



MINISTRY OF HEALTH OF UKRAINE
NATIONAL UNIVERSITY OF PHARMACY
Department of organization and economy of pharmacy

ASSESSMENT OF HEALTHCARE TECHNOLOGIES

(the name of educational component)

EDUCATIONAL WORK PROGRAM of educational component

training for _____ second (master's) degree _____
(Higher Educational Level Name)
in specialty « 226 Pharmacy, industrial pharmacy » _____
(Code and Specialty Name)
field of knowledge « 22 Healthcare » _____
(Code and Knowledge Field Name)
of educational program « Pharmacy » _____
(Educational Program Name)
in specialization(s) _____
(name of specialization, if available)

Kharkiv-2023
(Year of creation)

CONSIDERED AND APPROVED: National University of Pharmacy of the Ministry of Health of Ukraine

EDUCATIONAL COURSE TEAM:

NEMCHENKO Alla, Professor of the Department of Organisation and Economics of Pharmacy, Doctor of Pharmacy, Professor,

Nazarkina Victoria, Professor of the Department of Organisation and Economics of Pharmacy, Doctor of Pharmacy, Professor,

KOBA Tetiana, postgraduate student

Educational program has been considered and approved at the Department meeting

Record from «04» September 2023 № 2

a.i. head of the department



prof. Hanna Panfilova

Educational program has been approved at the meeting of the Methodical Commission of economic, managerial, social and humanitarian disciplines

Record from «5» September 2023 № 1

Head of Specialized Committee



prof. Alla NEMCHENKO

INTRODUCTION

The educational component study program "Healthcare Technology Assessment" compiled in accordance with the Standard of Higher Education of Ukraine (hereinafter referred to as the Standard) / Educational (educational-professional, educational-scientific) program of the second level of higher education

field of knowledge 22 Health care

specialty 226 Pharmacy, industrial pharmacy

of educational program "Pharmacy"

Description of the educational component (abstract)

The subject of the educational component "Assessment of Healthcare Technologies" is the modern methodology of planning, organising and conducting an assessment of the effectiveness of medical technologies in various aspects (socio-economic, medical, ethical components).

Interdisciplinary connections: "Assessment of Healthcare Technologies" is based on the study of the following educational components: pharmacology, organisation and economics of pharmacy, pharmaceutical management and marketing, social economics, pharmacoeconomics.

1. The purpose and objectives of the educational component

1.1. The purpose of teaching the educational component "Assessment of Healthcare Technologies" is to form a set of knowledge for masters on effective planning, use of limited healthcare resources and control over their targeted use in various areas of medical and pharmaceutical activities.

1.2. The main tasks of studying the educational component "Assessment of Healthcare Technologies" are

- formation of a set of knowledge, skills and abilities of higher education students regarding
- the essence of HTA and its role in the organisation of quality medical and pharmaceutical care;
- historical aspects of the development and modern models of the HTA system;
- methodological approaches to evaluating the effectiveness of medical technologies (clinical and economic efficiency, safety, legal and ethical components);
- legal and informational support of the HTA system;
- methodological skills of conducting HTA, documenting and using the results.

1.3 Competencies and program learning outcomes, the formation of which is facilitated by the educational component (relationship with the normative content of the training of higher education applicants, formulated in terms of learning outcomes in the Standard/educational program).

According to the requirements of the standard/educational program, the educational component ensures the acquisition of applicants for higher education

competences:

integral:

Ability to solve typical and complex specialized tasks and practical problems in the professional pharmaceutical activity of Healthcare on a socially-oriented basis or in the process of training, which involves conducting chemical, biopharmaceutical, biomedical, sociological, etc. research and / or implementation of innovations and is characterized by uncertainty of conditions and requirements; integrate knowledge, critically comprehend and solve complex issues, make decisions in complex unpredictable conditions, formulate judgments in the presence of incomplete or limited information, taking into account aspects of social and ethical responsibility; clearly and unambiguously to convey their conclusions and use their knowledge, reasonably substantiating them, to professional and non-professional audience.

general

GC 2. Ability to apply knowledge in practical situations, make reasonable decisions

GC 4. Ability to abstract thinking, analysis and synthesis, to learn and be modernly trained.

GC 6. Knowledge and understanding of the subject area and understanding of professional activity.

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

GC 12. Ability to conduct research at the appropriate level.

special (professional):

PC 4. Ability to ensure the rational use of prescription and over-the-counter medications and other pharmaceutical products in accordance with physicochemical, pharmacological characteristics, biochemical, pathophysiological features of a particular disease and pharmacotherapeutic regimens for its treatment.

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.

PC 12. Ability to use in professional activities the knowledge of regulations, legislation of Ukraine and recommendations of good pharmaceutical practices.

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

PLO 1. To carry out professional activities in social interaction based in humanistic and ethical principles; to identify future professional activities as socially significant for human health.

PLO 2. To apply knowledge of general and professional disciplines in professional activities.

PLO 4. To demonstrate the ability to independently search, analyze and synthesize information from various sources and use these results to solve typical and complex specialized tasks of professional activity.

PLO 6. To argue information for decision-making, to be responsible for in in standard and non-standard professional situations; to adhere to the principles of deontology and ethics in professional activities.

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

PLO 12. To analyze the information obtained as a result of scientific research, summarize, systematize and use it in professional activities.

PLO 14. To determine the advantages and disadvantages of medications of different pharmacological groups, taking into account their chemical, physicochemical, biopharmaceutical, pharmacokinetic and pharmacodynamic features. To recommend to consumers over-the-counter medications and other products of the pharmaceutical range with the provision of counseling and pharmaceutical care.

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.

PLO 24. To plan and implement professional activities on the basis of regulations of Ukraine and recommendations of good pharmaceutical practices.

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

know:

- The main stages of the historical development of the HTA system;
- legislative, regulatory and legal regulation of the functioning of the HTA system
- basic principles of building the HTA system;
- powers and functions of international organisations in the field of HTA;
- foreign experience in the functioning of the HTA system;
- principles of forming socio-economic lists of medicines based on HTA in foreign practice;
- basic methods of assessing the availability of pharmaceutical care, the effectiveness of pricing for medicines;

- description of methods of internal and external monitoring of prices for medicinal products;
- the essence of the main methods of pharmacoeconomic analysis used in the HTA;
- problems of effective implementation of HTA in healthcare and pharmacy practice.

be able to:

- formulate a medical problem and describe medical technology to solve it;
- analyse epidemiological indicators;
- determine the impact on the budget;
- to justify the comparator for conducting an HTA;
- analyse the availability of medicines;
- conduct price monitoring;
- evaluate the effectiveness of medicines pricing and their availability;
- document the results of the studies.

2. Information content of the educational component.

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

Content module 1: Introduction to health technology assessment

Topic 1: Basic theoretical concepts and historical aspects of the development of health technology assessment.

Topic 2. Principles of building a system of medical technology assessment in world practice. Organisation of intergovernmental cooperation. Regulations on HTA

Topic 3. Regulatory and legal regulation of medical technology assessment. Guidelines for the assessment of medical technologies.

Content module 2. HTA methodology and use of assessment results for decision-making

Topic 4. Methodological principles of medical technology assessment. Basic model of HTA.

Topic 5. Evaluation of clinical efficacy and safety of medicines.

Topic 6. Methods for assessing the economic feasibility of medical technologies. Impact on the budget.

Topic 7. Scientific and applied aspects of applying the results of medical technology assessment.

3. The form of semester supervision of study progress

Semester supervision is carried out in the form of a semester credit

4. Methodological support (educational content (lecture notes), plans for practical (seminar) classes, tasks for laboratory works, independent work, questions, problems, assignments or cases for current and semester control of knowledge and skills of higher education students, complex control work with educational component, etc.).

1. Study guide
2. Methodological materials for computer presentations of lectures.
3. Methodological recommendations for practical classes and independent work of students.
4. List of theoretical questions for the final module control.
5. Test tasks.
6. Tickets for the control of content modules.

5. Reading suggestions

6. The main reading suggestions

1. A Guide to ICER's Methods for Health Technology Assessment. Institute for Clinical and Economic Review, 2020. 43 p. URL: https://icer.org/wp-content/uploads/2021/01/ICER-HTA-Guide_102720.pdf
2. ICER Guide to Understanding Health Technology Assessment (HTA). Boston, Institute for Clinical and Economic Review, 2018. 12 p. URL: <https://icer.org/wp-content/uploads/2020/10/ICER-Guide-to-Understanding-Health-Technology-Assessment-6.19.18.pdf>

Supplementary reading suggestions

3. Angelis A., Lange A., Kanavos P. Using health technology assessment to assess the value of new medicines: results of a systematic review and expert consultation across eight European countries. *Eur. J. Health Econ.* 2018. Vol. 19, № 1. P. 123–152.
4. ATC/DDD Index 2022. WHO Collaborating Centre for Drug Statistics Methodology. URL: https://www.whocc.no/atc_ddd_index/.
5. Guidelines for the Economic Evaluation of Health Technologies: Canada. 4th ed. 2017. URL: https://www.cadth.ca/sites/default/files/pdf/guidelines_for_the_economic_evaluation_of_health_technologies_canada_4th_ed.pdf
6. Guiding principles for good practices in hospital-based health technology assessment units / L. Sampietro-Colom et al. *IJTAHC.* 2015. Vol. 31, №6. P. 457–465. DOI: <https://doi.org/10.1017/S0266462315000732>.
7. Health expenditure and financing. OECD.Stat. URL: <https://stats.oecd.org/index.aspx?DataSetCode=SHA>
8. Health technologies and pharmaceuticals programme: annual report 2018. Copenhagen, WHO Regional Office for Europe, 2019. 38 p.
9. Husereau, D., Drummond, M., Augustovski, F. et al. Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) statement: updated reporting guidance for health economic evaluations. *BMC Med* 20, 23 (2022). <https://doi.org/10.1186/s12916-021-02204-0>
10. Kosyachenko K. L., Nemchenko A. S. Methodological approaches to development of the national guidelines of the health technology assessment. *Вісник фармації.* 2014. № 1. С. 54–57.
11. Neumann P. J., Silver M. C., Cohen J. T. Should a drug's value depend on the disease or population it treats? Insights from ICER's value assessments. *Health Affairs blog.* URL: <https://www.healthaffairs.org/doi/10.1377/hblog20181105.38350/full/>
12. Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (Text with EEA relevance) <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R2282>
13. Role of Health Technology Assessment in Pharmaceutical Market Access in Developed Countries // *Pharmaceutical Market Access in Developed Markets* / R. Kahveci et al. SEEd: Torino, 2018.
14. The HTA Core Model: A novel method for producing and reporting health technology assessments / K. Lampe et al. *IJTAHC.* 2009. Vol. 25. P. 9–20.
15. The HTA Core Model – 10 Years of Developing an International Framework to Share Multidimensional Value Assessment / F. B. Kristensen et al. *Value Health.* 2017. Vol. 20, № 2. P. 244–250.

7. Electronic resources, including the Internet

1. Organization and economy of pharmacy department <http://economica.nuph.edu.ua/>
2. Scientific Library National University Of Pharmacy <http://lib.nuph.edu.ua>
3. Distance learning website <http://www.pharmel.kharkiv.edu/>
4. World Health Organisation website - <http://www.who.int/ru/>
5. European Network for Health Technology Assessment – <http://www.eunethta.eu/>