MINISTRY OF HEALTH OF UKRAINE
NATIONAL UNIVERSITY OF PHARMACY
Department of Pharmaceutical Management and Marketing

PHARMACOECONOMICS

(the name of educational component)

WORK PROGRAM
of educational component

educational background Master
(Level of Educational Background)

program subject area 22 Health Care
(Program Subject Area Title and Code)

in specialty 226 Pharmacy, industrial pharmacy
(Specialty Title and Code)

of educational program Pharmacy
(Educational Program Title)

in specialization(s)
(Code and Specialization Name)

2023
year of foundation

The work program of the educational component «Pharmacoeconomics» in specialty 226 Pharmacy, industrial pharmacy of educational program Pharmacy (4.10, full time study) for the students of 5 year.

Developed by: Volodymyr MALYI, Head of Department of Pharmaceutical Management and Marketing, D.Sc. in Pharmacy, professor

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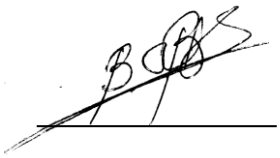
Work Program is considered and developed at the Meeting of the Department of Pharmaceutical Management and Marketing

Examination Record from «28» August 2023 No. 1

Head of Department  Prof. Volodymyr MALYI

Work Program approved at the Meeting of the Methodological Commission on the economic and management disciplines

Examination Record from «05» September 2023 No. 1

Head of the Methodological Commission on the economic and management disciplines

Prof . Alla NEMCHENKO

1. Description of the educational component

The language of the study: English

Status of the educational component: Elective

Prerequisites for studying the educational component: the educational component "Pharmacoeconomics" is based on the study by candidates of higher education of pharmacology, pharmacotherapy with pharmacokinetics, clinical pharmacy and pharmaceutical care, pharmaceutical marketing and management, organization and economics of pharmacy, which provides for the integration of teaching with these educational components and the formation of skills to apply knowledge of pharmacoeconomics in the process of further training and professional activities.

The subject of educational component "Pharmacoeconomics" study is the methodology of comparative assessment of various medical technologies (methods of diagnosis, treatment and prevention of various diseases) based on a simultaneous complex interrelated analysis of the clinical results obtained and the costs of using these technologies.

Information content of the educational component. 3 ECTS credit **90 hours** are assigned to the study of the educational component.

2. Objectives and tasks of the educational component

The purpose of teaching the educational component **«Pharmacoeconomics»** is to train specialists for the pharmaceutical industry who have a sufficient amount of theoretical knowledge and practical skills in conducting pharmacoeconomic analysis of methods of prevention, diagnostics, drug and non-drug treatment and rehabilitation of various diseases to improve the quality of medical care, rational use of funds for health care as by individual consumers, as well as by healthcare institutions and the state as a whole, optimization of the process of creation, production and use of pharmaceutical products in a market economy.

The main tasks of the educational component «Pharmacoeconomics» are:

- formation of a whole picture of the role of pharmacoeconomics in the modern health care system, the practical activities of specialists of pharmaceutical industry;
- formation of an understanding of the basic principles and provisions of evidence-based medicine;
- familiarization with the methods of conducting pharmacoepidemiological studies
- familiarization with the organization of the pharmacovigilance system, the methodology for collecting information on side and undesirable side actions of drugs, analysis of the economic aspects of the undesirable side actions of drugs;
- familiarization with the principles of pharmacoinformatics and databases on proven efficacy and safety of pharmaceutical products;
- providing theoretical knowledge and practical skills to determine the cost-effectiveness of using a particular drug (one or another medical technology);
- familiarization with the principles of using the results of pharmacoeconomic analysis when creating clinical protocols for the provision of medical care for various diseases, the formation of the National List of Essential Medicines, formularies of medicines of various levels;
- provision of theoretical knowledge and practical skills necessary for a comprehensive analysis of the parameters characterizing a new or generic drug, in order to determine the feasibility of bringing it to the market, the period of its presence on the market and exiting the market, taking into account the results of pharmacoeconomic studies;
- formation of "pharmacoeconomic thinking" among specialists of the pharmaceutical industry and motivation for the use of pharmacoeconomic analysis in solving various problems in various areas of their professional activity.

3. Competence and planned educational outcomes

Educational component "Pharmacoeconomics" ensures the acquisition of applicants for higher education the following **competences**:

- *integral:*

Ability to solve typical and complex specialized tasks and critically comprehend and solve the practical problems in the professional pharmaceutical and/or research and innovation activity using provisions, theories and methods of the fundamental, chemical, technological, biomedical, socio-economic science; integrate knowledge and solve complex issues, formulate judgments in the presence of incomplete or limited information, clearly and unambiguously to convey their conclusions and use their knowledge, reasonably substantiating them, to professional and non-professional audience.

- *general:*

GC 9. Skills in the use of information and communication technologies.

- *professional (special (objective):*

PC 5. Ability to monitor the effectiveness and safety of the population of medications according to the data on their clinical and pharmaceutical characteristics, as well as taking into account subjective signs and objective clinical, laboratory and instrumental criteria for the examination of a patient.

PC 11. Ability to analyze socio-economic processes in Pharmacy, forms, methods and functions of the pharmaceutical supply system and its components in world practice, indicators of need, efficiency and availability of pharmaceutical care in terms of health insurance and reimbursement of the cost of medications.

Integrative final program learning outcomes (PLO), the formation of which is facilitated by the educational component

PLO 9. To carry out professional activities using information technology, "Information Databases", navigation systems, Internet resources, software and other information and communication technologies.

PLO 17. To use clinical, laboratory and instrumental research data to monitor the efficacy and safety of medicines.

PLO 23. To take into account the data on socio-economic processes in society for the pharmaceutical provision of the population, determine the effectiveness and availability of pharmaceutical care in terms of health insurance and reimbursement of the cost of medicines.

As a result of studying the educational component, the applicant for higher education will be

know:

– the importance of pharmacoeconomics in the modern health care system, the practical activities of specialists of pharmaceutical industry;
– the concept of pharmacoeconomics, its goals and objectives;
– main pharmacoeconomic categories;
– the concept of pharmacoepidemiology and basic pharmacoepidemiological methods;
– basic principles and concepts of evidence-based medicine, its importance for improving the quality of medical care;
– the concept of "quality of life" and the methodology for assessing it using questionnaires;
– legislative base, organizational structure, main tasks and directions of activity of the pharmacovigilance system;
– methods of collecting information about the side effects of drugs;
– basic concepts of pharmacoinformatics;
– the purpose and structure of systematic reviews;
– the essence and purpose of meta-analysis;
– the purpose of evidence-based medicine databases and Cochrane databases;
– search algorithm for information on proven effectiveness and safety of pharmaceutical products;
– classification and main types of pharmacoeconomic costs;
– principles and stages of conducting pharmacoeconomic research of medicines and medical technologies;
– methods of pharmacoeconomic analysis and principles of their choice for the assessment of specific medical technologies
– methods of mathematical modeling and principles of their application in pharmacoeconomic research;
– the role of pharmacoeconomic research in quality management of medical care;
– basic principles of medical care standardization;
– main functions of the formulary system and the goals of its implementation in health care;

– the purpose of clinical protocols for medical care, the National List of Essential Medicines, formulary of medicines of various levels and the importance of pharmacoeconomic research in their creation;
– the importance of pharmacoeconomic research in the creation of new pharmaceutical products;
– the importance of pharmacoeconomic research in regulating the life cycle of a pharmaceutical product;

be able to:

– to search for sources of information on proven efficacy and safety of medicines;
– to determine the level of evidence of the results of clinical trials of pharmaceutical products;
– to choose among a large number of scientific sources of information those that are necessary for the pharmacoeconomic analysis of pharmaceutical products;
– to conduct an analyses of the consumption of medicines by the ATC / DDD method;
– to identify and classify the costs of specific medical technologies;
– to calculate the costs of specific medical technologies;
– to analyze the costs associated with the manifestation of the therapeutic and undesirable effects of drugs, the use of non-drug medical technologies;
– to use the methods of mathematical modeling in determining the effectiveness of medical technologies and calculating their costs;
– to draw up a plan for conducting a pharmacoeconomic study;
– to select criteria of efficacy and safety for individual medicines;
– to use systematic information sources on the efficacy and safety of drugs (systematic reviews and meta-analyses of the results of clinical trials) for pharmacoeconomic analysis;
– to choose and apply the appropriate method of pharmacoeconomic analysis for solving various professional problems;
– to carry out a comparative pharmacoeconomic assessment of certain drugs and drug therapy regimens using various methods of pharmacoeconomic analysis;
– to analyze the feasibility (rationality) of the choice of specific drugs for the treatment of major diseases among analogues according to the criteria of effectiveness, safety and cost;
– to analyze the quality of drug treatment of certain diseases using the results of ABC, VEN- and frequency analysis;
– to prove the economic feasibility of including certain drugs in the clinical protocols of medical care for various diseases, the National List of Essential Drugs, drug formularies;
– based on the results of pharmacoeconomic studies of the use of certain drugs, to draw conclusions about the advisability of their entry into the market, presence on the market or exit from it.

master:

– methods of pharmacoeconomic analysis;
– methods of conducting ABC-, VEN- and frequency analyses;
– approaches to the search for information on the effectiveness, safety of medical technologies and the costs of their application in various information sources;
– approaches to calculating the cost of medical care (including using discounting and building a mathematical model for the prevention and treatment of the disease).

4. The educational component structure

Names of content modules and topics	The amount of hours					
	4.10, full time study					
	the whole amount	including				
		lect.	sem	prac	lab	self study
1	*2*	*3*	*4*	*5*	*6*	*7*
MODULE 1						
CONTENT MODULE 1. Theoretical foundations of pharmacoeconomics and pharmacoepidemiology. Search and analysis of information on the effectiveness, safety of medical technologies and the costs of their use. Mathematical modeling in pharmacoeconomics						
Topic 1. Evidence-based medicine as a modern methodology in health care. Historical and socio-economic preconditions for the emergence of pharmacoeconomics as an applied science.	5					5
Topic 2. Pharmacoeconomics as a science, its goals and objectives. Main	4,5	0,5		2		2

pharmacoeconomic categories.						
Topic 3. Pharmacoepidemiology: essence and objectives. Quantitative pharmacoepidemiological studies of drug usage study.	4,5	0,5		2		2
Topic 4. Safety of medicines as a pharmacoeconomic category. Types of undesirable side action of a drug. Pharmacovigilance system.	4,5	0,5		2		2
Topic 5. Pharmacoinformatics as a science. Systematized sources of information.	4,5	0,5		2		2
Topic 6. Costs as a pharmacoeconomic category. Ways to optimize healthcare costs.	5	1		2		2
Topic 7. Mathematical modeling in pharmacoeconomics. The method of mathematical modeling is "decision analysis".	4					4
Topic 8. Markov mathematical model.	4					4
Control of content module 1	9			2		7
The whole amount of hours for content module 1	45	3		12		30
CONTENT MODULE *2.* Applied Pharmacoeconomics. Pharmacoeconomic analysis methods. Application of the results of pharmacoeconomic research in practical pharmacy and medicine.						
Topic 9. Pharmacoeconomic analysis: general provisions. Pharmacoeconomic analysis methods. Cost Of Illness Analysis. Cost Minimization Analysis.	4,5	0,5		2		2
Topic 10. Cost Effectiveness Analysis. The effectiveness of drugs as a pharmacoeconomic category.	4,5	0,5		2		2
Topic 11. Indicators of the usefulness of medical technologies: “quality of life”, QALY and DALY. Tools for assessing the "quality of life". Cost Utility Analysis.	4,5	0,5		2		2
Topic 12. Cost-Benefit Analysis. Sensitivity Analysis of the results of pharmacoeconomic studies	4,5	0,5		2		2
Topic 13. Pharmacoeconomic evaluation of symptomatic treatment of pathological conditions using non-prescription medical products. Pharmacoeconomic evaluation of prescription medical products used for the prevention and treatment of the most common diseases.	6					6
Topic 14. Quality of medical care. The list of essential pharmaceutical products as a document of state guarantees of the quality of medical care. Standardization in healthcare.	3	0,5		0,5		2
Topic 15. Formulary system. Formulary as an element of the formulary system.	3	0,5		0,5		2
Topic 16. Application of pharmacoeconomic research in the creation of medicines and in the regulation of the life cycle of medicines.	5					5
Control of content module 2	8			1		7
The whole amount of hours for content module 2	43	3		10		30
Semester credit from module	2			2		
The whole amount of hours for the course	90	6		24		60

5. Contents of the educational component

Module "General Pharmacoeconomics. Pharmacoeconomic analysis of medical technologies. Practical application of the results of pharmacoeconomic research"

CONTENT MODULE 1. ***Theoretical foundations of pharmacoeconomics and pharmacoepidemiology. Search and analysis of information on the effectiveness, safety of medical technologies and the costs of their use. Mathematical modeling in pharmacoeconomics***

Topic 1. Evidence-based medicine as a modern methodology in health care. Historical and socio-economic preconditions for the emergence of pharmacoeconomics as an applied science. Evidence-based medicine: concept, objective reasons for the formation of the principle of evidence in medicine. The place of evidence-based medicine technologies in making a doctor's clinical decision. International experience in the use of evidence-based medicine. Areas of medical science, formed in the

process of the formation of evidence-based medicine. Pharmacoeconomics as a component of evidence-based medicine.

Topic 2. Pharmacoeconomics as a science, its goals and objectives. Main pharmacoeconomic categories. Pharmacoeconomics as a science: definition, purpose, objectives, subject and objects of study. The relationship of pharmacoeconomics with related disciplines and its place in the system of higher pharmaceutical education. The practical importance of pharmacoeconomics. Consumers of the results of pharmacoeconomic studies. The role of pharmacoeconomics in the professional activities of a modern pharmacist. Factors contributing to the growth of government spending on healthcare. Ways to optimize budgetary and extra budgetary health care costs. Pharmacoeconomics as one of the possible ways to optimize state funds for health care. Main pharmacoeconomic categories: definition, evaluation criteria. Criteria for assessing the effectiveness and clinical effectiveness of medical technologies. World experience in conducting pharmacoeconomic studies and using their results in healthcare practice.

Topic 3. Pharmacoepidemiology: essence and objectives. Quantitative pharmacoepidemiological studies of drug usage study. Pharmacoepidemiology as a science: definition, purpose and objectives. The causes of pharmacoepidemiology. Pharmacoepidemiology as the basis of evidence-based medicine. Methods of pharmacoepidemiological research. Types of pharmacoepidemiological studies. Study of drug consumption in pharmacoepidemiology. The concept of the established daily dose of a drug (DDD). ATC / DDD methodology for assessing drug consumption. Indicators of clinical effectiveness in pharmacoepidemiological studies. Application of the results of quantitative pharmacoepidemiological studies of drug consumption to improve the quality of medical care. The concept of exposure and communication in pharmacoepidemiology. Determination of a causal relationship between taking a drug and various phenomena that occur after administration. Factors that can influence the results of pharmacoepidemiological studies. The practical importance of pharmacoepidemiological research: determining the relevance of medical technologies for medical practice.

Topic 4. Safety of medicines as a pharmacoeconomic category. Types of undesirable side action of a drug. Pharmacovigilance system. Safety of pharmaceutical products as a pharmacoeconomic category. Medical and socio-economic importance of drug therapy safety. Terminology used in drug safety studies. Factors contributing to the development of adverse drug reactions. Methods for detecting adverse drug reactions in the post-registration period. Pharmacovigilance system: definition, organization of activities at the global level. The importance of collection and registration of side effects of drugs for pharmacoeconomic research.

Topic 5. Pharmacoinformatics as a science. Systematized sources of information. Medical information, definitions. The relationship of medical information with pharmacoinformatics. Information sources: definition, classification. Assessment of the quality of medical information in accordance with evidence-based medicine technologies. Evidence levels in medicine and pharmacy. Determining the level of evidence for drug research results and the strength of the evidence (level of evidence). Pharmacoinformatics as a science: definition, purpose, objectives, scope. Criteria for selecting sources of information to answer a clinical question. Systematic reviews: definition, principles of compilation, goals, objectives and structure, practical significance. Meta-analysis: definition, purpose, objectives. Selection criteria for clinical trials for inclusion in the meta-analysis. Information database concept. International information databases on proven efficacy and safety of medicines. The Cochrane Collaboration Society: purpose, structure. The Merits of Cochrane Systematic Reviews. The use of medical databases when conducting pharmacoeconomic research, when organizing drug supply to the population.

Topic 6. Costs as a pharmacoeconomic category. Ways to optimize healthcare costs. Costs as a pharmacoeconomic category. Relevance of pharmacoeconomic costs. Cost classification. Direct medical costs: source of reimbursement, types, classification. Direct non-medical costs: sources of reimbursement, types. Indirect costs, their types. Relevance of indirect costs in relation to the patient and the state. Characteristic of uncalculated costs. Stages of calculating costs when conducting pharmacoeconomic studies. Sources of information for calculating costs in conducting pharmacoeconomic studies. Discounting: definition, application in calculating costs. Principles of reimbursement of drug costs around the world.

Topic 7. Mathematical modeling in pharmacoeconomics. The method of mathematical modeling is "decision analysis". Modeling: definition, types. Purpose of using modeling in pharmacoeconomic research. The practical importance of modeling methodology in pharmacoeconomic research. Objective prerequisites for the application of methods of mathematical modeling in pharmacoeconomic research.

Objects and stages of modeling in pharmacoeconomic analysis. Mathematical modeling using decision analysis techniques: essence, scope, stages of building a "decision tree". A mechanism for calculating costs by building a "decision tree". Pharmacoeconomic evaluation of treatment by building a "decision tree" on the example of individual diseases.

Topic 8. Markov mathematical model. Markov mathematical model: the essence of the model, scope, the concept of Markov states, Markov cycles, Markov assumptions, principles of constructing a “Markov cycles three”. Pharmacoeconomic evaluation of treatment using the Markov method on the example of individual diseases.

CONTENT MODULE *2. Applied Pharmacoeconomics. Pharmacoeconomic analysis methods. Application of the results of pharmacoeconomic research in practical pharmacy and medicine.*

Topic 9. Pharmacoeconomic analysis: general provisions. Pharmacoeconomic analysis methods. Cost Of Illness Analysis. Cost Minimization Analysis. Pharmacoeconomic analysis: definition, importance for health care. Stages of pharmacoeconomic analysis proposed by the International Society for Pharmacoeconomic Research and Treatment Results (ISPOR). The structure of the report on the pharmacoeconomic analysis. Basic methods of pharmacoeconomic analysis. Cost Of Illness Analysis: definition, purpose, features of the conduct, advantages, disadvantages and scope. Methodology for calculating the total cost of the disease. Application of the Cost Of Illness Analysis when calculating tariffs for medical services. Pharmacoeconomic assessment using the Cost Of Illness Analysis (on the example of individual diseases). Cost Minimization Analysis: definition, purpose, stages of implementation, advantages, disadvantages and scope. Methodology of calculating with using Cost Minimization Analysis. Pharmacoeconomic analysis of drug therapy schemes and other medical technologies using the Cost Minimization Analysis using the example of individual diseases.

Topic 10. Cost Effectiveness Analysis. The effectiveness of drugs as a pharmacoeconomic category. Cost Effectiveness Analysis: definition, purpose, stages of implementation. Mandatory conditions for conducting a pharmacoeconomic analysis using the Cost Effectiveness Analysis. Calculation of the cost-effectiveness ratio (CER); its use as the main criterion for choosing the optimal medical technology. The concept of "dominant alternative". Calculation of the coefficient of increase in cost effectiveness (incremental "cost-effectiveness" ratio - ICER). The concept of reference medical technology. Advantages, disadvantages and scope of the Cost Effectiveness Analysis. Pharmacoeconomic evaluation of treatment using the Cost Effectiveness Analysis on the example of selected diseases. The effectiveness of drugs as a pharmacoeconomic category. Requirements for the selection of performance indicators for various medical technologies when conducting Cost Effectiveness Analysis. The choice of criteria for the effectiveness of drugs when conducting pharmacoeconomic calculations, depending on the phase of clinical trials. Sources of information for conducting pharmacoeconomic analysis by the Cost Effectiveness Analysis.

Topic 11. Indicators of the usefulness of medical technologies: “quality of life”, QALY and DALY. Tools for assessing the "quality of life". Cost Utility Analysis. Quality of life: definition, its components. The main factors determining the impact of medical intervention on the quality of life. The value of the quality of life indicator for clinical and pharmacoeconomic studies. Fundamentals of the methodology for determining the quality of life indicator. Tools for assessing the "quality of life". Types of questionnaires for determining the quality of life, their advantages and disadvantages. Requirements for the quality of life questionnaire. “Quality of life” as a criterion for the utility of medical technologies. QALY indicator: definition, calculation method, assumption in its assessment. DALY indicator: definition and calculation method. Methods for determining the utility of medical technologies: "standard speculative gambling", "even exchange". Cost Utility Analysis: definition, purpose, advantages, disadvantages, scope. Methodology for calculating the cost-utility ratio (CUR) and the indicator of the cost of an additional unit of utility (ICUR). Pharmacoeconomic evaluation of treatment using the Cost Utility Analysis on the example of individual diseases.

Topic 12. Cost-Benefit Analysis. Sensitivity Analysis of the results of pharmacoeconomic studies. Cost-Benefit Analysis: definition, purpose, advantages, disadvantages, scope. Benefits from medical technology. Methods for assessing the results of medical technologies in monetary terms, their limitations and disadvantages. Calculations using the Cost-Benefit Analysis. Objective factors affecting the variability of the results of pharmacoeconomic studies. Sources of information on possible fluctuations in the initial

parameters when conducting pharmacoeconomic studies. Sensitivity Analysis of the results of pharmacoeconomic studies: definition, purpose, classification, stages of implementation.

Topic 13. Pharmacoeconomic evaluation of symptomatic treatment of pathological conditions using non-prescription medical products. Pharmacoeconomic evaluation of prescription medical products used for the prevention and treatment of the most common diseases. Medical and social significance and substantiation of the feasibility of conducting pharmacoeconomic studies for symptomatic therapy of various pathological conditions. Modern principles of symptomatic therapy of certain pathological conditions. Non-prescription medical products for symptomatic treatment of mild pathological conditions (cough, rhinitis, headache, etc.): clinical and pharmacological characteristics, market analysis, criteria for effectiveness and safety of use. Pharmacoeconomic evaluation of individual OTC drugs for symptomatic treatment of mild pathological conditions (cough, rhinitis, headache, etc.). The value of the results of pharmacoeconomic analysis of non-prescription medical products for the professional activity of a pharmacist in a pharmacy. Medical and social significance and justification of the feasibility of conducting pharmacoeconomic studies for the treatment of major diseases of the cardiovascular, urinary system, musculoskeletal system, respiratory system, digestion, acute allergies. Modern principles of therapy for diseases of the cardiovascular, urinary system, musculoskeletal system, respiratory system, digestive system, major acute allergies from the standpoint of evidence-based medicine. Pharmaceutical products for the treatment of diseases of the cardiovascular, urinary system, musculoskeletal system, respiratory system, digestion, acute allergies: clinical and pharmacological characteristics, market analysis, criteria for effectiveness and safety of use. Characteristics of treatment costs. Evaluation of therapy for diseases of the cardiovascular, urinary system, musculoskeletal system, respiratory system, digestion, acute allergies using various methods of pharmacoeconomic analysis. Interpretation of the results depending on the goal and objectives of the pharmacoeconomic study. The value of the results of pharmacoeconomic analysis for the work of health care institutions.

Topic 14. Quality of medical care. The list of essential pharmaceutical products as a document of state guarantees of the quality of medical care. Standardization in healthcare. Quality of health care: concepts, assessment method. Definition of the standard. Donabedian triad. Modern ways to improve the quality of medical care. The importance of pharmacoeconomic research for improving the quality of health care. Standardization in health care: concept, objects and functions of standardization. Characteristics of medical technology documents for standardization. The concept of essential (vital) medicines. Requirements for essential (vital) medicines (as defined by WHO). List of essential (vital) medicines as a document of state guarantees of the quality of medical care. Its importance at the present stage of development of the healthcare system. Prerequisites for the creation of a medical standardization system. International principles for setting standards in healthcare.

Topic 15. Formulary system. Formulary as an element of the formulary system. Formulary system: definition of the concept, principle, main functions, purpose and positive results of implementation in medical practice. Formulary as the main element of the formulary system. Formulary system as a necessary component of the standardization process in medicine, the basis for optimizing drug supply. Application of the principles of evidence-based medicine in the work of the formulary system. Principles of ABC-, VEN- and frequency analysis and comparison of their results. Using the results of ABC- and VEN-analysis in the implementation of the formulary system.

Topic 16. Application of pharmacoeconomic research in the creation of medicines and in the regulation of the life cycle of medicines. Pharmaeconomics as a science. Traditional ways of creating new drugs. Stages in the development of new drugs. Stages of marketing research before launching a new drug on the pharmaceutical market. Factors determining the intensity of drug promotion on the market. Life cycle of a medicinal product in the pharmaceutical market: characteristics of the main phases and types of life cycle curves. The use of pharmacoeconomic research in the creation of new drugs. The use of pharmacoeconomic research in the regulation of the life cycle of drugs in the pharmaceutical market. Calculation of liquidity ratios and solvency adequacy.

Semester module supervision

6. Topics of Lectures

No.	Topic	The amount of hours

		4.10, full time study
1	Topic 1. Evidence-based medicine as a modern methodology in health care. Historical and socio-economic preconditions for the emergence of pharmacoeconomics as an applied science.	
2	Topic 2. Pharmacoeconomics as a science, its goals and objectives. Main pharmacoeconomic categories.	0,5
3	Topic 3. Pharmacoepidemiology: essence and objectives. Quantitative pharmacoepidemiological studies of drug usage study.	0,5
4	Topic 4. Safety of medicines as a pharmacoeconomic category. Types of undesirable side action of a drug. Pharmacovigilance system.	0,5
5	Topic 5. Pharmacoinformatics as a science. Systematized sources of information.	0,5
6	Topic 6. Costs as a pharmacoeconomic category. Ways to optimize healthcare costs.	1
7	Topic 7. Mathematical modeling in pharmacoeconomics. The method of mathematical modeling is "decision analysis".	
8	Topic 8. Markov mathematical model.	
9	Topic 9. Pharmacoeconomic analysis: general provisions. Pharmacoeconomic analysis methods. Cost Of Illness Analysis. Cost Minimization Analysis.	0,5
10	Topic 10. Cost Effectiveness Analysis. The effectiveness of drugs as a pharmacoeconomic category.	0,5
11	Topic 11. Indicators of the usefulness of medical technologies: “quality of life”, QALY and DALY. Tools for assessing the "quality of life". Cost Utility Analysis.	0,5
12	Topic 12. Cost-Benefit Analysis. Sensitivity Analysis of the results of pharmacoeconomic studies	0,5
13	Topic 13. Pharmacoeconomic evaluation of symptomatic treatment of pathological conditions using non-prescription medical products. Pharmacoeconomic evaluation of prescription medical products used for the prevention and treatment of the most common diseases.	
14	Topic 14. Quality of medical care. The list of essential pharmaceutical products as a document of state guarantees of the quality of medical care. Standardization in healthcare.	0,5
15	Topic 15. Formulary system. Formulary as an element of the formulary system.	0,5
16	Topic 16. Application of pharmacoeconomic research in the creation of medicines and in the regulation of the life cycle of medicines.	
	The whole amount of hours	**6**

7. Topics of seminars

Not provided a working curriculum

8. Topics of practical classes

No.	Topic	The amount of hours
		4.10, full time study
1	Topic 1. Evidence-based medicine as a modern methodology in health care. Historical and socio-economic preconditions for the emergence of pharmacoeconomics as an applied science.	
2	Topic 2. Pharmacoeconomics as a science, its goals and objectives. Main pharmacoeconomic categories.	2
3	Topic 3. Pharmacoepidemiology: essence and objectives. Quantitative pharmacoepidemiological studies of drug usage study.	2
4	Topic 4. Safety of medicines as a pharmacoeconomic category. Types of undesirable side action of a drug. Pharmacovigilance system.	2
5	Topic 5. Pharmacoinformatics as a science. Systematized sources of information.	2
6	Topic 6. Costs as a pharmacoeconomic category. Ways to optimize healthcare costs.	2
7	Topic 7. Mathematical modeling in pharmacoeconomics. The method of mathematical modeling is "decision analysis".	
8	Topic 8. Markov mathematical model.	

9	Control of content module 1	2
10	Topic 9. Pharmacoeconomic analysis: general provisions. Pharmacoeconomic analysis methods. Cost Of Illness Analysis. Cost Minimization Analysis.	2
11	Topic 10. Cost Effectiveness Analysis. The effectiveness of drugs as a pharmacoeconomic category.	2
12	Topic 11. Indicators of the usefulness of medical technologies: “quality of life”, QALY and DALY. Tools for assessing the "quality of life". Cost Utility Analysis.	2
13	Topic 12. Cost-Benefit Analysis. Sensitivity Analysis of the results of pharmacoeconomic studies	2
14	Topic 13. Pharmacoeconomic evaluation of symptomatic treatment of pathological conditions using non-prescription medical products. Pharmacoeconomic evaluation of prescription medical products used for the prevention and treatment of the most common diseases.	
15	Topic 14. Quality of medical care. The list of essential pharmaceutical products as a document of state guarantees of the quality of medical care. Standardization in healthcare.	0,5
16	Topic 15. Formulary system. Formulary as an element of the formulary system.	0,5
17	Topic 16. Application of pharmacoeconomic research in the creation of medicines and in the regulation of the life cycle of medicines.	
18	Control of content module 2	1
	Semester credit from module	2
	The whole amount of hours	**24**

9. Topics of laboratorial classes

Not provided a working curriculum

10.Self-study work

No.	**Topic**	**The amount of hours** **4.10, full time study**
1	Topic 1. Evidence-based medicine as a modern methodology in health care. Historical and socio-economic preconditions for the emergence of pharmacoeconomics as an applied science.	5
2	Topic 2. Pharmacoeconomics as a science, its goals and objectives. Main pharmacoeconomic categories.	2
3	Topic 3. Pharmacoepidemiology: essence and objectives. Quantitative pharmacoepidemiological studies of drug usage study.	2
4	Topic 4. Safety of medicines as a pharmacoeconomic category. Types of undesirable side action of a drug. Pharmacovigilance system.	2
5	Topic 5. Pharmacoinformatics as a science. Systematized sources of information.	2
6	Topic 6. Costs as a pharmacoeconomic category. Ways to optimize healthcare costs.	2
7	Topic 7. Mathematical modeling in pharmacoeconomics. The method of mathematical modeling is "decision analysis".	4
8	Topic 8. Markov mathematical model.	4
9	Control of content module 1	7
10	Topic 9. Pharmacoeconomic analysis: general provisions. Pharmacoeconomic analysis methods. Cost Of Illness Analysis. Cost Minimization Analysis.	2
11	Topic 10. Cost Effectiveness Analysis. The effectiveness of drugs as a pharmacoeconomic category.	2
12	Topic 11. Indicators of the usefulness of medical technologies: “quality of life”, QALY and DALY. Tools for assessing the "quality of life". Cost Utility Analysis.	2
13	Topic 12. Cost-Benefit Analysis. Sensitivity Analysis of the results of pharmacoeconomic studies	2
14	Topic 13. Pharmacoeconomic evaluation of symptomatic treatment of pathological conditions using non-prescription medical products. Pharmacoeconomic evaluation of prescription medical products used for the prevention and treatment of the most	6

	common diseases.	
15	Topic 14. Quality of medical care. The list of essential pharmaceutical products as a document of state guarantees of the quality of medical care. Standardization in healthcare.	2
16	Topic 15. Formulary system. Formulary as an element of the formulary system.	2
17	Topic 16. Application of pharmacoeconomic research in the creation of medicines and in the regulation of the life cycle of medicines.	5
18	Control of content module 2	7
	The whole amount of hours	**60**

Tasks for self-study work

1. To prepare information messages on the topic "Evidence-based medicine as a modern methodology in health care".
2. To find scientific articles of domestic or foreign scientists with the results of pharmacoeconomic studies of the pharmacotherapy of certain diseases and to analyze them.
3. To characterize the phases of the life cycle of a medicinal product and to determine the importance of pharmacoeconomic studies at different stages of promoting a medicinal product on the pharmaceutical market.

11. Criteria and evaluation order of educational outcomes

The study of the educational component takes place during one semester, ends with a semester credit, therefore, the final grade from the educational component is set on the basis of the current success rate of the student of higher education.

The evaluation of the current activity of the student of higher education is carried out during work in practical classes (control of theoretical training and practical skills) and during the control of content module 1 and content module 2. The evaluation (in points) is reflected in the calendar and thematic plan of practical classes.

During work in classes, the control of theoretical preparation involves the answers of students of higher education to theoretical questions during the class and their testing at the end of the class; control of practical training - solving situational (calculation) tasks. The number of points that a student of higher education receives while working on a practical lesson ranges from 3 to 5 points.

Evaluation criterion	The number of points in the practical class
Theoretical training - gave comprehensive answers to theoretical questions of the teacher; - showed a comprehensive and deep knowledge of theoretical material on the topic, which are set out in the manual and lectures on the topic of the lesson; - demonstrates knowledge from additional literature on the topic of the lesson; - when testing gave correct answers to 90-100% of test tasks *Practical training* - correctly solved all the calculated (situational) tasks provided for by the topic of the lesson	5
Theoretical training - answered theoretical questions with inaccuracies and errors, which were eliminated with the help of the teacher; - well mastered the theoretical material on the topics, which are set out in the manual and lectures on the topic of the lesson; - when testing gave correct answers to 75-89% of test tasks *Practical training* - solved all the calculated (situational) problems provided for by the topic of the lesson, but made mistakes in mathematical calculations or when solving situational problems.	4

Theoretical training - gave unconvincing answers to theoretical questions of the teacher, with errors that he could not eliminate with the help of the teacher; - mastered the theoretical material on the topics that are set out in the manual and lectures on the topic of the lesson, but additional questions cause uncertainty or lack of stable knowledge; - when testing gave correct answers to 60-74% of test items *Practical training* - solved 50% of the calculated (situational) problems provided for by the topic of the lesson, made mistakes in mathematical calculations or when solving situational problems.	3
Theoretical training - did not answer theoretical questions of the teacher; - did not master the theoretical material on the issues of the topic, which are set out in the manual and lectures on the topic of the lesson; - gave correct answers when testing less than 59% of test items *Practical training* -did not solve any of the calculated (situational) tasks provided for by the topic	0-2,99

Control of mastering content modules 1 and 2 (CM1 and CM2) is carried out in the last lessons, which Control of content modules 1 and 2 (CM1 and CM2) is carried out in the last classes of studying the topics of the content modules. The means of diagnosing the knowledge of students during the CM1 control are the preparation of test tasks and answers to theoretical questions; during the control of CM 2, it is the preparation of test tasks and the solution of calculation tasks. The conditions for admission to the control of content modules are the presence of a minimum number of points for taking the content module and for control of content module 1 (for control of content module 2).

Content module	The minimum amount of points	The maximum amount of points
1	15	25
2	15	25

The structure of the ticket for controlling CM 1: 2 theoretical questions and 20 test tasks.
Evaluation of the ticket for the control of CM 1: theoretical questions – 10 points, test tasks – 15 points
Assessment of test tasks: 1 correct answer is 1 point. 20 tests ×0.75 = 15 points
Evaluation of the theoretical question: 5 points

Evaluation of the theoretical question

Points	Evaluation of the theoretical question
5	is assigned to the student whose question revealed a comprehensive, systematic, in-depth knowledge of the program material, is able to demonstrate knowledge provided at the level of creative use
4-4,99	is assigned to the student if answers to questions a student found to have full knowledge of the program material but made a separate insignificant mistakes
3-3,99	set when answering the questions, the student revealed insufficient knowledge of the primary program material to the extent necessary for further training and work program of the reproductive of reproduction;
0-2,99	exposed, if the answer to the question, the student found serious gaps in knowledge of the basic material, made a fundamental error

The structure of the ticket for controlling CM 2: 2 calculation tasks and 20 test tasks.
Evaluation of the ticket for control of CM 2: calculation tasks - 10 points, test tasks – 15 points
Assessment of test tasks: 1 correct answer is 1 point. 20 tests ×0.75 = 15 points

Evaluation of the calculation task: 5 points.

Criteria for evaluating the calculation task	Number of points
The definition of the concept for each of the indicators that are calculated is given The correct formulas for the calculation of certain indicators are given The correct course of the decision Correct mathematical calculations Complete substantiated answer with an explanation of the significance of the obtained quantitative values of the indicators calculated	5
The definition of the concept for each of the indicators that are calculated is given The correct formulas for the calculation of certain indicators are given The correct course of the decision Correct mathematical calculations Answer without explaining the significance of the obtained quantitative values of the calculated indicators	4
The definition of not all concepts in relation to the indicators that are calculated is given The correct formulas for the calculation of certain indicators are given The correct course of the decision Correct mathematical calculations Answer without explaining the significance of the obtained quantitative values of the calculated indicators	3
Not all concepts are defined in relation to the indicators that are calculated The correct formulas for the calculation of certain indicators are given The correct course of the decision Mathematical calculations are not correct Answer without explaining the significance of the obtained quantitative values of the calculated indicators The task is not solved	2
Not all concepts are defined in relation to the indicators that are calculated There are no formulas for calculating certain indicators The correct course of the decision Mathematical calculations are not correct Answer without explaining the significance of the obtained quantitative values of the calculated indicators The task is not solved	1
The solution of the task is absent in the answer of the applicant of higher education to the ticket on final modular control	0-0,99

The scheme of calculation and distribution points

Current control													Amount
Content module 1						Content module 2							
T 2	T 3	T 4	T 5	T 6	control of content module 1	T 9	T 10	T 11	T 12	T 14	T 15	control of content module 2	
5	**5**	**5**	**5**	**5**	**25**	**5**	**5**	**5**	**5**	**2.5**	**2.5**	**25**	**100**

T2 ... T15 – topics of content modules.

Points from the educational component are calculated according to this ratio:

Types of evaluation	Maximum number of points (% of the number of points per module - for content modules)
Module 1	
Content module 1: - evaluation of topics 2-6: work in classes (oral survey, writing test tasks, solving situational tasks); - supervision of content module 1 (evaluation of topics 1-8): the preparation of test tasks and answers to theoretical questions.	50 (50 %)
Content module 2: - evaluation of topics 9-12, 14-15: work in classes (oral survey, writing test tasks, solving situational (calculation) tasks); - supervision of content module 2 (evaluation of topics 9-16): the preparation of test tasks and the solution of calculation tasks.	50 (50 %)
Semester Supervision of Module 1	100

The individual work of applicants for higher education is evaluated during the control of knowledge at each lesson and during the content module supervision

The results of the semester control in the form of a semester credit are evaluated on a 100-point, undifferentiated scale ("credit ", " not credited ") and on the ECTS scale.

Rating scale:
100-point scale, ECTS rating scale and undifferentiated two-point scale

Total points on a 100-point scale	ECTS scale	Evaluation on a non-differentiated scale
90-100	A	credit
82-89	B	
74-81	C	
64-73	D	
60-63	E	
35-59	FX	not credited
1-34	F	

12. Forms of progress and semester supervision of academic achievements

Knowledge control at each lesson: answers to theoretical questions, writing test tasks, solving situational (calculation) tasks.
Control of content modules: answers to theoretical questions, preparation of test tasks, solving calculation problems.
Semester control form: semester credit

13. Methodological Support

1. The educational program of the educational component.
2. The work program of the educational component.
3. Syllabus of the educational component.
4. Course schedules of lectures and practical classes.
5. Multimedia presentations of the course of lectures on the "Pharmacoeconomics" educational component.

6. Textbook "Pharmacoeconomics" for independent extracurricular preparation of applicants of higher education for practical classes, test and work in the classroom.
7. Workbook on the "Pharmacoeconomics" educational component for classroom, extracurricular and independent work of applicants of higher education.
8. Guidelines for independent work of applicants of higher education in the "Pharmacoeconomics" educational component (test book).
9. Guidance papers for practical training in the "Pharmacoeconomics" educational component for teachers.
10. Bank of test tasks.
11. Bank of calculation tasks on pharmacoeconomic analysis of pharmacotherapy of the most common diseases.
12. List of theoretical questions for content module control.
13. A package of tickets for content module 1 control and content module 2 control with answer standards.
14. A package of tickets for the complex control work with answer standards.

14. Bibliographical Guidance

Main (basic)

1. Pharmacoeconomics: Manual for students of higher schools / L. V. Iakovlieva, O. O. Gerasymova, O. V. Tkachova, O. Ia. Mishchenko; Edited by Prof. L. V. Iakovlieva – 2-nd edition, revised and expanded. – Kharkiv: NUPh Publ., 2023. – 167 p.
2. Workbook on pharmacoeconomics / L. V. Iakovlieva [et al.]. – 2nd ed., revised and supplemented. – Kharkiv : NUPH, 2021. – P. 130.
3. Pharmacoeconomics : textbook for individual work for candidates of higher education (test tasks book)/ / L. V. Iakovlieva [et al.]. – 2nd ed., revised and supplemented. – Kharkiv : NUPh, 2021. – 93 p.

Auxiliary

1. Annemans, L. Health economics for non-economists: Principles, methods and pitfalls of health economic evaluations / L. Annemans. – 1st ed. – Pelckmans, 2018. – 136 p.
2. Peshek, S. C. A Practical Guide to Pharmacoeconomics / S. C. Peshek, J. M. Morrison. – Amer Pharmacists Assn, 2020. – 100 p.
3. Goncalves, F. N. R. Pharmacoeconomics Principles and Best Practices: a Practical Guide / F. N. R. Goncalves, L. Gulacsi, N. Abu-Shraie. – Innovative Healthcare Institute, 2020. – 282 p.
4. Revikumar, K. G. Pharmacoepidemiology and Pharmacoeconomics Concepts and Practice / K. G. Revikumar. – PharmaMed Press/BSP Books, 2016. – 327 p.
5. Fundamentals Of Pharmacoeconomics / S. Fuloria, S. Kumar, N. K. Fuloria, A. Singh. –1st ed. – Nirali Prakashan, 2018. – 264 p.
6. Pharmacoeconomics : From Theory to Practice / ed. by R. J. G. Arnold. –2nd ed. – CRC Press, 2020. – 334 p.
7. The Art of Pharmacoeconomics: A Guide to Getting Started / ed. by Dr. R. Kaakeh. – Salus Vitae Group LLC, 2021. – 241 p.
8. Pradelli, L. Pharmacoeconomics : Principles and Practice / L. Pradelli, A. Wertheimer. – SEEd medical publishers, 2022. – 202 p.
9. Rascati, K. L. Essentials of Pharmacoeconomics / K. L. Rascati. – 3rd ed. – Lippincott Williams and Wilkins, 2020. – 368 p.
10. GünerGören, H. An excel-based inventory control system based on ABC and VED analyses for pharmacy: a case study / H. GünerGören, O. Dağdeviren // Galore International Journal of Health Sciences & Research. – 2017. – Vol. 2, Issue 1. – P. 11-17.
11. Ceylan, Z. Drug inventory management of a pharmacy using ABC and VED analysis / Z. Ceylan, S. Bulkan // Eurasian Journal of Health Technology Assessment. – 2017. – Vol. 2, Issue 1. – P. 13-18.

12. Biswkarma, V. K. Emerging role of pharmacoeconomics into clinical trials and its outcomes: An overview / V. K. Biswkarma, S. Wadhawan // Indian J. Pharm. Pharmacol. – 2020. – Vol. 7, № 2. – P. 66-72.
13. Hollingworth, S. Measuring Medicine Use: Applying ATC/DDD Methodology to Real-World Data / S. Hollingworth, T. Kairuz // Pharmacy. – 2021. – Vol. 9, № 60. – P. 1-8.
14. Carta, A. On the Use of Markov Models in Pharmacoeconomics: Pros and Cons and Implications for Policy Makers / A. Carta, C. Conversano // Front. Public Health. – 2020. – Vol. 8. – P. 1-14.

15. Information resources, incl. on the Internet

1. https://www.who.int − World health organization.
2. https://www.ispor.org/ - The International Society for Pharmacoeconomics and Outcomes Research (ISPOR).
3. https://htai.org/ - An International Society for the promotion of Health Technology Assessment (HTAi).
4. https://pubmed.ncbi.nlm.nih.gov/ – resource PubMed (access to the MEDLINE database).
5. http:// https://www.cochrane.org/– Cochrane Library