

MEDICAL UNIVESRITY – PLOVDIV
FACULTY OF PHARMACY
DEPARTMENT OF ORGANISATION AND ECONOMICS
OF PHARMACY

PROGRAM

in

PHARMACOECONOMICS

Approved by the Department Council - Protocol № 01/09.01.2023

Confirmed by the Faculty Council - Protocol № 01/25.01.2023

**MEDICAL UNIVERSITY – PLOVDIV
FACULTY OF PHARMACY**

Syllabus

Discipline	Final exam/ semester	According to the Faculty of Pharmacy curriculum of MU-Plovdiv				ECTS	Academic hours in semester	
		Academic hours					IX semester	
		Auditorium	Lectures	Practices	Non-auditorium		L	P
Pharmacoeconomics	IX	60	30	30	77	5,5	30	30

DISCIPLINE:

Pharmacoeconomics

TYPE OF DISCIPLINE ACCORDING TO THE UNIFORM STATE REQUIREMENTS:

Mandatory

LEVEL OF QUALIFICATION:

Master (M)

FORMS OF TRAINING:

Lectures, practical classes, self-tuition

YEAR OF TRAINING:

V course

DURATION OF TRAINING:

One semester

ACADEMIC HOURS:

30 teaching hours of lectures, 30 teaching hours of practical classes

TECHNICAL EQUIPMENT APPLIED IN THE TRAINING:

Multimedia presentations, discussions, solving practical problems, developing a thesis

FORMS OF EVALUATION:

Examination (written and oral), colloquia, development of theses

EVALUATION CRITERIA:

The grade is formed based on the examination – written and oral, and the colloquium results

ASPECTS OF EVALUATION CRITERIA:

Participation in discussions, colloquia, development of theses

SEMESTER EXAM:

Yes (written and oral examination)

STATE EXAM:

No

LECTURER:

Habilitated lecturer from Department of Organisation and Economics of Pharmacy

DEPARTMENT:

Department of Organisation and Economics of Pharmacy

ANNOTATION

Economic research in healthcare gained great significance recently due to the restricted resources and the increasing public expectations regarding medicinal therapy. Pharmacoeconomics emerged in the beginning of 1980s as a new scientific field relating to the research of economic characteristics and possibilities for optimization of medicinal therapy from medical, economic and social point of view. It is defined as “discipline for analysis (gathering, calculation, comparison) of therapy costs and treatment outcome”. The recent widening of its field of application resulted in a broader definition for pharmacoeconomics: “Assessment of impact of forecasted costs and outcomes of pharmaceutical products on decision for termination or continuing of medicine development, as well as on its price formation, reimbursement and introduction into therapeutic practice”. The questions to which pharmacoeconomic research is looking for an answer in terms of medicines relate to: relative share of medicine costs in total healthcare expenditure; the cost of a medicine or a group of medicines, compared to others; the cost of medicinal therapy of various therapeutic approaches; higher prescription of drugs by some medical professionals compared to others; medicine use in a given country compared to other countries; loss of medicines; cost and consequences from a medicinal therapy, costs and outcomes of introduction of a new production line, reimbursement and cost formation for novel products, etc.

Obviously, the answers to these questions are inextricably linked with pharmaceutical practice and with finding reliable, dependable measures of economic and humanitarian aspects of medicines utilisation in society, as well as in development of evaluation indexes of these measures in terms of value. Therefore, acquiring knowledge in pharmacoeconomics is related to broadening the pharmacists’ knowledge about their social and economic environment, and providing proves for substantiated decision-making. The implementation of requirements to provide economic and pharmacoeconomic evaluation when drafting the positive list of medicines, the NHIF list and the cost formation of new medicinal products calls for broadening of pharmacists’ pharmacoeconomic knowledge to allow them to work easily with

terminology, apply correct pharmacoeconomic methods and analyse the results. This knowledge is of exceptional importance in terms of overall reorganisation in healthcare and pharmaceutical sector for work in market conditions and health insurance system, which requires very precise determining of not only the costs, but also the expected outcomes of medicinal therapy and making economically well-grounded, socially acceptable and medically effective decisions. With their knowledge of chemistry, technology, pharmacology of medicines and social pharmacy, pharmacists are very suitable for further development of pharmacoeconomics in our country, due to their understanding of the nature of medicines as well as of socio-economic environment of their distribution.

MAIN TASKS OF CURRICULUM

To familiarise the students with the main concepts, methods, calculation techniques and tools applied for pharmacoeconomic assessment of costs and consequences of medicinal therapy, as well as with implementation of pharmacoeconomic evidence in regulatory and applied pharmaceutical practice.

EXPECTED RESULTS

In the overall course of education, the students will have to analyse independently publications for application of pharmacoeconomics in practice or for manner of application of main methods.

At the end of the course of practical classes, the students have to be familiar with the principal methods, to be able to organise and carry out studies of pharmacoeconomic characteristics of medicinal utilisation, as well as to analyse the result of such studies.

LECTURES
Course V, Semester IX

№	TOPIC	HOURS
1.	Introduction to pharmacoeconomics.	2
2.	Measuring and estimating costs of the medical therapy.	2
3.	Measuring the outcomes of the medical therapy.	2
4.	Cost minimization analysis. Legislative requirements for proving equivalence and efficacy.	2
5.	Cost-effectiveness analysis.	2
6.	Cost-utility analysis.	2
7.	Cost-benefit analysis.	2
8.	Budget impact analysis.	2
9.	Pharmacoeconomic Modeling - " Decision tree".	2
10.	Pharmacoeconomic modeling- Markov modeling.	2
11.	Health Technology Assessment.	2
12.	Pharmacoeconomic evaluation and health care providers.	2
13.	Pharmacoeconomics in the pharmaceutical industry.	2
14.	Pharmacoeconomics in healthcare regulation, medication use and hospital pharmacy.	2
15.	Methodology of pharmacoeconomic research articles.	2

Total: 30 hours

PRACTICAL CLASSES CURRICULUM
Course V, Semester IX

№	TOPIC	HOURS
1.	Pharmacoeconomics – basic concepts, principles and methods. Users of pharmacoeconomic analyzes. Perspective of pharmacoeconomic researches.	2
2.	Costs. Cost categorization. Timing adjustments for costs Discounting. Problems solving.	2
3.	Cost of illness estimates. Cost-minimization analysis .Problems solving for minimization of medicinal therapy costs.	2
4.	Cost-effectiveness analysis. Cost-effectiveness grid. Methodology.	2
5.	Cost-effectiveness ratio estimation. Problems solving.	2
6.	Cost-utility analysis. Steps in calculating QALYs. Cost-utility grid.	2
7.	Cost-utility ratio estimation. Problems solving.	2
8.	Cost-benefit analysis. Willingness to pay. Methodology of CBA. Problems solving.	2
9.	Budget impact analysis. Methodology. Problems solving	2
10.	Problems solving on the topics CMA, CEA, CUA and CBA.	2
11.	Colloquium on topics 1-10.	2
12.	Pharmacoeconomic Modeling – "Decision tree".	2
13.	Modeling in pharmacoeconomics. Markov modeling. Extrapolation models. Examples and practical tasks.	2
14.	Application of Pharmacoeconomics in the production, pricing, reimbursement and pharmaceutical regulation practice.	2
15.	Discussing research articles. Research design and implementation of the pharmacoeconomic analyses	2

Total: 30 hours

LECTURES – THESIS

LECTURE № 1 Introduction to pharmacoeconomics

1. Basic concepts, theories and methods.
2. Application of pharmacoeconomic analyzes.
3. Health economics and pharmacoeconomics - common features and differences.
4. Perspectives of pharmacoeconomic evaluations .

LECTURE № 2 Measuring and estimating costs of the medical therapy

1. Basic concepts
2. Cost categorization
3. Perspective
4. Cost estimation
5. Timing adjustments for costs (discounting)

LECTURE № 3 Measuring the outcomes of the medical therapy

1. Effectiveness, sources for evidence of effectiveness.
2. Classification of outcome measures
3. Utility
4. Benefit

LECTURE № 4 Cost minimization analysis. Legislative requirements for proving equivalence and efficacy

1. Overview
2. Application
3. Methodology
4. Limitations of the analysis
5. Examples for CMA
6. Equivalence – categorization
7. Efficiency

LECTURE № 5 Cost-effectiveness analysis

1. Overview
2. Presentation of costs and effectiveness
3. Cost-effectiveness grid
4. Comparison of therapeutic alternatives
5. Methodology of CEA

LECTURE № 6 Cost-utility analysis

1. Overview
2. Measures of the outcomes in CUA
3. Concept and calculation of QALY
4. CUA methodology
5. Advantages and disadvantages of QALY

LECTURE № 7 Cost-benefit analysis

1. Definition and history
2. Application and disadvantages of CBA
3. Calculating costs and outcomes
4. "Willing to pay" method for estimating benefits
5. Steps in conducting a cost-benefit analysis

LECTURE № 8 Budget impact analysis

1. Overview
2. Methodology
3. Basic steps in the budget impact analysis
4. Legislative requirements for ABC analysis in Bulgaria

LECTURE № 9 Pharmacoeconomic Modeling – "Decision tree"

1. Pharmacoeconomic modeling – "Decision tree"
2. Steps in decision analysis
3. "Decision tree" – composition

LECTURE № 10 Pharmacoeconomic modeling – Markov modeling

1. Overview of Markov modeling
2. Steps in Markov modeling
3. Epidemiological models and extrapolation models

LECTURE № 11 Health Technology Assessment

1. Definitions
2. Historical overview
3. Methodological requirements
4. Bulgarian regulatory practice

LECTURE № 12 Pharmacoeconomic evaluation and health care providers

1. Pharmacoeconomics in the reimbursement of medicinal products
2. Pharmacoeconomics in the pricing of medicinal products

LECTURE № 13 Pharmacoeconomics in the pharmaceutical industry

1. Pharmaceutical industry.
2. Pharmacoeconomics in the pharmaceutical industry
3. Development of a policy for new production of medicinal products
 - 3.1. Calculation of investment costs
 - 3.2. Return on investment costs

LECTURE № 14 Pharmacoeconomics in healthcare regulation, medication use and hospital pharmacy

1. Relationship between medication use and pharmacoeconomics
2. Sources of data on medication use
3. Qualitative measures of medication use
 - 3.1. ABC analysis
 - 3.2. VED analysis
4. Application of pharmacoeconomics in hospital pharmacy

LECTURE № 15 Methodology of pharmacoeconomic research articles

1. Pharmacoeconomic research
2. Organization of pharmacoeconomic research
3. Appropriateness of methods of analysis

PRACTICALS – THESIS

PRACTICAL CLASS № 1 – 2 teaching hours

Pharmacoeconomics – basic concepts, principles and methods.

Users of pharmacoeconomic analyzes. Perspective of pharmacoeconomic researches.

1. Pharmacoeconomics.
2. Relationship of Pharmacoeconomics to other research.
3. Types of pharmacoeconomics studies
4. Perspective of pharmacoeconomic researches.
5. Questions and exercises.

PRACTICAL CLASS № 2 – 2 teaching hours

Costs. Cost categorization. Timing adjustments for costs Discounting. Problems solving.

1. Costing terms.
2. Cost categorization.
3. Resources of cost estimations.
4. Timing adjustments for costs. Discounting. Problems solving.

PRACTICAL CLASS № 3 – 2 teaching hours

Cost of illness estimates. Cost-minimization analysis. Problems solving for minimization of medicinal therapy costs.

1. Cost of illness estimates.
2. Cost-minimization analysis.
3. Problems solving for minimization of medicinal therapy costs.
4. CMA articles discussion.

PRACTICAL CLASS № 4 – 2 teaching hours

Cost-effectiveness analysis. Cost-effectiveness grid. Methodology.

1. Cost-effectiveness analysis.
2. Cost-effectiveness grid.
3. Efficacy versus effectiveness.
4. Problems solving.

PRACTICAL CLASS № 5 – 2 teaching hours

Cost-effectiveness ratio estimation. Problems solving.

1. Cost-effectiveness ratio estimation (CER).
2. Incremental cost-effectiveness ratio estimation (ICER).
3. Discussing CEA articles.

PRACTICAL CLASS № 6 – 2 teaching hours

Cost-utility analysis. Steps in calculating QALYs. Cost-utility grid.

1. Cost-utility analysis.
2. QALY.
3. Methods for utility determination.
4. Cost-utility grid.

PRACTICAL CLASS № 7 – 2 teaching hours

Cost-utility ratio estimation. Problems solving.

1. Cost-utility ratio (CUR) estimation.
2. Incremental cost-utility ratio estimation.
3. Discussion of CUA articles.

PRACTICAL CLASS № 8 – 2 teaching hours

Cost-benefit analysis. Willingness to pay. Methodology of CBA. Problems solving.

1. Cost-benefit analysis.
2. Methodology.
3. Willingness to pay.
4. Problems solving.

PRACTICAL CLASS № 9 – 2 teaching hours

Budget impact analysis. Methodology. Problems solving.

1. Budget impact analysis.
2. Study design. Perspective.
3. Uncertainty analysis. Problems solving.

PRACTICAL CLASS № 10 – 2 teaching hours

Problems solving on the topics CMA, CEA, CUA and CBA.

1. Cost-minimization analysis- problem solving.
2. Cost-effectiveness analysis-problem solving.
3. Cost-utility analysis-problem solving.
4. Cost-benefit analysis-problem solving.

PRACTICAL CLASS № 11 – 2 teaching hours

Colloquium on topics 1-10

PRACTICAL CLASS № 12 – 2 teaching hours

Pharmacoeconomic Modeling - "Decision tree".

1. Decision analysis. Decision tree.
2. Threshold analysis.
3. Questions and exercises.

PRACTICAL CLASS № 13 – 2 teaching hours

Modeling in pharmacoeconomics. Markov modeling. Extrapolation models. Examples and practical tasks.

1. Markov modeling.
2. Extrapolation models.
3. Disadvantages of Markov modeling.
4. Questions and exercises.

PRACTICAL CLASS № 14 – 2 teaching hours

Applied Pharmacoeconomics in the production, pricing, reimbursement and pharmaceutical regulation practice.

1. Applied pharmacoeconomics.
2. Application of pharmacoeconomics in the pricing and reimbursement practice.
3. Pharmacoeconomics in the pharmaceutical regulation.
4. Questions and exercises.

PRACTICAL CLASS № 15 – 2 teaching hours

Discussing research articles. Research design and implementation of the pharmacoeconomic analyses.

1. Appropriateness of methods.
2. Questions to use when critiquing research articles in pharmacoeconomics.
3. Questions and practical tasks.

BIBLIOGRAPHY

1. Г. Петрова, А. Стоименова, А. Савова, М. Манова, К. Андреевска, М. Димитрова, Д. Грекова, С. Георгиева, Учебник по ФАРМАКОИКОНОМИКА, София, ИНФОФАРМА ЕООД, 2013, ISBN 978-954-92652-5-5
2. Г. Нешев, Зл. Димитрова и кол., ЕВРОФАРМА-2, Избрани глави от съвременната клинична фармакология, фармакотерапия и клинична фармация, София, 2012, АРСО, ISBN 978-954-9301-81-6
4. Зл. Димитрова, Е. Христов, И. Първова-Христова, Основи на фармакоикономикта, София, 2016, Фармадвайс ЕООД, ISBN 978-619-90672-0-8
5. Нешев Г. и др. Фармакоикономика. ГорексПрес, 1999
6. Наръчник по фармакоикономика, GlaxoWellcome, 1999
7. Bootman J.L., Townsend R.J., McGhan W.F., Introduction of Pharmacoeconomics, 2-17
8. Boyer G.J., Hirsch J.D., Townsend R.J., Pharmacoeconomic research: Studing the costs and consequences of drug therapies, Drug intelligence and clinical pharm., 1988, 21-24
9. Drummond M., Method for the economic evaluation of health care programs, 2nd edition, 2000
10. Freund D.A., Dittus R.S., Principles of pharmacoeconomic analysis of drug therapy, Pharmacoeconomics, 1992 (1), 20-32
11. Kozma C.M., Reeder C.E., Richard M. S., Economic, Clinical and Humanistic Outcomes: A planing models for Pharmacoeconomics research, Excerpta Medica, 1993, (15), 6, 1121-1132
12. Plosker G.L., Milne R.J., Ondansteron - A pharmacoeconomic and quality-of-life evaluation of its antiemetic activity in patients receiving cancer chemotherapy, Pharmacoeconomics, 1992 (4), 285-304
13. The rational Evaluation of Drug therapies. The role of Economics, Health Econom.Research units, London, 1989
14. Rascati K., Essentials of Pharmacoeconomics, 2009, Wolters Kluwer, Lippincott Williams and Wilkins

EXAM TOPICS

1. Pharmacoeconomics. Basic concepts and methods. Health economics and Pharmacoeconomics – common features and differences. Efficiency and effectiveness. Areas of application and users of Pharmacoeconomics analyzes.
2. Costs. Types of costs. Timing adjustments for costs Perspectives of the pharmacoeconomic studies.
3. Measures of the outcomes of medical therapy.
4. Cost-minimization analysis. Proof of equivalence. Methodology, limitations, examples of application in the pharmaceutical practice.
5. Cost-effectiveness analysis. Methodology, limitations and advantages, examples for application in the pharmaceutical practice. Cost-effectiveness grid.
6. Cost-utility analysis. Methodology, advantages and limitations, examples of application in the pharmaceutical practice. Types of outcome measures.
7. Cost-benefit analysis. Methodology, limitations, examples of use in the pharmaceutical practice. "Willingness to pay" and formation of the psychological cost of medicinal products and services.
8. Budget Impact Analysis (BIA). Overview and methodology.
9. Pharmacoeconomic modeling. "Decision tree".
10. Pharmacoeconomic modeling. Markov modeling. Extrapolation models. Application and limitations of Markov modeling.
11. Assessment of health technologies. Application in the regulatory practice.
12. Pharmacoeconomics in the practice of pricing and reimbursement.
13. Pharmacoeconomics in pharmaceutical production.
14. Requirements and guidelines for conducting pharmacoeconomic studies. Basic steps in pharmacoeconomic studies.
15. Pharmacoeconomics in medication use and hospital pharmacy.