

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

**BANK OF ASSESSMENT TOOLS FOR DISCIPLINE**  
**INFORMATION SUPPORT FOR THE MEDICINE LIFECYCLE**

Training program (specialty): **33.05.01 PHARMACY**

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

Mode of study: **FULL-TIME**

Nizhny Novgorod  
2021

### 1. Bank of assessment tools for the current monitoring of academic performance, mid-term assessment of students in the discipline

This Bank of Assessment Tools (BAT) for the discipline "Information support for the medicine lifecycle" is an integral appendix to the working program of the discipline "Information support for the medicine lifecycle". All the details of the approval submitted in the WPD for this discipline apply to this BAT.

### 2. List of assessment tools

The following assessment tools are used to determine the quality of mastering the academic material by students in the discipline:

No.	Assessment tool	Brief description of the assessment tool	Presentation of the assessment tool in the BAT
1	Test	A system of standardized tasks that allows you to automate the procedure of measuring the level of knowledge and skills of a student	Bank of test tasks
2	Case-task	A problem task in which the student is offered to comprehend a real professionally-oriented situation necessary to solve this problem.	Tasks for solving cases
3	Colloquium	A tool of controlling the mastering of study materials of a topic, section or sections of a discipline, organized as a class in the form of an interview between a teacher and students.	Questions on topics/sections of the discipline
4	Workbook	A didactic complex designed for independent work of the student and allowing to assess the level of mastering study materials	Workbook sample

### 3. A list of competencies indicating the stages of their formation in the process of mastering the educational program and the types of evaluation tools

Code and formulation of competence	Stage of competence formation	Controlled sections of the discipline	Assessment tools
UC-1 Able to realize critical analysis of problem situations based on a systematic approach, develop strategy actions	Entry, Current, Mid-term	<b>Section 1.</b> Information support for the medicine lifecycle	Tests Case-tasks Colloquiums Workbooks
GPC-1 Able to use basic biological, physical-chemical, chemical, mathematical methods for the development,	Entry, Current, Mid-term	<b>Section 1.</b> Information support for the medicine lifecycle	Tests Case-tasks Colloquiums Workbooks

research and examination of medicines, the manufacture of medicinal products			
GPC-6 Able to understand the principles of modern information technologies and use them to solve the tasks of professional activity	Entry, Current, Mid-term	<b>Section 1.</b> Information support for the medicine lifecycle	Tests Case-tasks Colloquiums Workbooks
PC-4 Able to participate in monitoring the quality, effectiveness and safety of medicines and medicinal plant raw materials	Entry, Current, Mid-term	<b>Section 1.</b> Information support for the medicine lifecycle	Tests Case-tasks Colloquiums Workbooks
PC-9 Able to solve tasks of professional activities in the transfer of medicines through pharmaceutical and medical organizations	Entry, Current, Mid-term	<b>Section 1.</b> Information support for the medicine lifecycle	Tests Case-tasks Colloquiums Workbooks

#### 4. The content of the assessment tools of entry, current control

Entry /current control is carried out by the discipline teacher when conducting classes in the form of: test control, organization of a discussion, colloquium.

Assessment tools for current control.

##### 4.1. Bank of test tasks

Choose one correct answer:

№	Test tasks with multiple answers	The code of the competence for the formation of which the test task is aimed
1.	<p>PHARMACOECONOMICS IS science dealing with the economic analysis of the use of drugs in the treatment process</p> <p>Science investigating the use of medicines in large statistical populations</p> <p>A science that develops clinical research methods that make it possible to draw</p>	<p>UC-1</p> <p>OPC-1</p> <p>OPC-6</p> <p>PC-4</p> <p>PC-9</p>

	<p>fair conclusions by controlling for the impact of systematic and random errors</p> <p>a method of clinical research in which the results of modern treatment are compared with the observations of similar patients in the past</p>	
2.	<p>LIFE-SAVING MEDICINES USED IN CONDITIONS WITH LIFE-THREATENING WITHDRAWAL SYNDROME ARE CONSTANTLY NECESSARY FOR LIFESUPPORT</p> <p>a group of vital drugs</p> <p>group of necessary drugs</p> <p>a group of secondary drugs</p> <p>Drugs that account for less than 25% of the budget expenditures of a medical organization</p>	<p>UC-1</p> <p>OPC-1</p> <p>OPC-6</p> <p>PC-4</p> <p>PC-9</p>
3.	<p>THE COST OF THE DRUG USED REFERS TO</p> <p>medical expenses</p> <p>non-medical expenses</p> <p>indirect costs</p> <p>indirect costs</p>	<p>UC-1</p> <p>OPC-1</p> <p>OPC-6</p> <p>PC-4</p> <p>PC-9</p>
4.	<p>THE POSITIVE ASPECTS OF THE IMPLEMENTATION OF THE FORMULARY SYSTEM INCLUDE ALL OF THE FOLLOWING, EXCEPT</p> <p>with a decrease in the number of pharmacies</p> <p>and exclusion of unsafe and ineffective medicines from broad clinical practice</p> <p>national redistribution of funds for the purchase of medicines</p> <p>with a reduction in the total cost of treating certain diseases</p>	<p>UC-1</p> <p>OPC-1</p> <p>OPC-6</p> <p>PC-4</p> <p>PC-9</p>
5.	<p>THE COSTS THAT ARE ASSOCIATED WITH A PERSON'S DISABILITY DURING ILLNESS AND HIS INABILITY DURING THIS PERIOD TO BE USEFUL TO SOCIETY ENGAGED IN THE WORK PROCESS ARE CALLED</p> <p>Indirect</p> <p>direct non-medical</p> <p>direct medical</p> <p>intangible (intangible)</p>	<p>UC-1</p> <p>OPC-1</p> <p>OPC-6</p> <p>PC-4</p> <p>PC-9</p>
6.	<p>A PROSPECTIVE STUDY INVOLVES:</p> <p>formation of a group of patients in the present tense and targeted tracking of these patients in the future</p> <p>formation of a group of patients according to archival documents (medical histories, outpatient cards, etc.) and observation of it in the present tense</p> <p>the formation of a group of patients in the present tense and the collection of anamnestic information from them</p> <p>formation of a group of patients based on the anamnesis of their disease and targeted tracking of these patients in the future</p>	<p>UC-1</p> <p>OPC-1</p> <p>OPC-6</p> <p>PC-4</p> <p>PC-9</p>
7.	<p>RETROSPECTIVE RESEARCH INVOLVES:</p> <p>formation of a group of patients according to archival documents (medical histories, outpatient cards, etc.) and observation of it in the present tense</p> <p>the formation of a group of patients in the present tense and the collection of anamnestic information from them</p> <p>formation of a group of patients in the present tense and targeted tracking of these patients in the future</p> <p>formation of a group of patients based on the anamnesis of their disease and targeted tracking of these patients in the future</p>	<p>UC-1</p> <p>OPC-1</p> <p>OPC-6</p> <p>PC-4</p> <p>PC-9</p>
8.	<p>THE COST OF MEDICINES BELONGS TO THE CATEGORY OF COSTS</p>	<p>UC-1</p>

	<p>Direct medical</p> <p>Direct non-medical</p> <p>Indirect</p> <p>intangible (intangible)</p>	<p>OPC-1</p> <p>OPC-6</p> <p>PC-4</p> <p>PC-9</p>
9.	<p>INDIRECT COSTS ARE:</p> <p>economic losses from a decrease in labor productivity</p> <p>expenses incurred by the medical organization during the treatment of the patient</p> <p>general direct costs</p> <p>Expenditures on medicines</p>	<p>UC-1</p> <p>OPC-1</p> <p>OPC-6</p> <p>PC-4</p> <p>PC-9</p>
10.	<p>PHARMACOECONOMICS IS A SCIENCE THAT</p> <p>evaluates the results of use and the cost of pharmaceutical products to make a decision on their subsequent practical application and determine the pricing policy</p> <p>I am engaged in the study of medicines in application to humans</p> <p>studies the use of drugs and their effects at the level of populations or large groups of people for the rational use of the most effective and safe drugs</p> <p>evaluates the results and cost of medical services to optimize pricing policy.</p>	<p>UC-1</p> <p>OPC-1</p> <p>OPC-6</p> <p>PC-4</p> <p>PC-9</p>
11.	<p>WHAT IS THE MAIN DOCUMENT OF A CLINICAL TRIAL?</p> <p>Study protocol</p> <p>patient-signed informed consent</p> <p>Individual Registration Card</p> <p>Patient's outpatient record</p>	<p>UC-1</p> <p>OPC-1</p> <p>OPC-6</p> <p>PC-4</p> <p>PC-9</p>
12.	<p>MONITORING OF A CLINICAL TRIAL OF DRUGS IS</p> <p>a procedure for continuous monitoring of the progress of the clinical trial and its compliance with the requirements of the GCP</p> <p>systematic and independent verification of the documentation and activities of the parties involved in the study</p> <p>Responsibility for the organization, control and financing of a clinical trial</p> <p>submission of the research protocol to the state control bodies and the ethics commission</p>	<p>UC-1</p> <p>OPC-1</p> <p>OPC-6</p> <p>PC-4</p> <p>PC-9</p>
13.	<p>A CLINICAL TRIAL AUDIT IS</p> <p>systematic and independent verification of the documentation and activities of the parties involved in the study</p> <p>a procedure for continuous monitoring of the progress of the clinical trial and its compliance with the requirements of the GCP</p> <p>Decision-making on the conduct of a clinical trial</p> <p>submission of the research protocol to the state control bodies and the ethics commission</p>	<p>UC-1</p> <p>OPC-1</p> <p>OPC-6</p> <p>PC-4</p> <p>PC-9</p>
14.	<p>RANDOMIZATION IS</p> <p>Randomly assigning participants to the experimental and control groups</p> <p>Inclusion of patients in the study by random selection</p> <p>inclusion of incapacitated patients in the study without the consent of the trustees</p> <p>inclusion in the study of patients who are simultaneously participating in another study</p>	<p>UC-1</p> <p>OPC-1</p> <p>OPC-6</p> <p>PC-4</p> <p>PC-9</p>
15.	<p>WHAT DISCIPLINE STUDIES THE USE OF DRUGS AND THEIR EFFECTS AT THE POPULATION LEVEL?</p> <p>Pharmacoepidemiology</p> <p>PharmaEconomics</p>	<p>UC-1</p> <p>OPC-1</p> <p>OPC-6</p> <p>PC-4</p>

	Pharmacogenetics pharmacotherapy	PC-9
16.	WHAT PHARMACOECONOMIC CATEGORY CHARACTERIZES THE DEGREE OF COMPLIANCE BY THE PATIENT WITH THE REGIMEN PRESCRIBED BY THE DOCTOR FOR THE USE OF THE DRUG Compliance efficiency Clinical (therapeutic) efficacy security	UC-1 OPC-1 OPC-6 PC-4 PC-9
17.	WHAT PHARMACOECONOMIC CATEGORY CHARACTERIZES THE EFFICACY OF THE DRUG, ESTABLISHED IN THE CONDITIONS OF LIMITED CLINICAL TRIALS (BEFORE INTRODUCTION INTO WIDESPREAD MEDICAL PRACTICE) Clinical (therapeutic) efficacy efficiency Cost-effective use	UC-1 OPC-1 OPC-6 PC-4 PC-9
18.	WHICH PHARMACOECONOMIC CATEGORY MOST CHARACTERIZES THE EFFECT OF THE DRUG ON THE PATIENT'S QUALITY OF LIFE? poleznost efficiency Clinical (therapeutic) efficacy Cost-effective	UC-1 OPC-1 OPC-6 PC-4 PC-9
19.	THE LOSSES OF THE STATE CAUSED BY THE ABSENCE OF THE PATIENT AT THE WORKPLACE RELATE TO Indirect Direct non-medical intangible marginal	UC-1 OPC-1 OPC-6 PC-4 PC-9
20.	WHAT IS THE SUBJECT OF THE STUDY OF PHARMACOECONOMICS? Evaluation of the cost-effectiveness of treatment and prevention of the disease Evaluation of the effectiveness of the drug Estimating the cost of a medicinal product Estimating the costs of treatment and prevention of the disease	UC-1 OPC-1 OPC-6 PC-4 PC-9
21.	THE COST-EFFECTIVENESS ANALYSIS IS THAT It evaluates both the cost and the results of treatment (results in monetary terms) It measures both the added value between alternative therapies and the differences in health acquired after the use of each of the treatments (results in physical terms) allows you to compare the difference in the cost of alternative methods of drug therapy, provided that these methods give identical clinical results data on expenditure are combined with data on life expectancy and its quality	UC-1 OPC-1 OPC-6 PC-4 PC-9
22.	USEFULNESS IN PHARMACOECONOMIC ANALYSIS IS mathematical expression of the patient's preferences Indicator of clinical efficacy of the use of a new drug The importance of the likelihood of developing side effects of treatment The significance of the results of medical intervention from the point of view of the consumer	UC-1 OPC-1 OPC-6 PC-4 PC-9

23.	<p>THE PHARMACOECONOMIC METHOD OF ANALYSIS, IN WHICH A COMPARATIVE ASSESSMENT OF TWO OR MORE INTERVENTIONS CHARACTERIZED BY IDENTICAL EFFICACY AND SAFETY, BUT OF DIFFERENT COSTS, IS CALLED:</p> <p>Minimizing costs The cost of the disease Cost-effectiveness Cost-benefit</p>	<p>UC-1 OPC-1 OPC-6 PC-4 PC-9</p>
24.	<p>THE CONSTRUCTION OF A "GOAL TREE", NETWORK GRAPHS, SCIENTIFICALLY BASED SCHEMES IS CALLED</p> <p>Modeling Communications Documentation clerical work</p>	<p>UC-1 OPC-1 OPC-6 PC-4 PC-9</p>
25.	<p>PHARMACOECONOMIC ANALYSIS OF COST MINIMIZATION IS USED IN THOSE CASES</p> <p>when the compared treatments have the same clinical efficacy when the compared treatments have different clinical efficacy when the compared treatments have different costs when it is difficult to establish the clinical efficacy of the compared methods</p>	<p>UC-1 OPC-1 OPC-6 PC-4 PC-9</p>
26.	<p>THE APPLICATION OF PHARMACOECONOMIC COST-EFFECTIVENESS ANALYSIS IS MOST APPROPRIATE</p> <p>when one of the methods is more expensive but more effective when it is difficult to establish the clinical efficacy of the compared methods when the compared methods have the same efficacy when it is difficult to establish the cost of the compared methods</p>	<p>UC-1 OPC-1 OPC-6 PC-4 PC-9</p>
27.	<p>THE PHARMACOECONOMIC INDICATOR OF THE EFFECTIVENESS OF TREATMENT CAN BE EXPRESSED AT THE COST OF ONE SAVED YEAR OF LIFE</p> <p>in the cost-utility analysis in cost-effectiveness analysis in cost-benefit analysis in the analysis of cost minimization</p>	<p>UC-1 OPC-1 OPC-6 PC-4 PC-9</p>
28.	<p>COST-EFFECTIVENESS ANALYSIS IS USED TO DETERMINE</p> <p>how much money you need to spend extra to get a certain clinical advantage Which drug is cheaper What drug should be used to save money which drug should be used to obtain the greatest clinical efficacy</p>	<p>UC-1 OPC-1 OPC-6 PC-4 PC-9</p>
29.	<p>THE PURPOSE OF THE COST-UTILITY ANALYSIS IS</p> <p>determine the degree of usefulness of a medical intervention in QALY units determine the additional amount of money that needs to be spent to obtain an additional unit of efficiency show the advantage of a cheaper method of treatment or drug, which saves money calculate the benefits of the treatment method</p>	<p>UC-1 OPC-1 OPC-6 PC-4 PC-9</p>
30.	<p>MODELING IN PHARMACOECONOMIC STUDIES IS USED IN THE CASE WHEN</p> <p>insufficient reliable data to solve the problems facing the researcher</p>	<p>UC-1 OPC-1 OPC-6</p>

	<p>The task facing the researcher is not clearly defined</p> <p>The time of receipt of the results of the study does not matter</p> <p>The number of study participants (patients) is extremely large</p>	<p>PC-4</p> <p>PC-9</p>
31.	<p>INDICATORS REFLECTING THE YEARS OF QUALITY OF LIFE - QALY, ARE USED IN THE PHARMACOECONOMIC ANALYSIS BY THE METHOD</p> <p>"Cost-utility"</p> <p>"Cost-effectiveness"/"Cost minimization"</p> <p>"Cost-benefit"</p> <p>simulation</p>	<p>UC-1</p> <p>OPC-1</p> <p>OPC-6</p> <p>PC-4</p> <p>PC-9</p>
32.	<p>INDICATORS REFLECTING THE CLINICAL EFFICACY OF TREATMENT OR THE NUMBER OF YEARS OF SAVED LIFE ARE USED IN THE PHARMACOECONOMIC ANALYSIS BY THE METHOD</p> <p>"Cost-effectiveness"/"Cost minimization"</p> <p>"Cost-utility"</p> <p>"Cost-benefit"</p> <p>simulation</p>	<p>UC-1</p> <p>OPC-1</p> <p>OPC-6</p> <p>PC-4</p> <p>PC-9</p>
33.	<p>INDICATORS REFLECTING THE COST OF LOST WORKING TIME ARE USED IN FARMAK'S ECONOMIC ANALYSIS BY THE METHOD OF</p> <p>"Cost-benefit"</p> <p>"Cost-effectiveness"/"Cost minimization"</p> <p>"Cost-utility"</p> <p>simulation</p>	<p>UC-1</p> <p>OPC-1</p> <p>OPC-6</p> <p>PC-4</p> <p>PC-9</p>
34.	<p>INDICATORS REFLECTING THE DESIRE/WILLINGNESS TO PAY (WTP) ARE USED IN FARMAK'S ECONOMIC ANALYSIS BY THE METHOD OF</p> <p>"Cost-benefit"</p> <p>"Cost-effectiveness"/"Cost minimization"</p> <p>"Cost-utility"</p> <p>simulation</p>	<p>UC-1</p> <p>OPC-1</p> <p>OPC-6</p> <p>PC-4</p> <p>PC-9</p>
35.	<p>CRITERIA FOR EVALUATING EFFICACY, EXPRESSED IN "NATURAL" UNITS (FOR EXAMPLE, MMOL / L IN DETERMINING CHOLESTEROL LEVELS), AS WELL AS IN LIFE EXPECTANCY, ARE USED IN THE ANALYSIS BY THE METHOD</p> <p>"Cost-effectiveness"/"Cost minimization"</p> <p>"Cost-utility"</p> <p>"Cost-benefit"</p> <p>simulation</p>	<p>UC-1</p> <p>OPC-1</p> <p>OPC-6</p> <p>PC-4</p> <p>PC-9</p>
36.	<p>TO ANSWER THE QUESTION "HOW MUCH DO I HAVE TO PAY FOR THE ADDITIONAL BENEFIT OF A MORE EFFECTIVE METHOD OF TREATMENT?"</p> <p>incremental analysis</p> <p>analysis with the construction of a decision tree</p> <p>cost-benefit analysis</p> <p>analysis of willingness to pay</p>	<p>UC-1</p> <p>OPC-1</p> <p>OPC-6</p> <p>PC-4</p> <p>PC-9</p>
37.	<p>QUANTITATIVE VALUES REFLECTING THE SUBJECTIVE PREFERENCES OF INDIVIDUALS (DOCTORS, PATIENTS) REGARDING THE OUTCOMES OR METHODS OF TREATING THE DISEASE ARE USED IN THE ANALYSIS BY THE METHOD</p>	<p>UC-1</p> <p>OPC-1</p> <p>OPC-6</p> <p>PC-4</p> <p>PC-9</p>



	"Cost-utility" "Cost-effectiveness"/"Cost minimization" "Cost-benefit" simulation	
38.	WHEN CONDUCTING A COST-BENEFIT ANALYSIS Rates are estimated in monetary terms, the results of medical intervention in monetary terms Rates are estimated in monetary terms, and the results of medical intervention in statistical terms Statistical indicators are evaluated, and the results of medical intervention in monetary terms for expenses are evaluated in monetary terms, the results of medical intervention are evaluated by the patient	UC-1 OPC-1 OPC-6 PC-4 PC-9
39.	COST-UTILITY ANALYSIS IS A SPECIAL CASE OF THE METHOD OF ANALYSIS "Efficiency" Worth of Disease cost simulation "Forfeiting-profit"	UC-1 OPC-1 OPC-6 PC-4 PC-9
40.	GROUP "C" DURING THE ABC ANALYSIS INCLUDES PREPARATIONS, FOR WHICH THE 3-4% of the total cost of drugs 15-20% of the total cost of drugs 40-50% of the total cost of drugs 75-80% of the total cost of drugs	UC-1 OPC-1 OPC-6 PC-4 PC-9

#### 4.2. Bank of case-tasks for solving cases

№	Case-task	The code of the competence for the formation of which the case-task is aimed
1.	A patient with gastric ulcer was hospitalized in the therapeutic department of the hospital. The duration of the patient's stay in the hospital according to the standard of medical care for the treatment of LBJ is 24 days. The calculation of the cost of treatment according to the standard (24 days) is 4778 units (including diagnostic measures - 850 units). The cost of 1 bed-day in the hospital is 1600 units. In order to increase the efficiency of the use of beds due to the continuity of outpatient and inpatient care, part of the diagnostic procedures / analyzes is carried out in the outpatient clinic. The cost of diagnostics at the prehospital level for patients with LBJ is 850 units, and the duration of the patient's stay in the hospital according to the standard of treatment of LBJ is reduced by 4 days. Determine the new cost of treatment according to the standard of medical care for the treatment of LBJ, subject to partial diagnosis in an outpatient clinic. Conduct a comparative assessment of the costs in the treatment of LBJ according to the medical standard in two different ways: treatment of the patient, including all diagnostic measures in the hospital, and treatment of the patient with partial diagnosis at the outpatient level.	UC-1 OPC-1 OPC-6 PC-4 PC-9
2.	Highlight the direct and indirect costs of the following: diagnosis and	UC-1

	treatment; social services; payment by the patient for services; temporary disability; use of the drug; disability benefit; social exclusion; Staff payment.	OPC-1 OPC-6 PC-4 PC-9																																																																
3.	<p>Patients diagnosed with suspected glaucoma are examined in an ophthalmological clinic. Examination and diagnosis of patients with such a diagnosis can be carried out both in a round-the-clock hospital (7 days) and in a day hospital (7 days).</p> <p>The cost of a bed-day is 550 units in a round-the-clock hospital and 207 units in a day hospital.</p> <p>The cost of diagnostic manipulations according to the first scheme (only direct costs) is 7530 rubles. for the entire period. At the same time, indirect and direct non-medical costs account for 70% of the cost of diagnosing and monitoring a patient in a hospital.</p> <p>The cost of diagnostic manipulations according to the second scheme (only direct costs) is 6790 rubles. for the entire period. At the same time, indirect and direct non-medical costs account for 60% of the cost of diagnosing and monitoring a patient in a hospital.</p> <p>What are the cost savings when using alternative technologies for organizing the examination and diagnosis of patients diagnosed with suspected glaucoma?</p>	UC-1 OPC-1 OPC-6 PC-4 PC-9																																																																
4.	<p>A patient with LBJ was hospitalized in a hospital where, in addition to the traditional method of treating LBJ, the method of chipping an ulcer with gamma globulin is used. After clarifying the diagnosis, the doctor decides to treat the patient by chipping the ulcer with gamma globulin. The cost of treatment in the traditional way is 7,535 rubles, the cost of using gamma globulin is 21,000 rubles. The cost of a bed-day is 1200 rubles. With traditional treatment, the patient's stay in the hospital is 15 days, which is 3 times more than the second method.</p> <p>Conduct a comparative assessment of the costs of treating LBJ by the two methods.</p>	UC-1 OPC-1 OPC-6 PC-4 PC-9																																																																
5.	<p>Conduct an ABC/VEN analysis of the procurement structure of health care facilities, if the following drugs were purchased and consumed during the study period:</p> <table border="1" data-bbox="311 1303 783 1762"> <thead> <tr> <th>Препарат</th> <th>ЛФ</th> <th>Цена за упаковку, руб.</th> <th>Израсходовано за год упак.</th> </tr> </thead> <tbody> <tr><td>Линкомицин</td><td>амп</td><td>12</td><td>2000</td></tr> <tr><td>Солжосерил</td><td>амп</td><td>440</td><td>500</td></tr> <tr><td>Диклофенак</td><td>таб</td><td>26</td><td>1000</td></tr> <tr><td>Атенолол</td><td>таб</td><td>25</td><td>2500</td></tr> <tr><td>Рибоксин</td><td>амп</td><td>12</td><td>600</td></tr> <tr><td>Фуросемид</td><td>амп</td><td>8</td><td>1500</td></tr> <tr><td>Нитроглицерин</td><td>таб</td><td>9</td><td>3000</td></tr> <tr><td>Актовегин</td><td>амп</td><td>13</td><td>1400</td></tr> <tr><td>Верапамил</td><td>таб</td><td>5</td><td>1300</td></tr> <tr><td>Но-шпа</td><td>таб</td><td>4</td><td>7000</td></tr> <tr><td>Инсулин</td><td>фл</td><td>360</td><td>1100</td></tr> <tr><td>Преднизолон</td><td>амп</td><td>20</td><td>3300</td></tr> <tr><td>Ампициллин</td><td>таб</td><td>15</td><td>2500</td></tr> <tr><td>Кокарбоксылаза</td><td>амп</td><td>120</td><td>1250</td></tr> <tr><td>Дигоксин</td><td>таб</td><td>36</td><td>600</td></tr> </tbody> </table>	Препарат	ЛФ	Цена за упаковку, руб.	Израсходовано за год упак.	Линкомицин	амп	12	2000	Солжосерил	амп	440	500	Диклофенак	таб	26	1000	Атенолол	таб	25	2500	Рибоксин	амп	12	600	Фуросемид	амп	8	1500	Нитроглицерин	таб	9	3000	Актовегин	амп	13	1400	Верапамил	таб	5	1300	Но-шпа	таб	4	7000	Инсулин	фл	360	1100	Преднизолон	амп	20	3300	Ампициллин	таб	15	2500	Кокарбоксылаза	амп	120	1250	Дигоксин	таб	36	600	UC-1 OPC-1 OPC-6 PC-4 PC-9
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6.	<p>In the treatment of patients with small-focal myocardial infarction in sanatorium conditions, two methods of treatment were used: taking the lipid-lowering drug zocor and prescribing a specially developed therapeutic diet. The clinical results of the speech showed that positive results were observed with method 1 3-4 days earlier. The cost of treatment was 10600 rubles and 9100 rubles, respectively. The number of treated patients was 60 and 50 people, respectively. Calculate the conditional savings obtained by treating with a more optimal method of treatment.</p>	UC-1 OPC-1 OPC-6 PC-4 PC-9																																																																
7.	A patient diagnosed with primary open-angle glaucoma (POAG) was	UC-1																																																																

	<p>hospitalized in the ophthalmological clinic. In addition to drug therapy (MT) of POAG, the clinic uses surgical treatment by trabeculotomy (antiglaucomatous surgery - AGO).</p> <p>The table shows the cost of examination and treatment of a patient receiving drug therapy and a patient who underwent surgical treatment during the year and over a three-year period.</p> <p>Calculate the cost difference for the year and for 3 years. Make a conclusion.</p> <table border="1" data-bbox="276 427 970 633"> <thead> <tr> <th>Группа затрат</th> <th>MT</th> <th>АГО</th> </tr> </thead> <tbody> <tr> <td colspan="3" style="text-align: center;">За год</td> </tr> <tr> <td>Амбулаторно-поликлиническое обследование</td> <td colspan="2" style="text-align: center;">4419</td> </tr> <tr> <td>Лечение</td> <td>14830</td> <td>23785</td> </tr> <tr> <td colspan="3" style="text-align: center;">За трехлетний период</td> </tr> <tr> <td>Амбулаторно-поликлиническое обследование</td> <td>13257</td> <td>7365</td> </tr> <tr> <td>Лечение</td> <td>44490</td> <td>28204</td> </tr> </tbody> </table>	Группа затрат	MT	АГО	За год			Амбулаторно-поликлиническое обследование	4419		Лечение	14830	23785	За трехлетний период			Амбулаторно-поликлиническое обследование	13257	7365	Лечение	44490	28204	OPC-1 OPC-6 PC-4 PC-9
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8.	<p>Using the pharmacoeconomic method of cost-effectiveness analysis, compare two alternative methods of treating patients with myocardial infarction.</p> <p>For the second method of treatment, determine the cost of an additional unit of effectiveness.</p> <p>Draw a conclusion based on the results of the calculations.</p> <p style="text-align: center;">Характеристика альтернативных методов лечения больных, перенесших инфаркт миокарда</p> <table border="1" data-bbox="288 913 975 1043"> <thead> <tr> <th>Показатель</th> <th>Метод А</th> <th>Метод Б</th> </tr> </thead> <tbody> <tr> <td>Прямые затраты на лечение 1 больного на протяжении года</td> <td>72 000 руб.</td> <td>180 000 руб.</td> </tr> <tr> <td>Снижение смертности на протяжении года</td> <td>с 30% до 25%</td> <td>с 30% до 10%</td> </tr> </tbody> </table>	Показатель	Метод А	Метод Б	Прямые затраты на лечение 1 больного на протяжении года	72 000 руб.	180 000 руб.	Снижение смертности на протяжении года	с 30% до 25%	с 30% до 10%	UC-1 OPC-1 OPC-6 PC-4 PC-9												
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9.	<p>Using the pharmacoeconomic method of cost-benefit analysis, compare two alternative methods of treatment (radiation therapy and surgical treatment) of patients with laryngeal cancer.</p> <p>When making calculations, use the following data:</p> <ul style="list-style-type: none"> <li>– the cost of surgical treatment is 14,000 rubles;</li> <li>– the cost of radiation therapy is 9600 rubles;</li> <li>– radiation therapy prolongs the patient's life by 8 years with a quality of life index = 0.4;</li> </ul> <p>Surgical treatment prolongs the patient's life by 15 years with a quality of life index = 0.7.</p>	UC-1 OPC-1 OPC-6 PC-4 PC-9																					
10.	<p>By building a <i>decision tree</i>, compare the costs of using Plavix and Tiklid for the prevention of myocardial infarction and stroke in patients with vascular pathology.</p> <p>Draw a conclusion about the advisability of replacing the drug Tiklid with this pathology with a more effective, but expensive drug Plavix.</p> <p>When comparing drugs, consider the likelihood of developing agranulocytosis (as a side effect of treatment). The cost of a course of therapy for agranulocytosis with the use of Plavix or Tiklid for one patient is 2100 rubles.</p> <p style="text-align: center;">Характеристика альтернативных методов профилактики инфаркта миокарда и инсульта</p> <table border="1" data-bbox="268 1794 983 1877"> <thead> <tr> <th>Показатель</th> <th>Плавикс</th> <th>Тиклид</th> </tr> </thead> <tbody> <tr> <td>Стоимость курса лечения, руб.</td> <td>4 500</td> <td>1 900</td> </tr> <tr> <td>Вероятность развития агранулоцитоза</td> <td>0,4</td> <td>0,7</td> </tr> </tbody> </table>	Показатель	Плавикс	Тиклид	Стоимость курса лечения, руб.	4 500	1 900	Вероятность развития агранулоцитоза	0,4	0,7	UC-1 OPC-1 OPC-6 PC-4 PC-9												
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11.	<p>According to the results of a meta-analysis of randomized clinical trials, it was found that the effectiveness of antibiotic therapy for intra-abdominal infections is: for meropenem – 86.0%, for meropenem – 77.5%, for cefepime in combination with piperacillin – 75.3%, for a combination of cefoperazone and sulbactam – 76.8%. There were no statistically significant differences between the last three groups (08).</p>	UC-1 OPC-1 OPC-6 PC-4 PC-9																					

	<p>Determine the optimal antibacterial drug from a pharmacoeconomic point of</p> <table border="1" data-bbox="272 259 746 689"> <thead> <tr> <th>Прямые медицинские затраты, руб.</th> <th>Имипенем</th> <th>Меропенем</th> <th>Цефитим + метронидазол</th> <th>Цефоперазон + сульбактам</th> </tr> </thead> <tbody> <tr> <td>Стоимость курса лечения исследуемым антибиотиком</td> <td>23 173</td> <td>16 820</td> <td>9 360</td> <td>16 194</td> </tr> <tr> <td>Стоимость лечения дополнительным антибиотиком при смене схемы</td> <td>2 703</td> <td>3 477</td> <td>121</td> <td>93р.</td> </tr> <tr> <td>Стоимость лечения осложнений</td> <td>156</td> <td>148</td> <td>159</td> <td>40</td> </tr> <tr> <td>Стоимость терапии побочных эффектов</td> <td>95</td> <td>141</td> <td>125</td> <td>146</td> </tr> </tbody> </table>	Прямые медицинские затраты, руб.	Имипенем	Меропенем	Цефитим + метронидазол	Цефоперазон + сульбактам	Стоимость курса лечения исследуемым антибиотиком	23 173	16 820	9 360	16 194	Стоимость лечения дополнительным антибиотиком при смене схемы	2 703	3 477	121	93р.	Стоимость лечения осложнений	156	148	159	40	Стоимость терапии побочных эффектов	95	141	125	146	
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12.	<p>As a result of the use of Treatment A, the survival rate of patients is 1 year with a QoL value of 0.7, the cost of the treatment process is 140,000 rubles.</p> <p>The use of Treatment B increases survival to 1.2 years, but reduces QoL to 0.6. The cost of the treatment process is 216,000 rubles.</p> <p>Calculate the QALY score and give a pharmacoeconomic assessment of alternative treatment methods based on incremental analysis.</p>	<p>UC-1 OPC-1 OPC-6 PC-4 PC-9</p>																									
13.	<p>Various iron supplements are used to treat iron deficiency anemia. They differ in the content of Fe ++ in one tablet, but sooner or later all lead to the normalization of hemoglobin levels.</p> <p>The daily therapeutic dose of Fe ++ is 200 mg.</p> <p>Make a conclusion about which iron preparation is optimal from the point of view of pharmacoeconomics in terms of normalizing hemoglobin levels after 1 month of administration.</p> <table border="1" data-bbox="272 1211 727 1451"> <thead> <tr> <th>Показатель</th> <th>Железо+</th> <th>Феррум-Актив</th> <th>Ферропан</th> <th>Супер-Феррон</th> <th>Феррум-плюс</th> </tr> </thead> <tbody> <tr> <td>Содержание Fe<sup>++</sup> в одной таблетке, мг</td> <td>10</td> <td>100</td> <td>80</td> <td>45</td> <td>100</td> </tr> <tr> <td>Цена упаковки</td> <td>206</td> <td>318</td> <td>442</td> <td>95</td> <td>153</td> </tr> <tr> <td>Количество таблеток в упаковке</td> <td>100</td> <td>50</td> <td>30</td> <td>10</td> <td>30</td> </tr> </tbody> </table>	Показатель	Железо+	Феррум-Актив	Ферропан	Супер-Феррон	Феррум-плюс	Содержание Fe <sup>++</sup> в одной таблетке, мг	10	100	80	45	100	Цена упаковки	206	318	442	95	153	Количество таблеток в упаковке	100	50	30	10	30	<p>UC-1 OPC-1 OPC-6 PC-4 PC-9</p>	
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14.	<p>When analyzing the effectiveness of monotherapy for arterial hypertension, the quality of life of patients was assessed. Usefulness was assessed by patients on a visual analogue scale of quality of life from 0 to 10, where 0 is the worst state of health, and 10 is the best.</p> <p>Use the incremental indicator for the calculation.</p> <p>Make a conclusion about which drug is the most optimal in terms of usefulness.</p> <table border="1" data-bbox="272 1738 970 1928"> <thead> <tr> <th>Показатель</th> <th>Атенолол</th> <th>Амприлан</th> <th>Энап</th> <th>Норваск</th> </tr> </thead> <tbody> <tr> <td>Стоимость курса лечения (12 недель), руб.</td> <td>5 683</td> <td>4 989</td> <td>10 035</td> <td>17 464</td> </tr> <tr> <td>Среднее значение по шкале качества жизни</td> <td>22</td> <td>14</td> <td>95</td> <td>97</td> </tr> </tbody> </table>	Показатель	Атенолол	Амприлан	Энап	Норваск	Стоимость курса лечения (12 недель), руб.	5 683	4 989	10 035	17 464	Среднее значение по шкале качества жизни	22	14	95	97	<p>UC-1 OPC-1 OPC-6 PC-4 PC-9</p>										
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16.	<p>To determine the optimal approach from a pharmacoeconomic point of view to the treatment of patients with atherothrombosis at the outpatient stage.</p> <p>The duration of the course is 24 weeks.</p> <p>Compared approach: ASA at a daily dose of 125 mg, Clopidogrel at a daily dose of 75 mg, Combination of ASA + Clopidogrel every other day.</p> <p>The cost of medicines should be taken at current prices. The cost of medical supervision was 110,536 rubles for the ASC group, 16,764 rubles for the Clopidogrel group, and 14,291 rubles for the combination therapy group.</p> <p>The efficiency of platelet aggregation activity was 50% in the ASA group, 100% in the Clopidogrel group and 95% in the combination therapy group.</p>	UC-1 OPC-1 OPC-6 PC-4 PC-9												
17.	<p>To conduct a comparative pharmacoeconomic analysis of equivalent analogues of ultra-short-acting insulin per monthly course of therapy at a dose of 0.3 IU / day. The average weight of patients was 80 kg.</p> <p>When calculating the cost of pharmacotherapy, calculate the cost per unit of the active ingredient (Sed, ml) and the cost of the prescribed daily dose (PDD, IU / kg).</p> <p>Calculate the cost savings when using the most optimal drug and the indicator of "missed opportunities".</p> <table border="1"> <thead> <tr> <th>ЛП</th> <th>Форма выпуска</th> <th>Средняя цена, руб.</th> </tr> </thead> <tbody> <tr> <td>Инсулин А</td> <td>100МЕ/ 3мл/ №5</td> <td>2 326</td> </tr> <tr> <td>Инсулин Б</td> <td>100МЕ/ 3мл/ №5</td> <td>2 122</td> </tr> <tr> <td>Инсулин В</td> <td>100МЕ/ 3мл/ №5</td> <td>1 943</td> </tr> </tbody> </table>	ЛП	Форма выпуска	Средняя цена, руб.	Инсулин А	100МЕ/ 3мл/ №5	2 326	Инсулин Б	100МЕ/ 3мл/ №5	2 122	Инсулин В	100МЕ/ 3мл/ №5	1 943	UC-1 OPC-1 OPC-6 PC-4 PC-9
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18.	<p>Treatment of chronic heart failure is most effective if it is carried out starting from the early stages of the disease. For the diagnosis and treatment of the early stages, expensive equipment (echocardiographs, ultrasound scanners) and drugs (ACE inhibitors) are used. How can you tell if treating early-stage heart failure is cost-effective? Explain using the example of the Markov model.</p>	UC-1 OPC-1 OPC-6 PC-4 PC-9												
19.	<p>To determine the optimal approach from a pharmacoeconomic point of view to the treatment of patients with atherothrombosis at the outpatient stage.</p> <p>The duration of the course is 24 weeks.</p> <p>Compared approach: ASA at a daily dose of 125 mg, Clopidogrel at a daily dose of 75 mg, Combination of ASA + Clopidogrel every other day.</p> <p>The cost of medicines to take at current prices (aspirin No. 28 - 130 p., Clopidogrel No. 28 - 630 rubles). The cost of medical supervision was 110,536 rubles for the ASC group, 16,764 rubles for the Clopidogrel group, and 14,291 rubles for the combination therapy group.</p> <p>The efficiency of platelet aggregation activity was 50% in the ASA group, 100% in the Clopidogrel group and 95% in the combination therapy group.</p>	UC-1 OPC-1 OPC-6 PC-4 PC-9												
20.	<p>The cost of therapy A is 320,000 rubles. Additional life expectancy is 1.6 years</p> <p>The cost of therapy B - 20,000 rubles Additional life expectancy - 0.2 years</p> <p>The cost of therapy C - 50,000 rubles Additional life expectancy - 0.05 years</p> <p>Which treatment option is most cost-effective?</p>	UC-1 OPC-1 OPC-6 PC-4 PC-9												
21.	<p>To conduct a comparative pharmacoeconomic analysis of the use of ovestin in the treatment of urinary tract infections, using the following initial data:</p>	UC-1 OPC-1 OPC-6 PC-4												

	Медицинские технологии	Стоимость	Кратн. на 100 чел.		PC-9												
			Овестин	Плацебо													
	Профилактика ИМП (Овестин)	~2300 руб. в год на 1чел	1	0													
	Лечение ИМП (Ципрофлоксацин)	~13 руб. на 1 случай ИМП	50	590													
	Посещение гинеколога	400 руб./ед.	4	0													
	Посещение уролога	300 руб./ед.	100	1180													
	Анализ крови	250 руб./ед.	50	590													
	Анализ мочи	200 руб./ед.	50	590													
	БАК-посев	150 руб./ед.	50	590													
	Эффективность терапии, %		72	58													
22.	<p>In the HOPE study (The Heart Outcomes Prevention Evaluation), which took place for 4.5 years, 9297 people took part (4645 in the ramipril 10 mg / day group and 4652 in the placebo group).</p> <p>The cost of Tritace (ramipril) table. 10 mg No. 28, production of Sanofi-Aventis - 530 rubles. The progression of angina pectoris included additional treatment with antianginal drugs in the amount of 1450 rubles per month. The cost of one day of hospitalization in the cardiology department was 745 rubles, the average length of stay in the department was 14 days. The cost of myocardial revascularization surgery, together with a hospital stay, amounted to 83,000 rubles.</p> <p>Determine the cost of saving 1 year of life of 1 patient.</p> <table border="1" data-bbox="316 922 916 1106"> <thead> <tr> <th></th> <th>Рамиприл (n = 4645)</th> <th>Плацебо (n = 4652)</th> </tr> </thead> <tbody> <tr> <td>Сердечно-сосудистая смертность</td> <td>283</td> <td>377</td> </tr> <tr> <td>Прогрессирование стенокардии</td> <td>1107</td> <td>1220</td> </tr> <tr> <td>Госпитализации</td> <td>554</td> <td>565</td> </tr> <tr> <td>Операции по реваскуляризации</td> <td>742</td> <td>852</td> </tr> </tbody> </table>		Рамиприл (n = 4645)	Плацебо (n = 4652)	Сердечно-сосудистая смертность	283	377	Прогрессирование стенокардии	1107	1220	Госпитализации	554	565	Операции по реваскуляризации	742	852	UC-1 OPC-1 OPC-6 PC-4 PC-9
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23.	<p>In the treatment of disease X in placebo-controlled studies, the effectiveness of alternative medical strategies with the use of drugs A and B has been proven.</p> <p>In the placebo group, the mortality rate is 10%.</p> <p>With therapy A, the relative reduction in the risk of death is 0.4, with therapy B - 0.8.</p> <p>Therapy A requires a cost of 40 thousand rubles, therapy B - 20 thousand rubles.</p> <p>Which treatment option is preferable from an economic point of view?</p>	UC-1 OPC-1 OPC-6 PC-4 PC-9															
24.	<p>Therapy A requires a cost of 30,000 rubles. and provides a life expectancy of 10 years.</p> <p>Therapy B requires a cost of 130,000 rubles. and provides a life span of 10.1 years.</p> <p>What is the cost of 1 extra year of life with Therapy B compared to Therapy A?</p>	UC-1 OPC-1 OPC-6 PC-4 PC-9															
25.	<p>With therapy A, the mortality rate is 5%. The cost of therapy is 10,000 rubles, toxic effects requiring medical correction are observed in 10% of patients, the cost of their correction in 1 patient is 10,000 rubles.</p> <p>With therapy B, the mortality rate is 3%. The cost of therapy is 15,000 rubles, toxic effects requiring medical correction are observed in 5% of patients, the cost of their correction in 1 patient is 10,000 rubles.</p> <p>What is the cost of one additional life saved with therapy B compared to therapy A?</p>	UC-1 OPC-1 OPC-6 PC-4 PC-9															
26.	<p>With disease A, the mortality rate is 2%. The relative reduction in mortality during therapy is 20%, additional costs are 4000 rubles.</p> <p>With disease B, the mortality rate is 15%. The relative reduction in mortality during therapy is 10%, additional costs are 15,000 rubles.</p> <p>In case of disease C, mortality is 20%, a relative decrease in mortality during therapy is 5%, additional costs are 5000 rubles.</p>	UC-1 OPC-1 OPC-6 PC-4 PC-9															

In which case is therapy more cost-effective?																				
27.	Perform a pharmacoeconomic analysis of drugs used to treat migraine using the incremental method. Calculate the missed opportunity score. <table border="1" data-bbox="295 293 783 465"> <thead> <tr> <th>Препарат</th> <th>Затраты</th> <th>% больных с уменьшением головной боли через 2 часа</th> </tr> </thead> <tbody> <tr> <td>Аспирин</td> <td>1696</td> <td>10</td> </tr> <tr> <td>Суматриптан</td> <td>1547</td> <td>50</td> </tr> <tr> <td>Элетриптан</td> <td>1398</td> <td>67</td> </tr> <tr> <td>Зомиг</td> <td>1560</td> <td>43</td> </tr> <tr> <td>Релпакс</td> <td>2160</td> <td>52</td> </tr> </tbody> </table>	Препарат	Затраты	% больных с уменьшением головной боли через 2 часа	Аспирин	1696	10	Суматриптан	1547	50	Элетриптан	1398	67	Зомиг	1560	43	Релпакс	2160	52	UC-1 OPC-1 OPC-6 PC-4 PC-9
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### 4.3. Questions for colloquiums

1. Study of the clinical efficacy of pharmaceutical care.
2. Evidence-based medicine as a source of information on the effectiveness of medical interventions for pharmacoeconomic research.
3. Regulatory framework for pharmacoeconomic research.
4. Basic principles of economic evaluation of the effectiveness of pharmacotherapy.
5. Parameters for evaluating efficacy (efficacy, clinical efficacy, cost-effectiveness).
6. Cost categories.
7. Types of regulatory documentation for standardization.
8. Goals and objectives of pharmacoeconomics.
9. Basic principles of pharmacoeconomic research.
10. Types of pharmacoeconomic studies (depending on the target audience of the results obtained, methods for collecting information on effectiveness, etc.).
11. Prospects for the use of the results of pharmacoeconomic analysis at different levels in the health care system.
12. The target audience of the results of pharmacoeconomic studies.
13. Pharmacoeconomic analysis as an element of post-marketing research of randomized clinical trials of drugs.
14. The relationship between marketing and pharmacoeconomics.
15. The structure of the pharmacoeconomic study: the formulation of goals and objectives, the choice of alternative interventions, the definition of criteria for the inclusion of patients.
16. Selection of performance evaluation criteria, selection of the observation period, ensuring the homogeneity of the compared groups, development of an individual registration card,
17. Conducting pharmacoeconomic research, processing the results obtained and formulating conclusions.
18. Basic and auxiliary methods of pharmacoeconomics.
19. The choice of the method of pharmacoeconomic analysis depending on the goals and parameters for assessing the pharmacoeconomic efficiency.
20. Pharmacoeconomic method "analysis of the cost of the disease": purpose, features, advantages, disadvantages, scope, calculation formulas.
21. Pharmacoeconomic method "cost minimization analysis": purpose, features, advantages, disadvantages, scope, calculation formulas.
22. Pharmacoeconomic method of cost-effectiveness analysis: purpose, features, advantages, disadvantages, scope, formulas for calculating coefficients.
23. Pharmacoeconomic method of cost-benefit analysis: purpose, features, advantages, disadvantages, scope, calculation formulas.
24. Usefulness indicators. Quality of life as a criterion for the effectiveness of medical interventions. Parameters for assessing the quality of life.
25. Methods for quantifying the prognostic state of health.
26. Pharmacoeconomic method of cost-benefit analysis: purpose, features, advantages, disadvantages, scope, calculation formulas.

- 27. Pharmacoeconomic modeling. Methodology of decision analysis.
- 28. Principles of building a decision tree, the Markov model.

**4.4. Workbook sample**

**TOPIC 1 – THE MEDICINE LIFECYCLE CONCEPT**

**1.1. The product lifecycle is ...**

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**1.2. Conduct a comparative analysis of approaches to the description of a lifecycle model (the economic product lifecycle model, the lifecycle model by ICH Q10 Pharmaceutical Quality System, the detailed lifecycle model). Schematically illustrate the points of intersection (common stages) of different approaches.**

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**1.3. Why the classical economic model of the lifecycle of goods does not fully meet the challenges of describing the lifecycle of such a specific type of goods as medicines? What are the specific features of the product "medicines"?**

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**1.4. The duration of which stages of the lifecycle should the developers (or owners of registration certificates for medicines) strive to increase? And which – to shorten? Explain your answer.**

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**1.5. The concept of lifecycle can be used to describe the lifecycle of:**

- 1) a product class (e.g., ...)
- 2) ... (e.g., ...)
- 3) ... (e.g., ...)

Compare the duration of their lifecycles.

Give examples of: 1) a product class, 2) ..., 3) ..., whose lifecycle is already completed and which are no longer produced and are not in circulation now

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**1.6. Describe the stages of the lifecycle of a product. How sales volumes, profits, promotion costs, number and activity of competitors change at different stages?**



1.7. What is the difference between the lifecycle of an original MP and the lifecycle of a generic MP? Illustrate the answer graphically.

1.8. What factors can influence the product's passing through the stages of the classical model of the lifecycle of a product? What variants of the product lifecycle curve are possible? Give examples of products with a lifecycle curve different from the classical (traditional) one.

Variant of the product lifecycle curve	Example of a product

1.9. How can a MP be modified when sales (demand) drop (in order to prolong the product at some stage of the lifecycle or to give a new boost to growth)?

Approach to modifying the LP	Example

1.10. Describe the stages of the detailed model of the lifecycle of medicines.



A) The definition and objectives of pharmaceutical development. Registration dossier.

What data should be provided during pharmaceutical development for active substances, excipients, dosage form and technological process?

B) What is a directed drug design? Describe its basic concepts: target, medicine, ligand (types of ligands, their characteristics).

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B) Screening, its significance in the search for new medicines, types of screening (pharmacological, high-throughput, virtual) and their brief characteristics.

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Г) Describe other directions of pharmaceutical development: molecular construction of drugs; reproduction of biogenic substances; targeted modification of the chemical structure; targeted synthesis; search for prodrugs; synthesis of antimetabolites; random finds.

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Д) Define the concept of drug development:

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Preclinical trials: the definition, objectives, regulation, assessment directions within the framework of PCTs, stages of PCTs and their characteristics

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Clinical trials: the definition, objectives, regulation, assessment directions within the framework of CTs, stages of CTs and their characteristics

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Characteristics of Phase I CTs

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Characteristics of Phase II CTs

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Characteristics of Phase III CTs

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E) Give the definition of state registration. Registration dossier. The purpose, regulation, the main stages of the procedure of state registration of MPs.

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## **5. The content of the assessment tools of mid-term assessment**

Mid-term assessment is carried out in the form of an exam (in the 4<sup>th</sup> semester).

### **5.1 The list of control tasks and other materials necessary for the assessment of knowledge, skills and work experience**

#### **5.1.1. Questions for the discipline exam**

1. Study of the clinical efficacy of pharmaceutical care.
2. Evidence-based medicine as a source of information on the effectiveness of medical interventions for pharmacoeconomic research.
3. Regulatory framework for pharmacoeconomic research.
4. Basic principles of economic evaluation of the effectiveness of pharmacotherapy.
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26. Pharmacoeconomic method of cost-benefit analysis: purpose, features, advantages, disadvantages, scope, calculation formulas.
27. Pharmacoeconomic modeling. Methodology of decision analysis.

28. Principles of building a decision tree, the Markov model.

**6. Criteria for evaluating learning outcomes**

*For the credit:*

Learning outcomes	Evaluation criteria	
	Not passed	Passed
<b>Completeness of knowledge</b>	The level of knowledge is below the minimum requirements. There were bad mistakes.	The level of knowledge in the volume corresponding to the training program. Minor mistakes may be made
<b>Availability of skills</b>	Basic skills are not demonstrated when solving standard tasks. There were bad mistakes.	Basic skills are demonstrated. Typical tasks have been solved, all tasks have been completed. Minor mistakes may be made.
<b>Availability of skills (possession of experience)</b>	Basic skills are not demonstrated when solving standard tasks. There were bad mistakes.	Basic skills in solving standard tasks are demonstrated. Minor mistakes may be made.
<b>Motivation (personal attitude)</b>	Educational activity and motivation are poorly expressed, there is no willingness to solve the tasks qualitatively	Educational activity and motivation are manifested, readiness to perform assigned tasks is demonstrated.
<b>Characteristics of competence formation*</b>	The competence is not fully formed. The available knowledge and skills are not enough to solve practical (professional) tasks. Repeated training is required	The competence developed meets the requirements. The available knowledge, skills and motivation are generally sufficient to solve practical (professional) tasks.
<b>The level of competence formation</b>	Low	Medium/High

*For the exam:*

Learning outcomes	Assessment of competence developed			
	unsatisfactory	satisfactory	good	excellent
<b>Completeness of knowledge</b>	The level of knowledge is below the minimum requirements. There were bad mistakes	The minimum acceptable level of knowledge. A lot of light mistakes were made	The level of knowledge in the volume corresponding to the training program. A few light mistakes were made	The level of knowledge in the volume corresponding to the training program, without errors
<b>Availability of skills</b>	Basic skills are not demonstrated when solving standard tasks. There were bad mistakes	Basic skills are demonstrated. Typical problems with light mistakes have been solved. All tasks have been completed, but	All basic skills are demonstrated. All the main tasks have been solved with light mistakes. All	All the basic skills were demonstrated, all the main tasks were solved with some minor shortcomings, all the tasks were

Learning outcomes	Assessment of competence developed			
	unsatisfactory	satisfactory	good	excellent
		not in full.	tasks have been completed, in full, but some of them with shortcomings	completed in full
<b>Availability of skills (possession of experience)</b>	Basic skills are not demonstrated when solving standard tasks. There were bad mistakes	There is a minimal set of skills for solving standard tasks with some shortcomings	Basic skills in solving standard tasks with some shortcomings are demonstrated	Skills in solving non-standard tasks without mistakes and shortcomings are demonstrated
<b>Characteristics of competence formation*</b>	The competence is not fully formed. The available knowledge and skills are not enough to solve professional tasks. Repeated training is required	The formation of competence meets the minimum requirements. The available knowledge and abilities are generally sufficient to solve professional tasks, but additional practice is required for most practical tasks	The formation of competence generally meets the requirements, but there are shortcomings. The available knowledge, skills and motivation are generally sufficient to solve professional tasks, but additional practice is required for some professional tasks	The formation of competence fully meets the requirements. The available knowledge, skills and motivation are fully sufficient to solve complex professional tasks
<b>The level of competence formation*</b>	Low	Below average	Intermediate	High

*For testing:*

Mark "5" (Excellent) - points (100-90%)

Mark "4" (Good) - points (89-80%)

Mark "3" (Satisfactory) - points (79-70%)

Mark "2" (Unsatisfactory) - less than 70%

Developer:

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