region	217	551		
Volyn Region	278	484		
Chernihiv Region	179	473		
Kirovohrad Region	265	573		
Chernivtsi Region	175	503		

For calculations

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6.2. Analyze the electronic prescriptions issued and dispensed by regions in Ukraine, in particular, calculate the proportion (%) of refusals. Rank the regions in terms of refusal rate – high, medium, low refusal rate. Complete the Table 2.

Table 2

Results of analysis of electronic prescriptions prescribed and dispensed

Administrative divisions	E-prescriptions prescribed, million	E-prescriptions dispensed, million	Part of refusals, %	Refusal rate
1	2	3	4	5
Donetsk Region	1,019	0,872		
Dnipropetrovsk Region	2,183	1,842		
Kiev	0,991	0,857		
Kyiv Region	0,722	0,618		
Kharkiv Region	1,545	1,317		
Lviv Region	1,207	1,047		
Odesa Region	0,829	0,693		
Luhansk Region	0,370	0,324		
Zaporizhzhia Region	0,983	0,871		
Vinnytsia Region	0,963	0,794		
Poltava Region	0,797	0,676		
Ivano-Frankivsk Region	0,523	0,445		
Khmelnytskyi Region	0,762	0,656		
Zakarpattia Region	0,535	0,442		

1	2	3	4	5
Zhytomyr Region	0,814	0,683		
Cherkasy Region	0,606	0,526		
Rivne Region	0,481	0,414		
Mykolaiv Region	0,691	0,584		
Sumy Region	0,612	0,525		
Ternopil Region	0,596	0,507		
Kherson Region	0,497	0,427		
Volyn Region	0,442	0,386		
Chernihiv Region	0,552	0,459		
Kirovohrad Region	0,485	0,401		
Chernivtsi Region	0,385	0,306		

For calculations

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6.3. Calculate the number of prescriptions dispensed by pharmacies by region in Ukraine. Rank the regions according to the level of caseload - high, medium, low. Complete the Table 3.

Table 3

Results of the analysis of the pharmacy caseload indicator by region of Ukraine

Administrative divisions	E-prescriptions dispensed	Number of pharmacies taking part in the program	Caseload, e-prescriptions per pharmacy	Level of caseload
1	2	3	4	5
Donetsk Region	872134	373		
Dnipropetrovsk Region	1841982	783		
Kiev	857200	568		
Kyiv Region	617701	491		
Kharkiv Region	1316638	896		
Lviv Region	1046729	745		
Odesa Region	693390	383		
Luhansk Region	323960	256		
Zaporizhzhia Region	870645	371		
Vinnytsia Region	794089	475		
Poltava Region	676490	489		
Ivano-Frankivsk Region	445034	292		
Khmelnytskyi Region	652735	368		
Zakarpattia Region	441874	224		
Zhytomyr Region	682754	344		

1	2	3	4	5
Cherkasy Region	526199	339		
Rivne Region	414129	381		
Mykolaiv Region	584281	256		
Sumy Region	524896	278		
Ternopil Region	507231	248		
Kherson Region	426588	217		
Volyn Region	386456	278		
Chernihiv Region	458751	179		
Kirovohrad Region	401442	265		
Chernivtsi Region	305899	175		

For calculations

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6.4. Based on the results of the calculations in Tables 1 – 3, group the regions according to their participation in the program reimbursement "Affordable Drugs" and draw a conclusion.

	Rate of engagements	Refusal rate	Rate of caseload
HIGH			
MEDIUM			

LOW			

Conclusion:

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Task 7.

Analyze the most common pharmaceutical mobile apps and identify their main functions for patients. Complete the Table 4.

- Medication directories:
  _____
- Mobile apps for finding medicines in pharmacies:
  _____
- Mobile apps for quality control of medicines:
  _____
- Mobile apps to monitor rational pharmacotherapy:
  _____

Table 4

Characteristics of pharmaceutical mobile apps

Name	*Purpose of use*	*Functional content*
1	**2**	**3**

1	2	3

General conclusions: _____

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Lesson 7

Topic 9: WORLD EXPERIENCE IN HEALTHCARE AND PHARMACY REFORM. HEALTH LITERACY AS ONE OF THE KEY ELEMENTS OF THE INTERNATIONAL HEALTH STRATEGY

Purpose: to study the issues of health literacy as one of the determinants of healthcare: concept, structure, general information; learn about international approaches to implementing health literacy initiatives across the world.

Theoretical questions:

1. State policy in the field of health care: world experience.
2. Public health: basic provisions and structure. Pharmaceutical literacy as a component of health literacy.
3. The relationship of public health with medical and pharmaceutical literacy.
4. Health literacy: definition and its components, directions.
5. International experience in patients' medical literacy. Development of medical literacy programs.

Practical tasks:

Task 1

Match the terms (1-5) with their definitions (A-F):

1.	Health literacy	**A.**	the degree to which individuals can obtain, comprehend, communicate, calculate and process patient-specific information about their medications to make informed medication and health decisions in order to safely and effectively use their medications, regardless of the mode by which the content is delivered (e.g. written, oral and visual)
2.	Pharmaceutical literacy	**B.**	a state of complete physical, mental and social well-being and not merely the absence of disease and infirmity
3.	Health promotion	**C.**	the science and art of preventing disease, prolonging life and improving quality of life through organized efforts and informed choices of society, organizations (public and private), communities and individuals
4.	Health	**D.**	the economic and social conditions that influence individual and group differences in health status
5.	Public health	**E.**	process of enabling people to increase control over, and to improve their health

6.	Social determinants of health	**F.**	the degree to which individuals have the capacity to obtain, process, and understand basic health information needed to make appropriate health decisions

Answer:

1. f	**2. a**	**3. e**	**4.**	**5.**	**6.**

Task 2

A conceptual model for health literacy, proposed by the European Health Literacy Consortium, defines the main dimensions of health literacy. This model involves the ability to receive, understand, evaluate and apply health information in situations related to health care, disease prevention and health promotion. Describe the main sub-aspects of the conceptual model of literacy according to the above steps. Complete table 1.

Table 1

Health literacy	**Access/obtain information**	**Understand information**	**Process / appraise information**	**Apply / use information**
Health and pharmaceutical care	1.	2.	3.	4.
Disease prevention	5.	6.	7.	8.
Health promotion	9.	10.	11.	12.

Task 3.

Give answers to test questions:

1. *Select the main benefits of pharmaceutical literacy from the options below:*

- Correct use of OTC drugs in the framework of responsible self-medication;
- Understanding the importance of compliance;
- Reduction of cases of drug interactions with the simultaneous use of drugs;
- Organization of a health statistics system.

2. *From the proposed options, select the main areas of work of a pharmacist in the formation of pharmaceutical literacy of the population:*

- Providing the population with the necessary information about medications;
- Carrying out pharmaceutical care when dispensing medications;
- Identification of cases of drug abuse.
-

3. *Pharmaceutical literacy is a component of the formation of knowledge in the use of drugs and other goods in the pharmacy:*

- Promotes Responsible Self-Care Skills;
- Forms knowledge of correct and correct drug intake, taking into account individual characteristics;
- Forms individual and collective decision-making ability in matters of taking prescription drugs.

Task 4

Analyze the incidence statistics for coronavirus infection in the world (https://covid19.who.int/) and characterize the dynamics of changes in the incidence rate in any of the countries proposed on the website. Complete table 2.

Table 2

Country	Cases – cumulative total	Cases – cumulative total per 100,000 population	Cases – newly reported in last 7 days	Cases – newly reported in last 7 days per 100,000 population

Review the data provided and select those countries that have the highest number of COVID-19 cases – newly reported in last 7 days per 100,000 population. Select the

countries that have the highest increase in the number of cases of COVID-19 in a given period. Complete table 3.

Table 3

Country	Cases – cumulative total	Cases – cumulative total per 100,000 population	Cases – newly reported in last 7 days	Cases – newly reported in last 7 days per 100,000 population
Highest number of cases – cumulative total				
Highest number of cases – cumulative total per 100,000 population				
Highest number of cases – newly reported in last 7 days				
Highest number of cases – newly reported in last 7 days per 100,000 population				

Task 5

Indicate the main symptoms and complications of coronavirus infection. Complete Figures 1 and 2.

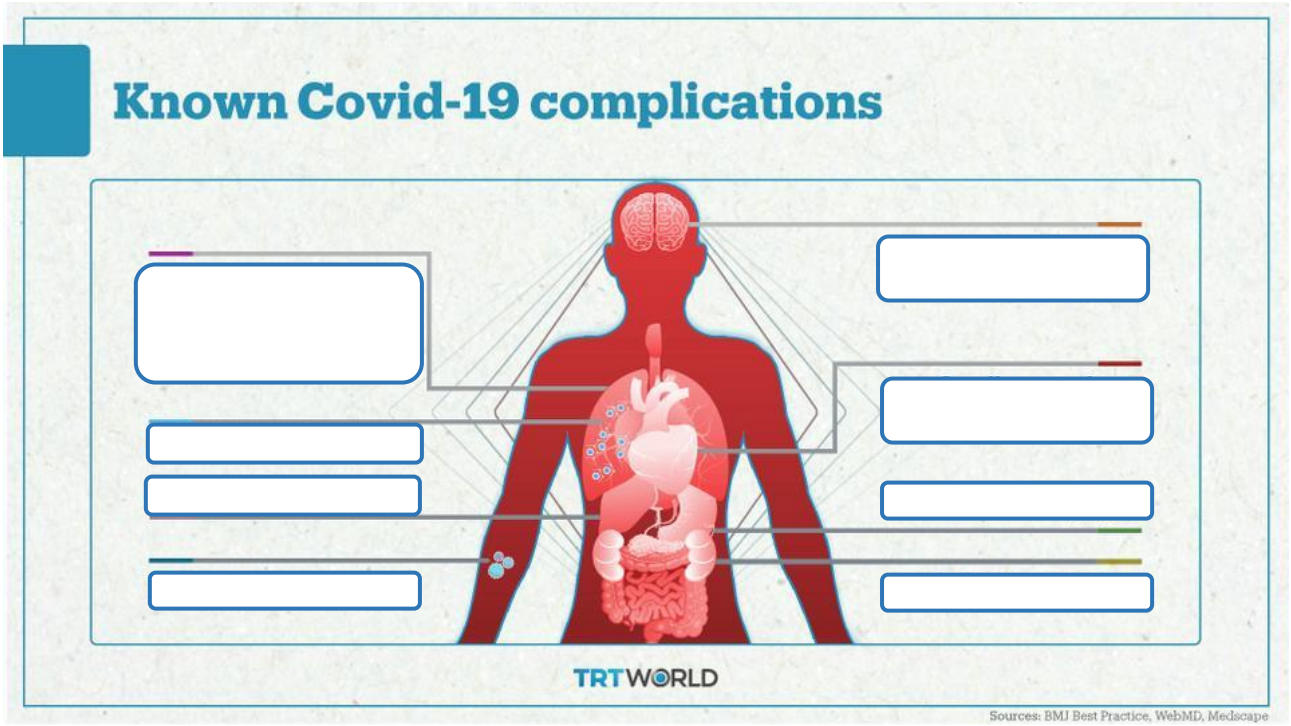


Fig 1. Most common complications COVID 19

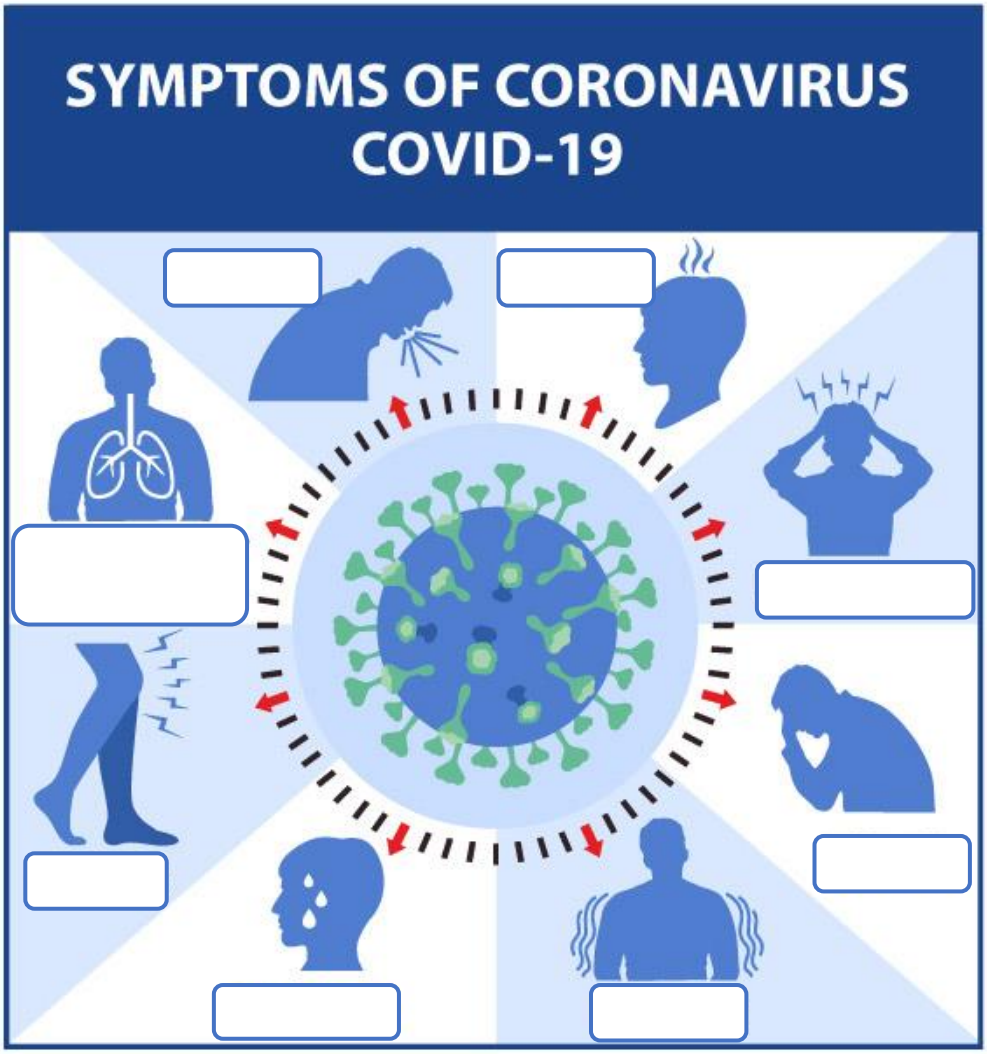
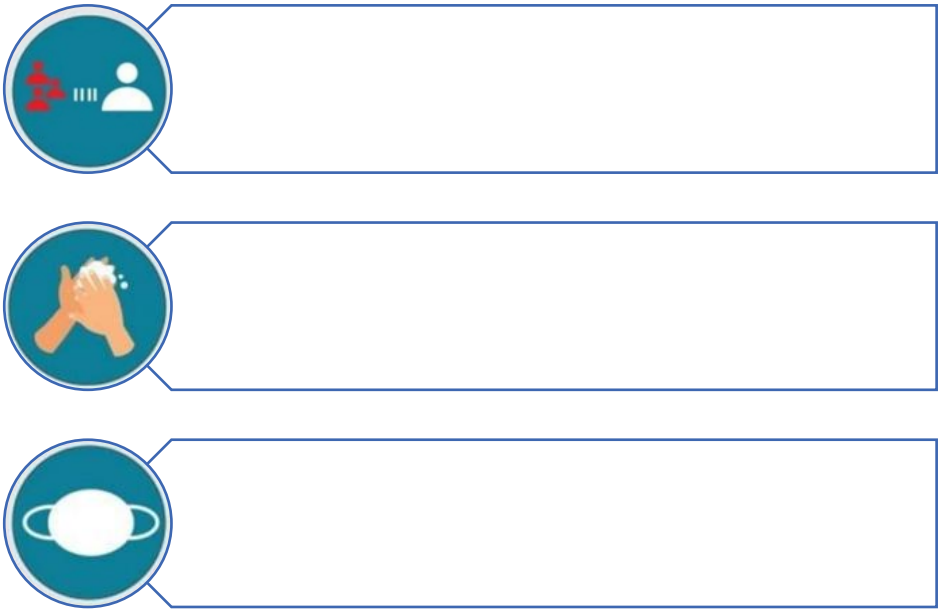


Fig 2. Most common complications COVID 19

Task 6

List some ways to prevent the spread of COVID-19. Complete the figure 3.



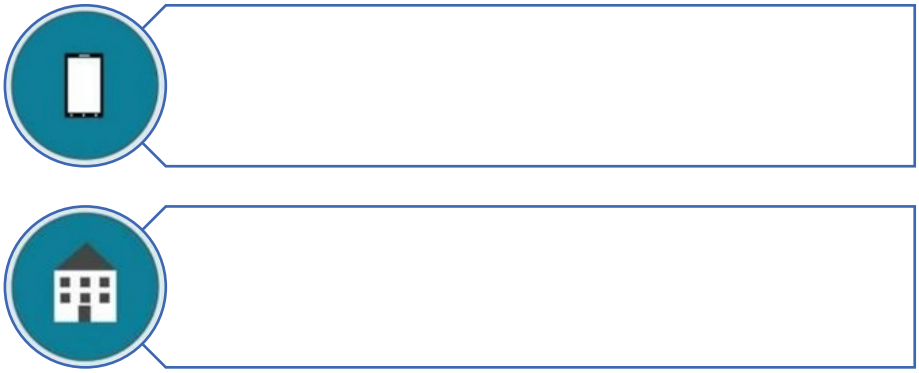


Fig 3. Ways to prevent the spread of COVID-19

Task 7

One of the most affordable and effective means of protection against coronavirus infection is barrier protection, and the most common of them is a mask. Indicate the existing degree of probability of human infection through contact with a patient with coronavirus infection, depending on the observance of the rules for wearing a mask and observing a safe distance. Complete the Fig. 4

Fig 4. COVID-19 Transmission Probability

Task 8

One of the types of barrier methods of protection are cloth masks, which gained universal popularity during the pandemic. List the rules that should be followed when using this type of mask as recommended by the WHO. Indicate the missing captions for Fig. 5.

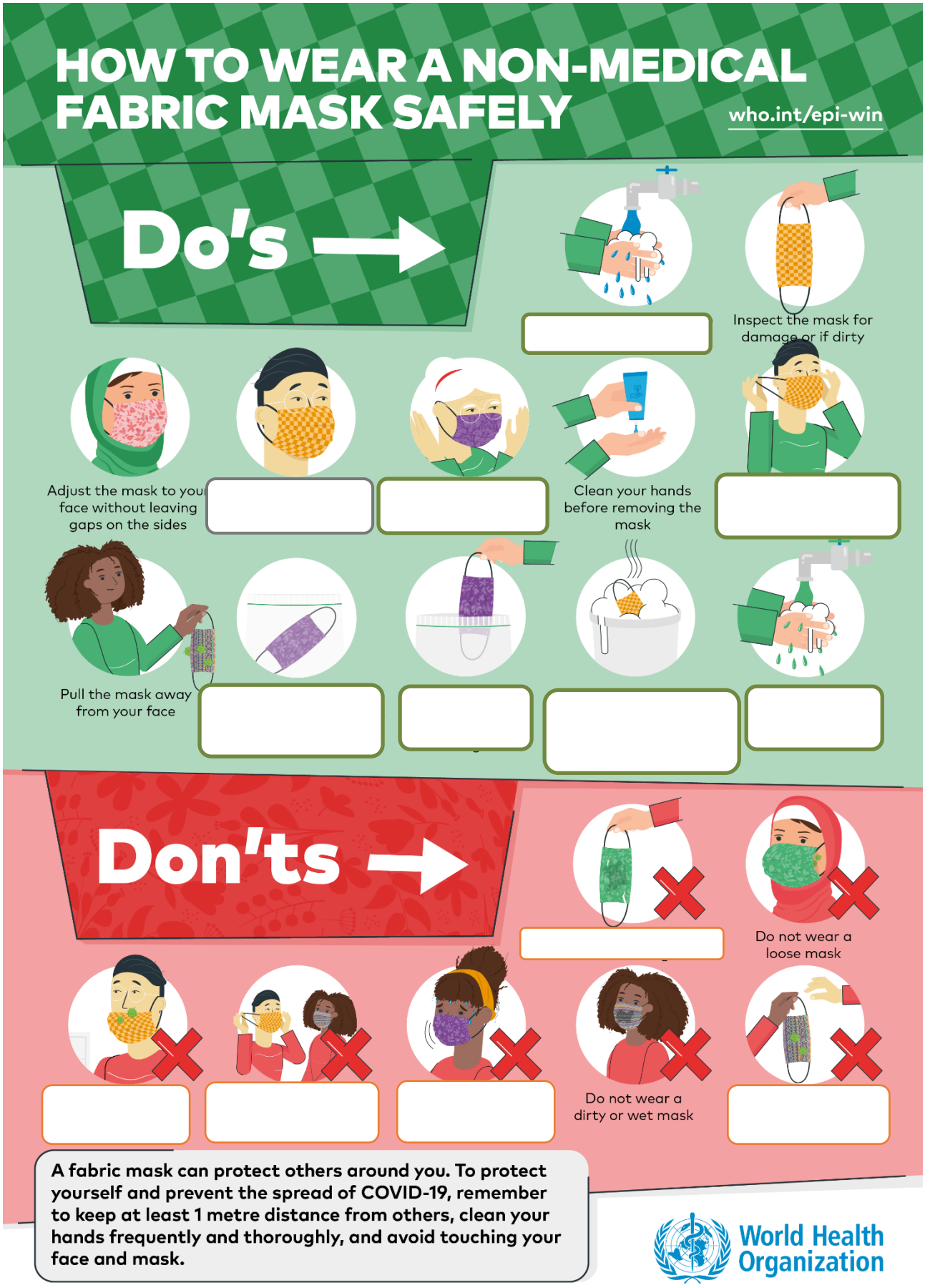


Fig 5. Rules for the safe use of fabric masks according to WHO recommendations

INDIVIDUAL TASK

Prepare a report on the role of the pharmaceutical worker in disease prevention, healthy lifestyles and improving the quality of life in accordance with the chosen topic.
Possible topics of the reports:

- vaccination;
- antibiotic resistance;
- palliative care;
- COVID 19;
- non-communicable diseases (cardiovascular diseases, diabetes…) and the reasons that motivate their development (smoking, e-cigarettes and vaping, alcohol, healthy eating, active lifestyle);
- infectious diseases (measles, influenza, hepatitis);
- orphan diseases ……

Recommendations for reports:

1. Correspondence of the content of the report to the chosen topic.
2. Information saturation of the report.
3. Structure of the report:
   - title slide with the title of the report and the performer;
   - relevance and purpose of the report;
   - results of the research;
   - own conclusions and visions on the studied issue;
   - references.
4. Presence of independent work of the student on a problem, expression of own opinion.
5. Use of pharmaceutical terminology.
6. Logical sequence of presentation.
7. Free possession of the text of the report
8. Compliance with regulations within 3-5 minutes.

List of theoretical questions to Final module control

1. Social pharmacy: origin, formation and prospects of development. Social pharmacy as an interdisciplinary and interdisciplinary science.
2. Health care reform strategy.
3. System of indicators of socially effective pharmaceutical support
4. System of rational use of drugs: principles, purpose, tasks, functions, mechanisms of regulation and directions of realization.
5. Characteristics of the main elements of standardization of medical and pharmaceutical information.
6. Pharmaceutical support for palliative patients.
7. Pharmaceutical support for patients with rare (orphan) diseases.
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14. Negative consequences of drug use: types, status, registration, control.
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Практикум для аудиторної роботи призначено для використання на практичних заняттях з дисципліни «Соціальна фармація» здобувачами вищої освіти спеціальності 226 Фармація, промислова фармація факультету з підготовки іноземних громадян.

Видання містить перелік теоретичних питань до кожної з тем відповідно до змісту навчальної програми дисципліни, практичні та ситуаційні завдання для виконання на заняттях, список рекомендованої літератури.

Навчальне видання

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