

## МЕДИЦИНА

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### **SOCIO-HISTORICAL PREREQUISITES FOR THE DEVELOPMENT OF HEALTH TECHNOLOGY ASSESSMENT**

**Abstract.** *With the development of scientific, technical and production capacity, improvement of international standards of medical care and standards of pharmaceutical products, expansion of medical services, there is a need to apply innovative technologies in health care. The application of the latest effective health technologies has an impact both on the healthcare system as a whole and on the health policy. Specialists are faced with the task of using the most effective health technologies at an affordable price with the subsequent prognosis of improving patients' quality of life [4]. Taking into account the economic, social, legal and ethical aspects of implementing health technologies, there is a need for their assessment from the standpoint of evidence-based medicine. Therefore, health technology assessment (HTA) has to be conducted with regard to all aspects that affect both the patient's condition from an ethical, socio-economic, legal perspective, and the policy in the healthcare system as a whole. Hence, the study of socio-historical prerequisites of the development of HTA in the world and in Ukraine is key to understanding social and economic processes taking place in medicine and pharmacy today.*

**The aim of the research** is to determine socio-historical prerequisites for the emergence of HTA, get acquainted with the practice of introducing HTA, systemize historical facts that prompted the introduction of HTA at the world level and in Ukraine, study and summarize the stages of HTA development in the world and in Ukraine.

**Methods.** A review of domestic and foreign resources was conducted using information retrieval databases, scientometric databases Scopus, Web of Science, etc.; the collection and systematization of information in the form of tables, analysis of legal documents, which regulate HTA in Ukraine, was carried out.

The following research methods were used: information retrieval by keywords using search systems, databases and websites; content analysis of documents adopted at the world level and within the Ukrainian legislation; systematization of information.

**Results.** The analysis of international legal documents, a review of foreign scientific papers and websites found that HTA emerged due to international integration processes that took place in clinical epidemiology, pharmacy, health care management and economics, which led to the development of pharmacoeconomics, medical insurance, price-setting, etc. In Ukraine, the implementation of HTA began in 2010 with the opening of ISPOR pharmacoeconomic research offices.

**Key words:** health technology assessment (HTA), pharmacoeconomics, public health, socio-historical prerequisites for the development, modern medicine and pharmacy, clinical pharmacy, evidence-based medicine.

## СОЦІАЛЬНО-ІСТОРИЧНІ ПЕРЕДУМОВИ РОЗВИТКУ ОЦІНКИ МЕДИЧНИХ ТЕХНОЛОГІЙ

**Анотація.** З розвитком науково-технічного і виробничого потенціалу, удосконалення міжнародних стандартів надання медичної допомоги та стандартів фармацевтичної продукції, розширення медичних послуг, виникає необхідність у застосуванні інноваційних технологій в галузі охорони здоров'я. В свою чергу, застосування новітніх ефективних медичних технологій має вплив як на систему охорони здоров'я в цілому, так і на політику у галузі охорони здоров'я. Перед фахівцями постає питання застосування найефективніших медичних технологій за доступну ціну з подальшим прогнозом покращення якості життя пацієнтів [4]. Враховуючи економічні, соціальні, правові та етичні аспекти впровадження медичних технологій, виникає необхідність у їх оцінці з позицій доказової медицини. Тож, вирішення цих питань призвело до необхідності проведення оцінки медичних технологій (ОМТ) з урахуванням усіх аспектів, які впливають як на стан пацієнта з етичної, соціально-економічної та правової точки зору, так і на політику в системі охорони здоров'я в цілому. Очевидним є вивчення соціально-історичних передумов розвитку ОМТ у світі та в Україні для розуміння соціально-економічних процесів, які відбуваються сьогодні в галузях медицини і фармації.

**Ключові слова:** оцінка медичних технологій (HTA), фармакоекономіка, громадське здоров'я, соціально-історичні передумови розвитку, сучасна медицина та фармація, клінічна фармація, доказова медицина.

### Analysis of the latest research and publications.

The insights on the prerequisites for the emergence, further development and implementation of HTA presented in the publications of such domestic scientists as O. Zaliska, O. Zahlada, K. Kosiachenko, V. Nazarkina, A. Nemchenko, O. Piniashko, are of great scientific interest for our study. In particular, O. Zaliska in her scientific works focused on pharmacoeconomic study of medical care for patients with urological diseases [36]; the basic terminology of pharmacoeconomics has been defined and introduced into the practice of health care for the first time, and the discipline of pharmacoeconomics has been implemented into professional educational programs of master's and postgraduate education. The issues of medical care for patients with gynecological diseases and the systemic implementation of HTA into the health care system of Ukraine based on the European model were studied by O. Piniashko [24]. In the scientific works of A. Nemchenko and K. Kosiachenko, the main stages of the development of HTA at the world level have been determined for the first time and, accordingly, the main ways of HTA implementation in Ukraine have been defined; the system of professional training of HTA experts in the European space was described, and professional educational programs for training masters in HTA were developed [21]. The study of international documents and scientific works of D. Banta [1], Emilio Q. Daddario [8], C. Goodman [10], E. Jonsson [1], F. Kristensen [16], K. Lampe, W. Oortwijn, B. O'Rourke [23], T. Schuller, J. Wong [35] and others indicate that in-depth analysis of socio-historical prerequisites of the emergence of HTA was done, resulting in the solution of complex problems associated with HTA implementation and its further development. The analysis of scientific papers on socio-historical prerequisites for the development of HTA shows that the challenges of further improvement and development of HTA at the global level are highlighted by the authors. However, there is a lack of consistency in the chronology of historical events.

**Formulation of the aim of the article.** Given the purpose of the study, it should be noted that the

history of the emergence and development of health technology assessment was not the object of a special study and is relevant for understanding all processes that occur during HTA at all levels of research, from HTA users to patients. For this purpose, scientific databases, literature reviews, websites of international organizations, such as WHO, FDA, ISTAHC, Cochrane, NCHCT, INAHTA, ISPOR, EUnetHTA, HEOR, etc, were analyzed.

### Presentation of the main research material.

It was found that the historical prerequisites for the emergence of HTA, according to J. Wong (2014), to some extent, can be considered the approaches of the U.S. Food and Drug Administration (FDA, USFDA), which was responsible for the safety of food products, biologically active additives, drugs, vaccines, medical devices and equipment, veterinary products and cosmetics. In 1938, FDA adopted the Food, Drug, and Cosmetics Act (FDCA), which required the registration of new drugs, medical devices, and labeling for aforementioned products. At that time, the Food, Drug, and Cosmetics Act did not require pre-market testing of new drugs and medical devices. The FDA's current approach established the foundations to the regulation of drugs and medical devices. Under the influence of socio-economic factors, the Food, Drug, and Cosmetics Act was gradually amended to control the quality of medicinal products, adverse drug events [35].

Thus, specialists from various fields of science were involved to improve the quality and availability of medical and pharmaceutical care. In 1967, Emilio Q. Daddario, Chairman of the Subcommittee on Science, Research and Development of the Committee on Science and Astronautics used the term "Technology Assessment" (TA) in the U.S. House of Representatives. He developed and introduced a draft law on the creation of the Technology Assessment Council to "provide a method for identifying, assessing, publicizing and considering the consequences of applied research and technology" [8]. The term "Technology Assessment" was used to describe "sociotechnical research that discloses the benefits and risks to society" regarding

drugs, biological supplements and medical devices, as well as the results of research on the development of scientific and technological opportunities.

In the early 1970s, Archie Cochrane and Jack Wennberg actively raised the issue of unwanted side effects of drugs that were used in medical practice and caused problems of unjustified variations in healthcare. The scientists emphasized the lack of evidence verifying the effectiveness of many standard medical practices. This type of research by A. Cochrane and J. Wennberg led to the emergence of evidence-based medicine (EBM). As a result of the above-mentioned events, the issue of assessing the broad social impact of new health technologies has raised concerns, which could cause excessive use of some health technologies and a decrease in demand for other health technologies [35]. Based on the results of the first studies on HTA, published by the US National Science Foundation, Congressional hearings were held. In 1973, the Office of Technology Assessment was established, as a result of its activity in 1975 the national program of the HTA system was created. Later, in 1976, based on the results of the activity of the Office of Technology Assessment, the first report on HTA appeared [23]. Over three years, from 1972 to 1975, more than 750 reports on HTA were produced, which had an impact on changes in healthcare policy regarding the legislative framework for medicinal products [35].

To disseminate the results of HTA to the public, the Office of Technology Assessment in the United States started the first conferences in 1977, and such conferences have been held since that time at a rate of approximately 5 per year. The main goal was to bring together various concerned parties (physicians, researchers, economists, epidemiologists, consumers, ethicists, and so on) to seek consensus "on the

scientific basis of the safety, efficacy, and appropriate conditions" for use of various healthcare technologies. The conferences were attended by concerned representatives from Sweden, Denmark, Finland, France, the Netherlands, and the United Kingdom [1]. The reports presented at the conferences addressed "cost-effectiveness, clinical trial results, ethical implications, legal implications, systems analysis" and constructive decision-making regarding the use of medicines [35].

It should be noted that at the same time, in 1978, the international conference "Primary Health Care" was held in Almaty (Republic of Kazakhstan) under the auspices of the World Health Organization. Based on the results of the conference, the Declaration of Alma Ata on Primary Health Care was adopted, which referred to "essential health care based on practical, scientifically sound methods and technologies" [32].

Thus, the main prerequisites for the emergence of medical technology assessment can be systematized (Table 1) and the fields of medicine and pharmacy that began their development and were involved in HTA can be identified. These include quality control of pharmaceuticals and medical products, clinical epidemiology, public health management, standardization of medical care, and HTA.

Further steps in the development of HTA was the creation of the National Center for Health Care Technology (NCHCT) in the USA in 1980, which became the first national agency in the world. Thanks to NCHCT, in 1983, the program on Medicare technologies was developed. The systematic reviews of selected technologies have been conducted for the first time, and methods for setting priorities between health technologies have been developed [1]. It should be noted that according to historical data, Medicare is "a

Table 1

#### Prerequisites for the Emergence of Health Technology Assessment

Year	Organization, author	Event	Results	
1	2	3	4	
1938	FDA, USA	Act on Food, Drug, Cosmetics, Medical Products, Package Labeling	Regulation of the quality of pharmaceuticals and medical products	Quality control of pharmaceuticals and medical products
1967	Emilio Q. Daddario, USA	Introduction of the term "technology assessment"		
1970s	Archie Cochrane, John Wennberg, Great Britain	Issue of undesirable side effects of drugs	Emergence of evidence-based medicine	Evidence-based medicine, pharmacovigilance
1973	National Science Foundation, USA	Management of HTA	National program of the HTA system	
1975	National Science Foundation, USA	The first report on HTA	Changes in the health care policy and legal documents	Standardization of medical care
1978	WHO, Almaty	Adoption of the Declaration on Primary Health Care	Medical care based on practical, scientifically sound methods and technologies	

cost-based reimbursement system to a Prospective Payment System (PPS)". Thanks to this system, health care providers were paid on the basis of a specified fixed amount. As a result, "the amount paid for a given service depended on the classification system for that service". A particular payment was supposed to take into account the average resources required to treat the underlying condition and adjust these payments for variables such as hospital location, proportion of low-income patients [35], etc. The main output of NCHCT was publication of a scientific paper in the field of HTA entitled "Health Technology Assessment". In 1982, NCHCT ceased to exist and was reorganized into the Council on Health Care Technology.

Gradually, HTA began to be held on the territory of the American and European countries. In 1982, the Committee for Evaluating Medical Technologies in Clinical Use (*French* – Comité d'Evaluation et de Diffusion des Innovations Technologiques) was established on the territory of the European Union, which was one of the first to start working at the hospital level [17]. This influenced further development prospects in healthcare. Thus, since the 80s, the executive body of the EU, the European Commission, has supported several studies and meetings related to HTA. Further steps in the development of HTA in the European region (the Netherlands) were the assessment of the most expensive medical technologies, such as organ transplantation and cancer screening programs. At the same time, the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) was established at the end of the 80s [1].

In 1984, the WHO European Office adopted a project for the development of the European Region prior to 1990, which stated that "all the Member States should have established a formal mechanism to systematically assess the appropriate use of health technologies and verify that they respond to the national health programs and the country's economic means" [34].

In 1985, the first international association for health technology assessment, ISTAHC, was founded under the leadership of President Seymour Perry. ISTAHC included more than 1,500 people. The official journal of the organization was the *International Journal of Technology Assessment in Health Care*.

Two years later, HTA was joined by representatives of the World Bank, who provided substantial support for the development of HTA in China. Further assistance from the World Bank facilitated the development of HTA in Malaysia, Poland, Romania and Serbia [1].

In 1988, the Council on Health Technology Assessment (*French* CETS – Conseil d'évaluation des technologies de la santé) was organized in the province of Quebec (Canada), which later grew into the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) [17].

On the WHO website, in the section "Health Products Policy and Standards", subsection "Health Technology Assessment", it is historically documented that in 1989 the Pan American Health Organization (AMRO/PAHO) became the second WHO region to publish information on HTA. In the early 1990s, WHO organized several consultations dedicated to national health care programs [33].

The introduction of the system of reference pricing in the Netherlands (Geneesmiddelen Vergoedings Systeem, GVS) in 1991 became a landmark event in the history of HTA in Europe. Using HTA, a "positive list" of medicines was developed, the cost of which was reimbursed by a third-party payer [17].

It should be noted that in connection with the dissemination of evidence-based medicine data collected by A. Cochrane and J. Wenberg, at that time there was a need for systematization and compilation of clinical studies into a single database. According to the results of scientists' work, in 1992, the Cochrane Centre [5] in the United Kingdom was established to facilitate and coordinate systematic reviews of randomized controlled trials. The systematization of data from evidence-based medicine and randomized controlled trials led to the adoption of new clinical decisions in healthcare policy [1].

Four years later, in 1993, the WHO HQ offices held a meeting of WHO Regional Advisers on Technology Development, Assessment, and Transfer in Alexandria, Egypt. On 1 June 1994, there was a meeting of a working group in Geneva, WHO HQ, named "Promoting the Use of Health Technology Assessment to Improve Health Care in Developing Countries" [33].

Thus, it is possible to observe the initiation and spread of health technology assessment around the world, the introduction of medical insurance, reimbursement and systematization of evidence-based medicine data (Table 2), which integrated health technology assessment into scientific research, the academic community, and clinical practice.

Subsequently, with the spread of HTA in the world, there was a need for communication between HTA agencies located in different parts of the world to share knowledge and cooperate at the global level. This led to the formation of a new international organization INAHTA in 1993, within which the decision was made to introduce medical insurance in the Netherlands, France, Switzerland, Spain, the United Kingdom, and some countries in Latin America (Brazil, Argentina, and Uruguay) and in Asia (Taiwan).

In 1994, with EU support, the European Commission financially supported the first EUR-ASSESS project (1994-1997), joined by fifteen EU member states. The project prompted the study of the ways to improve the coordination of HTA in Europe [8].

In 1995, the Association for Pharmacoeconomics

Table 2

**Development and Spread of Health Technology Assessment**

Year	Organization, author	Event	Results	
1	2	3	4	
1980 – 1982	NCHT, USA	National Center for Health Care Technology	Program on Medicare technologies; Scientific paper “Health Technology Assessment”	Medical insurance
1982	European region	Committee for Evaluating Medical Technologies in Clinical Use	Implementation of hospital HTA; assessment of the most expensive medical technologies	
1984	WHO	European Region Development Project	Creation of a formal mechanism to systematically assess appropriate use of health technologies prior to 1990	
1985 – 2003	ISTAHC	Establishment of the first international organization for conducting HTA	Official publication “International Journal of Health Technology Assessment”	
1987	World Bank	Involvement in cooperation	Development of HTA in Malaysia, Poland, Romania and Serbia	
1988	Canada	Council on Health Technology Assessment	Coordinating Office for Health Technology Assessment	
1989	WHO	AMRO/PAHO	The second organization for HTA and consulting on national health care programs	
1991	Netherlands	Implementation of the system of reference pricing	The list of medicines, the cost of which is reimbursed by the country	Reimbursement
1992	Archi Cochrane, John Venberg, Great Britain	Cochran Center; systematization of evidence-based data	Making new clinical decisions in health care policy	
1993	WHO, Egypt	Meeting of WHO regional advisers	“Promoting the Use of Health Technology Assessment to Improve Health Care in Developing Countries”	
	INAHTA	Establishment of a new international organization	Introduction of medical insurance in the Netherlands, France, Switzerland, Spain, the United Kingdom, some countries in Latin America (Brazil, Argentina, and Uruguay) and in Asia (Taiwan)	

and Outcomes Research (APOR) was established by a small group of dedicated scientists with the goal of serving as a catalyst to advance the science and practice of health economics and outcomes research (HEOR). It was led by its founding Executive Director, Marilyn Dix Smith, PhD. Later, the name APOR was changed to ISPOR.

As the activity of HEOR in the field of health care economics has grown, so has ISPOR. The Society's membership has expanded from just 240 members at its founding to more than 19,000 individual and chapter members from more than 110 countries worldwide. The Society's membership included a wide variety of healthcare stakeholders, including researchers and academicians, assessors and regulators, payers and policy makers, the life sciences industry, healthcare providers, and patient engagement organizations [13].

One of the results of close cooperation between INAHTA (the international network of HTA agencies), Health Technology Assessment international (HTAi)

and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) was the development and implementation of the HTA glossary in five languages, which is constantly updated [11]. At this time, knowledge about HTA expanded, and in 1998 C. Goodman (1998) proposed the definition of HTA as “a systematic evaluation of properties, effects or other impacts of health technologies, the purpose of which was to inform technology-related policymaking in healthcare” [10].

In 1997, Dr. Daniel Lopez Acuna, Director Division of Health Systems and Services Development of the WHO, took part in the 12th Annual Meeting of ISTAHC on the methodology and practical application of HTA in Mexico and Chile as a moderator. Based on the results of the conference, in 1998, a book “Development of Health Technology Assessment in Latin America and the Caribbean” by Alberto Infante was published. This was the second edition of the Pan American Health Organization (AMRO/PAHO). The materials of this

edition encouraged the expansion of HTA concepts and methodology in the region and South America [33].

It should be noted that the development and implementation of HTA was carried out by a community of like-minded people from various fields of science, passionate about the idea of providing quality and effective medical services at an affordable price. Qualitative research required more and more financial contributions and attracting new investors. Therefore, the first international organization ISTAHC was liquidated for financial reasons in 2003. In the same year, a new international society, HTAi, was formed in Canmore (Alberta, Canada), with Chris Henshall as president. Today, it is a vibrant and growing community of multidisciplinary advisors, academics, scientists, professionals, public and private organizations, students, patients, and citizen members who are dedicated to better health for all people and the future of HTA worldwide [12].

By defining key policy priorities on the territory of the European Union in 2004, the European Commission and the EU Council of Ministers recognized the need to establish "a sustainable European network on HTA". The results of the activities of HTA agencies of various European countries and the subsequent implementation of the results of health technology assessment led to the establishment of a new European project EUnetHTA in 2005, led by the Danish Center for Evaluation and Health Technology Assessment (DACEHTA) in Copenhagen. The project included

35 HTA organizations from different countries. The consequent activities of the European Network for HTA (EUnetHTA) were organized through establishment of the EUnetHTA 2009, the EUnetHTA 2010-2012 projects, which are constantly prolonged and continue to this day. HTA agencies from various EU countries are involved in the projects.

It should be mentioned that as a result of EUnetHTA activities, the structure and tools of cooperation between HTA agencies in the European Union were improved, where special attention was paid to global events in HTA. Thanks to the implementation of the project activities of the European Network on HTA, the practical application of tools and approaches to cross-border HTA collaboration was strengthened, guided by the Regulation of the European Parliament 2011/24/EU on HTA collaboration [9].

As part of the project of the European Network on HTA, the HTA Core Model® was developed as a science-based framework for assessing the cost aspects of health technology assessment in 2006-2008 to "facilitate production and sharing of health technology assessment information, such as evidence on efficacy and effectiveness" and to make informed decisions in the industry of health care [16].

Therefore, it is possible to observe the development and spread of HTA in the world, the emergence of pharmacoeconomics as a science and its development, the adoption of regulatory and legal documents in the field of healthcare (Table 3).

Table 3

#### Development and Introduction of Health Technology Assessment in the World

Year	Organization, author	Event	Results	
1	2	3	4	
1994	European Union	The first EUR-ASSESS project	Studying the possibilities of improving the coordination of HTA in Europe	Pharmacoeconomics
1995	HEOR	Health care economics	Foundation of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR)	
1998	HTAi, INAHTA, ISPOR	The HTA glossary in five languages	Introduction of the term "medical technology assessment" by C. Goodman	Making managerial decisions in health care
	WHO	The second edition of the Pan American Health Organization (AMRO/PAHO)	"Development of Health Technology Assessment in Latin America and the Caribbean" by Alberto Infante	
2003	Chris Henshall, Canmore, Alberta, Canada	Establishment of a new international organization HTAi		
2004	EUnetHTA, European Union	Establishment of the European HTA project	Regulation of the European Parliament 2011/24/EU	

Starting from the 90s of the 20th century, the first publications on pharmacoeconomics appeared in Ukraine, and the basics of pharmacoeconomic research were gradually introduced into educational curricula. Thus, in 2006, a program was developed as part of the European Union project "Supporting the Development of the Medical Standards System in Ukraine" [25]. In order to develop the economy of healthcare, since 2010, representatives of the pharmaceutical faculties of Danylo Halytsky Lviv National Medical University and the National University of Pharmacy have actively cooperated with representatives of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), initiating one of the directions for the introduction of HTA in Ukraine. At that time, the issues regarding the lack of sources of clinical data in pharmacoeconomic modeling were raised, namely local electronic scientific databases, compliance with the standards of other countries regarding some nosologies [18].

The issue of HTA implementation in Ukraine in 2011 was raised by K. Kosiachenko in his scientific research, which focused on methodology of conducting HTA, and the existing regulatory and legal framework in Ukraine at that time. The author made a conclusion about the need for its improvement for further development of HTA in Ukraine. In 2012, A. Nemchenko and K. Kosiachenko conducted an analysis of the international experience in HTA and emphasized the need for budget funding of the national HTA agency, briefly presenting the sequence of stages for HTA [22].

Based on the results of the initial research and study of international experience, the first international conference "Health Technology Assessment and Possible Mechanisms of its Implementation in Ukraine" was held in Kyiv in October 2012. In November of the same year, in Berlin, a large group of Ukrainian scientists, led by O. Zaliska, representing Danylo Halytsky Lviv National Medical University, presented the results of pharmacoeconomic studies conducted in Ukraine at the European Congress of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) [31].

According to the requirements of the order of the Ministry of Health of Ukraine No.751 of 28.09.2012 "On the Creation and Implementation of Medical and Technological Documents on Standardization of Medical Care in the System of the Ministry of Health of Ukraine" [30], as of January 2014, 15 orders were developed, which approved 40 unified clinical protocols for providing medical care, 5 standards for providing medical care, and 21 adapted clinical guidelines [26].

The next step in the development of HTA in Ukraine was the issuance of the order of the Ministry of Health of Ukraine "On Approval of the Composition of the Working Group on Introducing the System for

Technology Assessment in Health Care" in May 2014 [27].

In the Law of Ukraine No.2168 of 19.10.2017 "On State Financial Guarantees of Medical Services for the Population" [28], the term "**medical technology assessment**" is mentioned for the first time and its definition is provided. In February 2018, the Expert Committee of the Ministry of Health of Ukraine on the Selection and Use of Essential Medicines of the Ministry of Health of Ukraine developed and approved by order of the Ministry of Health of Ukraine the Guidelines (version 1.1) "Guidelines for Health Technology Assessment" [14]. It identifies several blocks on health technology assessment: analysis of the effectiveness and safety of medicines, pharmacoeconomic analysis, analysis of the impact on the budget of the health care system, and analysis of problem solving.

In January 2019, State Enterprise "State Expert Center of the Ministry of Health of Ukraine" established the Department of Health Technology Assessment (HTA) with the aim of assessing health technology in Ukraine at the national level [15].

And only in 2020, the resolution of the Cabinet of Ministers of Ukraine No.1300 of 12.23.2020 "On Approval of the Procedure for the State Health Technology Assessment" establishes the procedure for the state health technology assessment [19]. In the following year, the representatives of the State Expert Center of the Ministry of Health of Ukraine developed and adopted the industry Standard: Guidelines "Health Technology Assessment for Medicines" ST-N MOZU 42-9.1:2021 [20], approved by the order of the Ministry of Health of Ukraine "On Approval Guidelines on the State Health Technology Assessment for Medicines" in 2021 [29].

Later, in 2022, the Expert Committee for Health Technology Assessment of the State Enterprise "State Expert Center of the Ministry of Health of Ukraine" was created [6] and its members were appointed [7].

In view of the foregoing, it can be concluded that HTA in Ukraine is in the initial stage of the development and management decision-making in health care (Table 4). It is obvious that HTA implementation at the state level has led to changes in the Ukrainian legislative framework in view of international documents; implementation of programs in the educational process within professional higher and postgraduate education [3; 2], continuous professional development. However, the introduction of HTA and the adoption of management decisions in health care today are completely dependent on state authorities.

#### **Conclusions and prospects of further study:**

- Regulation of the quality of drugs and medical devices, the development of evidence-based medicine regarding unwanted side effects of drugs, the implementation of standards for providing

Table 4

**Chronology of the Introduction of Health Technology Assessment and Changes in the Ukrainian Legislation Regarding HTA**

Year	Organization	Event	Results
1	2	3	4
the 90s of the XX century	Ukrainian Scientific Society	The first publications of pharmaco-economic studies	Implementation of the principles of pharmaco-economics in educational programs
2006	EU project	Support of the development of the system of medical standards in Ukraine	Standardization of medical care for the population
2010	ISPOR representative offices	Danylo Halytsky Lviv National Medical University, National University of Pharmacy, Kharkiv	Pharmaco-economic modeling (O. Zaliska, A. Nemchenko)
2011	National University of Pharmacy, Kharkiv	Analysis of legal documents of Ukraine regarding the standardization of medical care for the population	Stages of HTA (A. Nemchenko, K. Kosiachenko)
2012	National University of Kyiv-Mohyla Academy, Kyiv	The first international conference "Health Technology Assessment and Possible Mechanisms of its Implementation in Ukraine"	Report of O. Zaliska
	ISPOR	European Congress of the International Society for Pharmaco-economics and Outcomes Research	Report of O. Zaliska on pharmaco-economic study
	Order of the Ministry of Health of Ukraine No.751 dated 28.09.2012	Changes in the Ukrainian legislation regarding the standardization of medical care for the population	Making managerial decisions at the country level
2015	USPOR, Danylo Halytsky Lviv National Medical University	Implementation of educational programs on HTA and pharmaco-economics in the system of continuous professional development	Educational website on pharmaco-economics
2017	Law of Ukraine No.2168 dated 19.10.2017	"On State Financial Guarantees of Medical Care of the Population"	Introduction of the term "health technology assessment"; Introduction of the concept of reimbursement; List of medicines, the cost of which is reimbursed by the country
2018	Ministry of Health of Ukraine	Guidelines for health technology assessment	Implementation of HTA at the country level
		National Classification of Ukraine	Expert on health technology assessment
	National University of Pharmacy, Kharkiv	Approval of the master's professional educational program	Technology assessment in health care
2019	State Enterprise "State Expert Center of the Ministry of Health of Ukraine"	Establishment of the Department of Health Technology Assessment	
	Shupyk National Healthcare University of Ukraine, Kyiv	Approval of the program of thematic improvement courses in postgraduate education	Current issues of technology assessment in health care
2020	Resolution of the Cabinet of Ministers of Ukraine No.1300 dated 23.12.2020	On approval of the procedure for state assessment of health technology	Making managerial decisions at the country level
2021	State Enterprise "State Expert Center of the Ministry of Health of Ukraine"	Development of an industry standard for conducting HTA for medicinal products	Standard: Guidelines "Health Technology Assessment for Medicines" ST-N MOZU 42-9.1:2021
	EUnetHTA	Membership of representatives of the State Enterprise "State Expert Center of the Ministry of Health of Ukraine"	Participation in the EUnetHTA project
2022	State Enterprise "State Expert Center of the Ministry of Health of Ukraine"	The Expert Committee on HTA	Approval of the composition of the Expert Committee on HTA



medical care to the population have led to changes in the international legal framework and integration of socio-economic requirements for health technology assessment.

– Scientific studies on health technology assessment led to the development and implementation of health insurance, a program for reimbursement of the cost of medicinal products, which influenced the development of pharmacoeconomics and changes in the system of pricing for medicinal products.

– Since the end of the 90s of the 20th century, there has been a scientific interest in conducting the first pharmacoeconomic studies on the territory of Ukraine. HTA in Ukraine began to be implemented in 2010 together with the reform of the health care system. Subsequently, there are changes in the Ukrainian legislative framework regarding the implementation of the medical guarantee program and the program for reimbursement of the cost of medicinal products. The first pharmacoeconomic modeling of medicinal products is being carried

out regarding their inclusion in the National List of Medicinal Products and the Register of Medicinal Products that are subject to cost reimbursement under the medical guarantee program.

Further development of HTA in Ukraine involve the following priority tasks:

– Further implementation of HTA into the educational process within professional higher education, postgraduate education and continuous professional development;

– Availability of various training programs to a wide range of HTA users;

– Making changes and additions to the legislative framework of Ukraine in order to conduct an independent HTA by agencies that are not subordinate to the Ministry of Health of Ukraine to prevent a conflict of interests between the applicant and the state authorities;

– Standardization of the quality of medical devices, implementation and approval of standards for HTA for medical devices at the state level.

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