UDC 614.2:615.4
DOI: 10.15587/2519-4852.2024.314005

MODERN APPROACHES TO TYPOLOGIZATION AND MODELING IN THE HEALTH TECHNOLOGY ASSESSMENT

Mykhailo Babenko, Kostyantin Kosyachenko

The aim: *to develop a typology of the current management systems for health technology assessment (HTA) based on the identification of typological features in order to scientifically and practically substantiate a typological model that combines the most stable properties and can be implemented in a variety of modifications, taking into account the dynamic development of the health care system (HCS).*

Materials and methods. *The study used scientific publications, official information from the websites of national or regional bodies/agencies, international organizations on HTA, reports, databases and official documents of the World Health Organization (WHO). The research used the following methods: the system analysis, content analysis, institutional analysis, structural-functional analysis, generalization, comparison, systematization, classification, synthesis, typology, and modeling. To conduct a typological analysis, 34 countries were selected in which the HTA has been implemented in the decision-making process for the use and financing of medical technologies (MTs).*

Research results. *An institutional analysis of national HTA systems was conducted. The status of HTA in the national health care systems of the selected countries and, in particular, the role of HTA in the decision-making process regarding the use of certain MTs were studied. The author analyzes the institutional capacity of the HTA system (availability of a special authorized body, level of centralization/decentralization, financing, regulatory framework and human resources). The functionality and areas of activity of HTA bodies (organizations), the level of accountability, openness and interaction with various stakeholders are analyzed. The systematization and generalization of foreign experience made it possible to conduct a typological analysis by characteristic features). Four types of HTA management systems are identified (starting, centralized, decentralized, and balanced).*

Conclusions. *The study identifies and analyzes the areas of activity of the bodies/organizations in most countries of the world that carry out HTA in terms of their mission, vision and functionality, as well as assesses the level of their openness and interaction with various stakeholders. The scientific generalization and systematization of modern approaches and models of HTA systems made it possible to typologize them on the basis of certain characteristic classification features*

Keywords*: public administration, health care system, health technology assessment, modeling, classification and typologization, typology, type (model, sample)*

How to cite:
Babenko, M., Kosyachenko, K. (2024). Modern approaches to typologization and modeling in the health technology assessment. ScienceRise: Pharmaceutical Science, 5 (51), 78–88. http://doi.org/10.15587/2519-4852.2024.314005

1. Introduction

Health technologies assessment (HTA) fulfills the most important socio-economic tasks of public management in the health care system (HCS) and pharmaceutical provision of the population, in particular, as a tool to support the adoption of management decisions regarding the rational distribution of limited resources in order to ensure the state-guaranteed maximum possible level of providing high-quality medical and pharmaceutical care [1]. Due to the fact that HTA developed in parallel in different countries of the world, there is a huge variety of models and forms of organization of such activities. Despite the significant efforts of intergovernmental associations in the field of HTA to unify the assessment methodology, approaches, methods, means, tools and technologies for organizing and conducting HTA differ significantly in each individual country [2–4]. At the current stage, the mechanisms for harmonizing the procedures and methodology of conducting HTA and joining efforts at the global level are being developed, including within the framework of the implementation of the requirements of the European Regulation on Health Technology Assessment (Regulation (EU) 2021/2282 on HTA) [5].

In connection with the implementation of the Law of Ukraine "On Medicinal Products" dated 07/28/2022 No. 2469-IX, significant changes are taking place in the regulatory environment in the field of registration and circulation of medicinal products, which entails reformatting of the institutional structure, mechanisms and principles of management, in particular, it is planned to create a new regulatory body with expanded powers, which will perform functions according to the full cycle of state supervision, which will combine the functions and powers of the State Service of Ukraine on Medicines and Drugs Control (Derzhliksluzhba) regarding licensing of subjects of pharmaceutical activity, inspection and medicines qual-

ity control, as well as the State Enterprise "State Expert Center of the Ministry of Health of Ukraine" (SE "SEC of the MOH of Ukraine") regarding medicines registration and post-registration monitoring – pharmacovigilance. According to the Resolution of the Cabinet of Ministers of Ukraine (CMU) No. 1300 dated 23.12.2021, temporarily until the creation of a state unitary commercial enterprise, which will be entrusted with the performance of functions for conducting state HTA, the performance of these functions is entrusted to the SE "SEC of the MOH of Ukraine", on HTA. Therefore, Ukraine is currently at the stage of choosing an effective model for the organization of HTA activities and public management in this area, which would consider the positive world experience and the peculiarities of the domestic HCS.

According to WHO, HTA agencies/bodies are currently established in more than 80 countries of the world, most of which are in Europe. HTA systems of different countries have differences depending on their place and role in the decision-making process in HCS [6]. In this sense, typological analysis (typologization), which involves the study of a certain set of objects from the point of view of a systemic approach and the identification of characteristic properties (common and special, similar and different), allows you to order and group these objects in a certain way and distinguish them according to many parameters certain generalized models of this or that object/phenomenon. So, a type is considered as a model (sample) of certain objects (phenomena, processes), which contains a necessary and sufficient set of essential features for their grouping, and in this combination forms a certain system (type). In our case, typology allows us to determine certain characteristic features of HTA. Classification and typology are considered as a certain sequence of cognitive procedures and techniques that reflect the flow of thought from unregulated diversity to the creation of a structurally defined integrity. This is the movement of scientific knowledge from the level of empirical accumulation to the level of theoretical synthesis (generalization and ordering of knowledge) [7, 8]. Therefore, research aimed at developing a typology of management systems and a modern HTA model, which considers the development of domestic HCS, is relevant and timely.

Therefore, **the aim of the study** was to substantiate typological features and develop a typology of modern management systems and a theoretical model of HTA, which combines various characteristics and modifications of classification features, considering the dynamic development of domestic HCS.

2. Research planning (methodology)

To conduct the research and achieve the set goal, the following stages were performed (Fig. 1).

Scientists in the fields of sociology, political science, and law often use classification and typology in their research, noting their ontological, epistemological, and prognostic value. However, the interpretation of these categories is ambiguous. Thus, typology can be considered as a separate method of scientific knowledge, as a special type of scientific classification, while some scientists consider classification to be a component of typology. In our opinion, it is appropriate to apply the typology to dynamic HCSs that are developing and constantly reforming, since new components and elements may appear in such systems, new connections may be established, which fully applies to modern HTA models.

Since the early 1970s, scientists have been constantly working on classifications and typologies in HCS and pharmacy: to compare HCS [9–13], state-management relations [14, 15], HTA methodology [16–19]. Typologies allow scientists and practitioners to more effectively compare socio-economic indicators in different countries over different periods.

The typologies can also help identify institutional indicators that appear to be particularly promising in comparing HCS and pharmacy management systems and their reform processes, including the implementation and development of HTA.

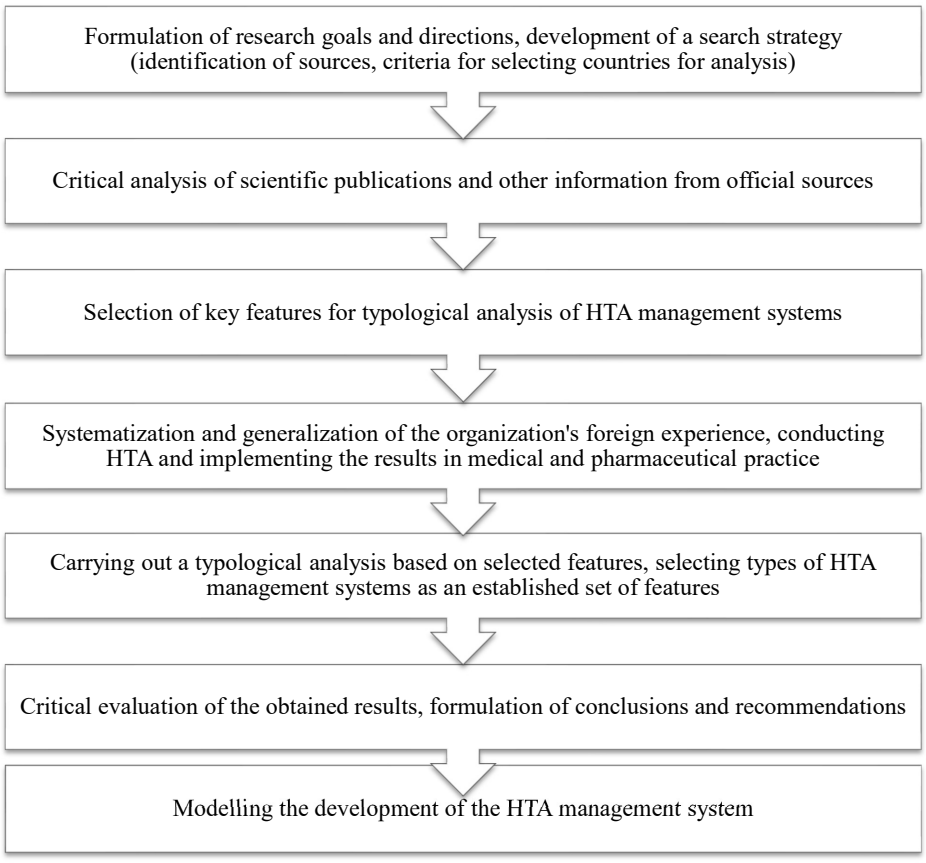

Fig. 1. Research design regarding the typology of HTA management systems

3. Materials and methods

At the first stage, the goals and directions of the research were determined, and a search strategy was developed (reliable sources of information, clear criteria for selecting countries and sources of information, key questions regarding the organization of HTA). In our research, we relied on general methodological approaches and principles of organizing the main processes of HTA, which are regulated by international and national regulatory documents (guidelines, in particular, the HTA Core Model). The study covers the period 2015–2024.

Empirical data from the 2020–2021 WHO global study was used to conduct an institutional analysis of the development of HTA in international practice, and we selected 34 countries from different regions of the world for a more detailed study. The main criteria for the selection of countries: official recognition of HTA results and their use in the decision-making process regarding access to the MT market, pricing, reimbursement, etc. These are, first of all, European countries (Belgium, Bulgaria, Great Britain, Greece, Ireland, Spain, Italy, Cyprus, Latvia, Netherlands, Germany, Norway, Portugal, Romania, Serbia, Slovakia, Hungary, Ukraine, France, Czech Republic, Sweden, Switzerland), as well as other countries with a sufficiently developed HTA system: Argentina, Brazil, Canada, Mexico, Cuba, China, India, the Republic of Korea, Japan, Malaysia, UAE, Morocco. Particular attention was paid to the peculiarities of the organization of HTA in European countries, including at the level of the European Union. The analysis was carried out by the method of a systematic search in literature sources and on the websites of competent bodies of various countries that carry out HTA (national and regional HTA bodies, Ministries of Health (MOH), national health insurance organizations), as well as research institutions that work in this relevant scientific and practical direction.

It seems that typology and classification are independent methods of scientific knowledge, but if we define classification as the division of the scope of a concept into types, groups or other classification sets based on a certain characteristic, property, then typology is the process of grouping certain systemic phenomena of reality based on theoretical model (type). One type includes objects (phenomena, processes) that have the same necessary and sufficient set of key features for their grouping. The construction of a model (a certain model, an ideal type) is based on an understanding of the systemic unity of signs and properties that are its basis.

The research used methods: system analysis, content analysis, institutional analysis, structural-functional analysis, generalization, comparison, systematization, classification, synthesis, typology, modelling. For the typological analysis, 34 countries were selected in which HTA is implemented in the decision-making process regarding the use and financing (reimbursement, procurement, in particular under managed entry agreements – MEA) of MTs.

4. Research result

Typological analysis and construction of typological schemes provides an understanding of the process of development of such phenomena and their successive transition from one qualitative state to another, from one type to another. So, the typology provides an understanding of the internal logic and regularities of the process of forming the HTA management system and acts as a basis for forecasting further development.

The scientific generalization and systematization of the thematic reviews allowed us to identify groups of features, according to which it is expedient to conduct a typology of HTA management systems. These are, first of all, the following key features (Fig. 2).

Therefore, according to the HTA status in the HCS, all analyzed countries can be conditionally divided into:

1) countries with full implementation and centralized management, when HTA is included in the decision-making process at the national level (and this is fixed by legislation), appropriate scientific and methodological support has been developed. Inclusion in the decision-making process at the national and regional level is characteristic of countries with a decentralized management system (Argentina, Brazil, Canada, Spain, Sweden, UAE). It is worth noting that a very important (determining) moment is also the clear identification of a systematic decision support process in HCS as HTA with all the relevant consequences (institutional support, methodological base, etc.);

2) to the second group we included countries that occupy an intermediate position, i.e., for example, in Cyprus, Morocco, Switzerland and the UAE, such activities are not associated with HTA, therefore, taking into account the results of HTA in the decision-making process is not regulated by law (that is, such activities are not officially recognized HTA and accordingly there are no standards, guidelines, established methodology);

3) the third group of countries – do not have appropriate institutional and regulatory support (we did not include them in the sample).

The results of a comparative analysis of the role and place of HTA in the decision-making system in HCS and pharmacy are summarized in Table 1.

Table 1

The status of HTA in the decision-making system in HCS and pharmacy

Feature		Examples of countries
System process of decision support	National	All
	Regional	Argentina, Brazil, Canada, Spain, Sweden, UAE
Official name of HTA		All except Cyprus, Morocco, Switzerland, UAE
Standard method/guideline		All except Cyprus, Morocco, UAE n/a Netherlands, Switzerland
Legal conditions considering the results of HTA		Except Belgium, Canada, India, Japan, Malaysia, Morocco, Sweden; n/a UAE

Institutions conducting HTA at the national level are mostly independent of the competent authorities with which they cooperate (e.g. MOH, health insurance organizations, pricing committees), although their activities are generally accountable to these authorities.

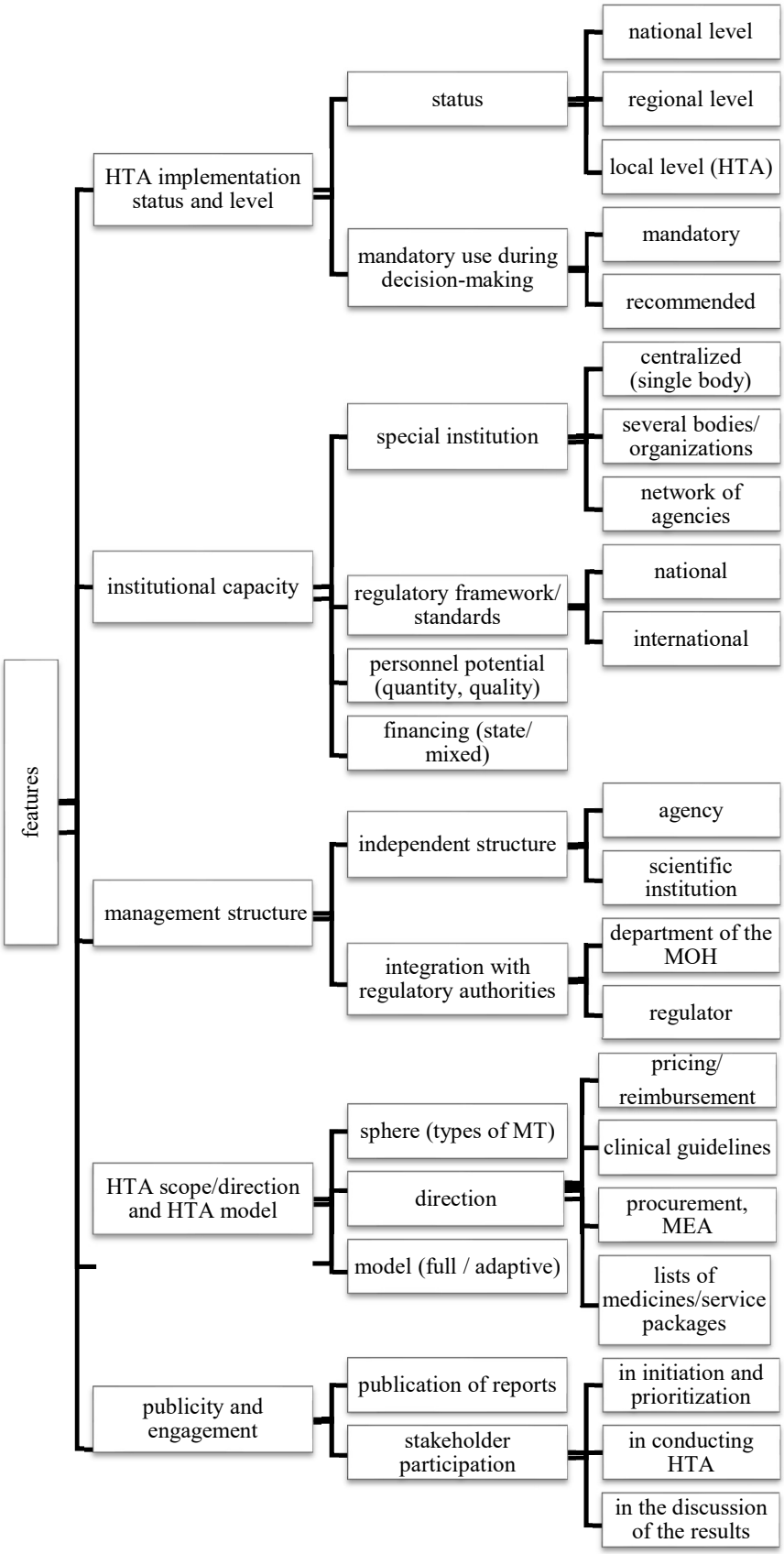

Fig. 2. Key features of the typology of HTA management systems

In our view, HTA bodies that work "at arm's length" have a place in more developed HTA management systems and provide an appropriate level of transparency and independence, as well as impartiality. The less developed HTA systems (in Greece, Cyprus and Malta) are often integrated into the competent authorities, which in itself implies a certain limitation of independence, impartiality and transparency, as the assessments are internal and the recommendations are not published in the public domain, making the decision-making processes and negotiations opaque.

At the same time, the integrated functions of the HTA system can be used as a starting point in the implementation of HTA activities, especially under conditions of insufficient potential for the creation of an independent body with HTA, in particular in Ukraine. Generally, most independent bodies publish their HTA reports and results publicly, while integrated ones keep them confidential.

The next important evaluation criterion is the scope (subject and object) and features (model) of conducting HTA. It has been established that some bodies evaluate only a certain type of MT.

The results of the analysis show that all analyzed countries have well-developed processes for the evaluation of drugs but are often absent for medical devices (MD) and other MTs. The presence of more than one HTA agency at the national level often indicates that these HTA bodies have different mandates and assess different MTs [17]. For example, the Finnish Medicines Agency (FIMEA) conducts an assessment exclusively for medicines used in hospital, while SUKL (State Institute for Drug Control) in the Czech Republic and TLV in Sweden – on the contrary, only for medicines used in outpatient treatment [18].

So, HTA can be conducted "full cycle" according to the HTA Basic Model (i.e., include clinical effectiveness, safety, economic analysis, assessment of legal, social and ethical aspects), or analysis of the specific consequences of the use of MT (as a rule, in comparison with another MT or placebo). Evaluation of the clinical efficacy and safety of MT at the stage of market access and inclusion in the reimbursement system is often carried out more formally, based on the available evidence. For P&R decision-making, listing is often done as a rapid benchmarking exercise, with an economic focus on cost and budget impact [20].

Recently, in connection with the limitation of resources and the acceleration of the process of accessing the market of new medicines (including those with high uncertainty, for the treatment of rare diseases), the so-called "adaptive HTA", that is, HTA that is maximally adapted to a specific situation and carried out according to a shortened procedure (rapid review (RR), rapid submission by the manufacturer, transfers, CEA rapid comparative assessment, de facto HTA) [21].

It was established that only three of the studied countries (Great Britain, Slovakia, UAE) widely use HTA for the development of clinical guidelines, for planning, budgeting, price negotiations, etc. (Table 2).

Thus, 73.5 % of the analyzed countries (*n*=25) use HTA for pricing and as an argument during negotiations with producers; 67.7 % (23 countries) – for the development of clinical guidelines; 61.7 % each (21 countries) – for planning, budgeting, as well as for developing packages of medical services; 44 % each (15 countries) – for substantiation of indicators of the quality of medical care, as well as substantiation of protocols of public health programs; 26.5 % (*n*=9) rely on HTA when concluding MEA (payment-for-result schemes).

The analysis showed that in many countries, the regulation of the circulation and use of various MTs (medical procedures, medicines, diagnostic tests, etc.) belong to the competence of different bodies, and the processes of evaluation and use of results are divided accordingly, considering the spheres of influence.

As for the distribution between levels of management (national, regional), it mainly depends on the peculiarities of the HCS organization and the political system of the state in general. It is typical for many countries to implement different HTA procedures by different bodies/organizations, which allows in certain ways to achieve the goal and ensure impartiality and transparency, the participation of various stakeholders in the assessment, independent examination and use of the results.

The distribution of actual HTA procedures between different bodies/organizations and levels of management can also take different forms. Thus, in Hungary, Japan, Malaysia, Switzerland, China, the Republic of Korea, Spain, these functions are clearly divided. Quite often, assessment and expertise (Appraisal/Assessment) are carried out by the same organizations, and recommendations (at the level of policy development and decision-making) are joined by other interested parties. There may be another combination, when the decision-making body responsible for the implementation of the recommendations conducts an appraisal of the HTA conclusions, as is currently the case in Ukraine.

A fundamental question in the context of the study is the fact that who among the interested parties initiates the HTA and prioritizes and selects the interventions for review. Due to the relevant limitations (personnel, time, financial), it is impossible to evaluate all MTs that need it. Therefore, the decision-making processes regarding the expediency and priority of HTA, as well as the allocation of resources, are influenced by important "players".

It was established that, as a rule, these issues are taken care of by the Ministry of Health or its separate structural unit (office, department) (58.8 %), the executive board of the HTA or a body authorized to make decisions regarding certain aspects of the application of MT – 44.1 %, HTA scientific committee or decision-making body – 35.3 % (Table 3).

As for the assessment of HTA results (expertise), the following was established (Table 4):

1) in the majority of analyzed countries (23 countries, i.e. 67.7 %) there are official national guidelines on economic evaluations;

2) 20 countries (58.8 %) carry out cost control using databases of costs or prices for MT;

3) the official threshold of economic efficiency is established in 11 countries, and its value is absolutely incomparable, which is determined by the level of socio-economic development of countries and the peculiarities of the organization of HCS and health insurance.

Table 2

Scope/ direction of use of HTA

Area/direction of HTA	Number of countries	Examples of countries
Pricing/negotiations	25	Austria, Belgium, Bulgaria, Brazil, Great Britain, Greece, India, Spain, Italy, Canada, China, Republic of Korea, Latvia, Malaysia, Germany, Norway, UAE, Portugal, Serbia, Slovakia, France, Czech Republic, Sweden, Switzerland, Japan
Clinical guideline	23	Argentina, Bulgaria, Brazil, Great Britain, Canada, Cyprus, China, Republic of Korea, Cuba, Greece, India, Ireland, Hungary, Latvia, Malaysia, Mexico, Norway, UAE, Romania, Slovakia, Spain, France, Czech Republic, Sweden
Planning, budget	21	Argentina, Austria, Belgium, Brazil, Great Britain, Ireland, Spain, Canada, Cuba, Latvia, Malaysia, Morocco, Mexico, Norway, UAE, Portugal, Romania, Slovakia, Hungary, Ukraine, Czech Republic
Development of packages of medical services	21	Argentina, Austria, Brazil, Canada, China, Republic of Korea, Cuba, Germany, India, Ireland, France, Latvia, Malaysia, Netherlands, Norway, United Kingdom, Portugal, Slovakia, Spain, Switzerland
State procurement of medicines	15	Austria, Brazil, China, Cyprus, Greece, Latvia, Malaysia, Morocco, Norway, UAE, Portugal, Slovakia, Sweden, Ukraine, United Kingdom
Protocols of public health programs	15	Argentina, Austria, Cyprus, Great Britain, Ireland, Spain, France, Malaysia, Morocco, Mexico, UAE, Portugal, Romania, Slovakia, Switzerland
Pay-for-result schemes (MEA)	9	Bulgaria, Great Britain, Italy, UAE, Portugal, Slovakia, Hungary, Czech Republic, Sweden

Table 3

The influence of various stakeholders on the selection of MT for evaluation

HTA entities	Number of countries	Examples of countries
HTA scientific committee/competent body*	12	Argentina, Brazil, China, France, Hungary, India, Italy, Malaysia, Mexico, Korea, Sweden, Switzerland
HTA executive board/ competent body*	15	Brazil, Bulgaria, China, Cyprus, France, Hungary, India, Italy, Malaysia, Mexico, Netherlands, Norway, Portugal, Korea, Sweden
Director of the HTA body/competent body*	9	Brazil, China, Italy, Malaysia, Mexico, Portugal, Korea, Romania, Sweden
Department/MOH	20	Brazil, France, Greece, Hungary, India, Ireland, Malaysia, Mexico, Morocco, Netherlands, Portugal, Romania, Serbia, Slovakia, Spain, Sweden, Switzerland, Ukraine, UAE, United Kingdom
National Health Service	9	Brazil, Ireland, Malaysia, Mexico, Romania, Serbia, Spain, Sweden, United Kingdom
Patient organizations	6	Brazil, Germany, Ireland, Spain, Sweden, Great Britain
Community	2	Brazil, Great Britain

*Note: * – body authorized to make certain decisions*

Table 4

Peculiarities of evaluation of HTA results (Appraisals) in different countries

Feature	Number of countries	Examples of countries
National guidelines for economic assessments	23	Belgium, Bulgaria, Brazil, Great Britain, Canada, Cuba, Czech Republic, France, Hungary, Ireland, Italy, Latvia, Malaysia, Mexico, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Ukraine, Japan
Availability of cost/price databases for MT	20	Belgium, Bulgaria, Brazil, Great Britain, Greece, Ireland, Spain, Italy, Latvia, Netherlands, UAE, Portugal, Romania, Serbia, Ukraine, France, Switzerland, Sweden, Japan
Official threshold of economic efficiency	11	Great Britain, Ireland, Spain, Latvia, Malaysia, Netherlands, Slovakia, Hungary, Ukraine, Czech Republic, Japan
Participation of stakeholders in the discussion	18	Argentina, Bulgaria, Brazil, China, India, Italy, Latvia, Malaysia, Norway, Portugal, Republic of Korea, Serbia, France, Sweden, Switzerland, Great Britain, Japan
Declaration of conflict of interest	27	Argentina, Belgium, Bulgaria, Brazil, Great Britain, Greece, India, Ireland, Italy, China, Cyprus, Latvia, Malaysia, Mexico, Netherlands, Germany, UAE, Portugal, Republic of Korea, Serbia, Slovakia, Hungary, Ukraine, France, Sweden, Switzerland, Japan

The study showed that various stakeholders can be involved in the discussion of the evaluation results (this is foreseen in 18 of the analyzed countries, which is 52.9 %). At the same time, great attention is paid to avoiding conflict of interest (for which the mechanism of mandatory declaration of conflict of interest by all participants in the HTA process is used).

The potential of HTA and the strength of the institutional structure differ significantly in the studied countries (Table 5). So, for example, in Bulgaria, Latvia and Romania, the number of full-time employees (FTE) in HTA bodies is from 1 to 5, while in Canada, China, the Netherlands, Germany, the Republic of Korea, Switzerland and Great Britain – more than 100. Of course, this is to some extent determined by the size of the country and the needs of the HCS. 6 countries (Brazil, the Czech Republic, Italy, Malaysia, Norway, Portugal) have medium capacity agencies from 21 to 50 FTE, and 3 countries (France, Morocco, Spain) with a larger capacity – from 51 to 100.

Most of the analyzed countries (n=28) have budget financing. Additional financing from private funds is foreseen in 6 countries. At the same time, for example, in Germany, the share of private sources of financing is set at 5 %, in Great Britain – 11 %, in the Czech Republic – 25 %, etc.

The duration of HTA also differs significantly in different countries – from 1–3 months in France, Hungary, Italy, Ukraine to more than a year in Japan and Sweden. At the same time, more than 900 assessments are conducted in France every year, 270 in Hungary. Other countries have moderate indicators that do not correlate with the strength of the personnel potential. So, with more than 100 FTEs, Germany performs about 100 HTAs every year, the Netherlands – 50, Great Britain – 150, China – 21. Of course, the number of assessments depends on the needs of the HCS, the level of innovation and the very mechanism of selection of MT to analyze and justify the need for such evaluations.

It is worth noting that only eight countries provide for the possibility of challenging HTA results. 55.8 % of the analyzed countries have a separate body responsible for providing recommendations based on HTA results.

As a result of the conducted research, it was also determined what are the main obstacles to the development of HTA in different countries, as well as problems and barriers to using the results of such an assessment in practical HCS at different levels. Such information was not available for some countries, so the analysis was conducted for 25 countries (Table 5).

It was established that one of the main problems is awareness (representatives of 21 out of 25 countries indicated this), and 10 ranked it first in importance, 8 ranked second. Institutional capacity, appropriate man-

dates, political support and qualified professionals are also important issues. The main barriers to the development of potential are the lack of a formed professional environment and the availability of evidence. Adequate funding and knowledge of HTA methodology are other important challenges.

It is worth noting that both national and regional level agencies and those integrated into individual hospitals (hospital HTA, mini-HTA) conduct HTA and prepare reports. Organizations with HTA can be divided into two groups: those directly engaged in the development and dissemination of HTA, and organizations with broader powers (for example, regulatory bodies) [2, 3]. The differences lie in the extent to which the HTA organizations themselves and the results of their activities (reports) are related to decision-making. This largely depends on whether there are formalized decision-making processes. Since HTA systems have developed organically in most European countries; as a result, they differ significantly in terms of process and methodology [2, 6].

National legal frameworks for HTA currently exist in all EU Member States. Despite some convergence of national HTA systems in Europe, there are also significant differences.

The primary role of most HTA organizations is to conduct independent review and provide recommendations for pricing and reimbursement decisions, some also develop quality standards and/or clinical guidelines, conduct horizon scans, maintain registries, or advise MT developers. The vast majority of HTA organizations are public bodies, usually funded from the government's annual budget; however, the number and types of resources allocated to them vary widely: for example, the number of staff varies from zero to 600. The initial evidence base for evaluation often consists of applications submitted by manufacturers, while an increasing number of countries conduct their own evaluations. When using sectoral dossiers, the scope of the review carried out by the HTA varies and may cover aspects such as lack of evidence, errors in the evidence submitted, and the internal and external validity of the evidence submitted. Some HTA bodies carry out additional analysis of the evidence. All states evaluate individual MTs (particularly those entering the market) against MD standards, while some also evaluate multiple MTs used for a specific indication. Differences are also evident in the number of assessments carried out per year (ranging from 5 to 390), the time required to complete an assessment (reflecting the choice between rapid and full assessment as well as capacity) and stakeholder involvement [6].

Following this distinction between scientific assessment (assessment), assessment in context (appraisal) and making a final decision, it can usually be seen that HTA reports are the basis, but not the only consideration, that determines the recommendations, often the recommendations are not binding and can to have certain differences of opinion in their final decision (although usually in this case they have to justify their choice) [4, 6].

To build an effective and transparent HTA system, which should implement modern principles of public management in HCS and a patient-oriented approach, the participation of interested parties in the HTA process becomes relevant. Consultation with various stakeholders, including professional associations and community organizations, patients, citizens, insurance companies, ethicists, and representatives of the pharmaceutical industry and distributors, is currently a component of HTA, which promotes inclusiveness, transparency, and reduced appeals. At the same time, participation in HTA can be implemented as committee members or as external experts [16].

The analysis showed that the practice of involving stakeholders to work in HTA committees is widespread in all analyzed organizations (except for Great Britain, Denmark, Finland). At the same time, the degree of "openness" of the system and, accordingly, the categories of persons participating in the decision-making process in different countries vary from representatives of insurance and social security organizations, economists in the field of HCS, medical and pharmaceutical workers to representatives of public organizations.

HTA results in different countries have different legal status and level of implementation in the decision-making process by competent authorities. If the use of HTA results is mandated by law, purchasers/customers of medical services must necessarily rely on prepared evidence when making decisions. In other cases, when the results are of a recommendatory nature, a negative conclusion does not necessarily entail a refusal to finance MT.

HTA recommendations and reports have been found to be non-binding in 80 % of cases. However, any MT acquires a certain status based on the results of the assessment (for example, receives a marketing permit, recommendations for inclusion in the regulatory list or reimbursement system).

Differences in HTA methodology, as well as differences in HCS priorities and national income levels create certain limitations in the application of HTA results. This determines the importance of developing and implementing national programs with HTA, taking into account all the fundamental points.

Most countries at different stages of the HTA process involve a certain number of interested parties: scientists, manufacturers, medical and pharmacy workers and patients, who will influence the selection of priority problems regarding HTA, the development of relevant recommendations, and will also participate in a transparent discussion of the obtained results. A higher level of involvement of participants in the HTA process will contribute to better quality assessments and fuller implementation of the recommendations developed because of the HTA.

According to the results of the analysis, most institutions with HTA have a national scale (70 %), are independent (74 %), play an advisory role (54 %), evaluate mainly or exclusively drugs (78 %), evaluate MT based on their clinical and economic effectiveness (73 %) and involve various stakeholders as committee members with HTA (94 %) and/

or through external consultations (76 %). The majority of HTA results do not have binding legal force (80 %) [6].

In many countries, HTA recommendations have an impact on insurance coverage decisions, and HTA is sometimes used to a limited extent to inform decisions about the feasibility of including MT in reimbursement lists.

In general, HTA is seen in most countries as a transparent tool for creating an evidence base that is used by many stakeholders, including in other countries. But given the high cost and labor-intensiveness of HTA procedures, it is important to pay due attention to the selection of MT for assessment and their prioritization. Industry representatives, patients, and the public may be involved in this process. Therefore, the degree of "openness" of the HTA system can also be one of the criteria for typology.

Thus, all the above, taking into account the implementation of modern principles of public management, made it possible to develop a typological model of the HTA management system, which includes four types of such systems (Table 6).

Table 5

Peculiarities of HTA organization in different countries

Characteristics		Number of countries	Names of countries
The number of FTE in the HTA body	1–5	3	Bulgaria, Latvia, Romania
	6–20	12	Belgium, Cyprus, Greece, Hungary, India, Ireland, Japan, Serbia, Slovakia, Switzerland, Ukraine, UAE
	21–50	6	Brazil, Czech Republic, Italy, Malaysia, Norway, Portugal
	51–100	3	France, Morocco, Spain
	More than 100	7	Canada, China, Germany, Netherlands, Republic of Korea, Sweden, Great Britain
HTA funding sources	Budget financing	28	All analyzed countries except Canada, Cyprus, Portugal, Romania, Serbia, Ukraine
	Private	6	Czech Republic, Germany, Italy, Latvia, Morocco, Great Britain
Possibility of appeal of HTA (body and procedure)		8	Cyprus, India, Latvia, Netherlands, Portugal, Korea, Slovakia, UAE
Separate body that conducts examination and provides recommendations		19	Canada, Cyprus, Hungary, India, Ireland, Italy, Japan, Latvia, Malaysia, Netherlands, Norway, Portugal, Republic of Korea, Serbia, Slovakia, Spain, Switzerland, Ukraine, UAE

Table 6

Scientific and practical substantiation of the typological model of HTA management based on typological analysis

–	Type 1 Launching	Type 2 Centralized	Type 3 Decentralized	Type 4 Balanced
Special body with HTA	Absent, HTA is carried out by various bodies and organizations	Included in the structure of the Ministry of Health, regulators (non-independent)	Several bodies responsible for different areas	Independent body accountable to government (or network of regional agencies)
Directions for using HTA	Limited to individual cases	Use for procurement, pricing, reimbursement	Use in various areas (budgeting, clinical guidelines, etc.)	HTA is included in the decision-making process in HCS in many areas
Coordination of HTA efforts (centralization)	Low or no coordination	Centralization of all functions in one body	Decentralization, distribution of functions by bodies and levels of management	Appropriate level of centralization, achieving balance
Normative framework, guidelines	Absent	The use of mainly international norms	Fragmented, adaptation of international norms	Clear and understandable regulatory framework
Personnel potential	Missing / low	There is not enough personnel with proper qualifications, the involvement of experts from various fields	System of training and advanced training of personnel is being formed	High, a system of training, evaluation and professional development of personnel
Use of evidence, reports	The use of available evidence by individual health care facilities, institutions without proper justification, prioritization, and a clear methodology	Adaptation to national conditions, the methodology is inconsistent	Expert assessment, developed own methodology of economic assessment	Expert evaluation based on our own economic evaluation methodology, approved efficiency thresholds, generation of evidence
Implementation (mandatory recommendations)	Use of HTA is optional	Recommended in certain cases	Recommended in many cases	Mandatory application at different levels of management
Openness, transparency	Publication of reports is optional, limited stakeholder participation	Publication of reports is not mandatory, stakeholders are limited in the discussion	Publication of reports is mandatory, stakeholders participate in evaluation and discussion	Publication of results is mandatory, stakeholders can initiate HTA and participate in evaluation, discussion, expertise, etc.

Of course, the manifestation of certain traits can be more or less pronounced, so, accordingly, certain subtypes can be distinguished. So, we can talk about a more stable "starter" model (type 1) and "balanced" (type 4). At the same time, under the conditions of dynamic changes, intermediate (transitive) options may change slightly depending on the situation.

Thus, our systematic study of key HTA processes in international practice made it possible to establish that the construction of the organizational structure of the HTA system is carried out mainly at the national level, except for countries with decentralized HCS (Italy, Spain, Great Britain, Sweden), which is due to the peculiarities of the state system and structure of the system itself. In countries where HTA activities are carried out at both national and regional levels, assessing the clinical benefit of a single MT may imply duplication of functions.

That is why various forms of cooperation in the field of HTA and horizon scanning are encouraged at the EU level, the Regulation on HTA has been implemented, which is aimed at simplifying the procedure for conducting HTA, unifying the methodology and optimizing costs for HCS. Institutions conducting HTA at the national level are mostly independent of the competent authorities with which they cooperate (Ministry of Health, health insurance organizations, pricing committees), although their activities are generally accountable to these authorities. In our opinion, HTA bodies that work "at arm's length" have a place in more developed HTA systems and provide an appropriate level of transparency and independence. The less developed HTA systems (in Greece, Cyprus and Malta) are often integrated into the competent authorities, which in itself implies a certain limitation of independence, impartiality and transparency, since the assessments are internal and the recommendations are not published in public, making the decision-making processes and negotiations opaque. At the same time, the integrated functions of the HTA system can be used as a starting point in the implementation of HTA activities, especially under conditions of insufficient potential for the creation of an independent body with HTA, in particular in Ukraine. As a rule, most independent bodies publish their HTA reports and results in public, while integrated ones keep them confidential [16].

5. Discussion of research results

The need for a more unified environment for the development of the scientific and practical direction of HTA has been recognized over the last decade as a global problem not only in Europe, but also at the international level. The methodologies and processes used to conduct HTA can vary from country to country and even between regions, especially where decision-making is decentralized (e.g. Italy and Spain).

One of the most innovative scientific and practical results of the European association EUnetHTA was the development of a basic model of HTA, which defines the structure and key content necessary for conducting HTA to support the exchange of information between specialized agencies [22]. The basic HTA model was designed to provide information exchange in a common format that can be transferred between members at national and international levels, and the 9 domains can be divided into two groups: technical (health issues, technology description, safety, clinical and cost-effectiveness), others.

Along with this, there is also a recognized need for an objective description and classification of HTA systems at both European and international levels. Allen and colleagues developed and described two new non-ranking taxonomies for classifying agencies performing HTA [23, 24].

The 67th session of the World Health Assembly recognized the importance of European and international cooperation in the field of HTA and «urges Member States: to consider also collaborating with other Member States' health organizations, academic institutions, professional associations and other key stakeholders in the country or region in order to collect and share information and lessons» [25].

A study (Allen et al. 2017) evaluated 9 European reimbursement systems by assessing HTA processes and relationships between regulatory authorities and decision-making organizations. Each national HTA agency was classified according to the two new taxonomies [26]. The taxonomy, as a typology tool, was described by the authors from the positions of the HTA agency in the national reimbursement system according to the relationship between the regulator, the HTA agency, and the reimbursement decision-making body [27].

Practical significance. Typological analysis and construction of a typological model is an extremely important stage of substantiating the further development of the scientific and practical direction of HTA in Ukraine, in particular, the improvement of public management in this area, taking into account the existing potential, institutional capacity and features of the management system of health care and pharmacy.

Study limitations. The number of HTA agencies/organizations selected for comparison was limited due to the varying depth of information published online, and the included agencies are homogeneous in terms of their economic development.

Prospects for further research. Applied aspects of the use of typological modelling using the proposed typological model to improve the HTA management system, primarily at the national level for countries that are at the starting and centralized levels, in particular the development of such a system in Ukraine, can become a promising direction of research.

6. Conclusions

It was established that, on the one hand, the current models of HTA in different countries have differences regarding their role in the decision-making process in HCS, and on the other hand, there is an urgent need to create a common HTA environment not only at the national, but also at the international level in order to effectively use of resources, in particular information, and avoidance of duplication of research. In this sense, typological analysis allows to organize, group and highlight classification features, as well as conduct typological modelling of HTA systems.

This approach made it possible to conduct a typology of HTA management systems operating in more than 80 countries of the world, namely: an institutional analysis of the status of HTA in national HCSs. For this, an analysis of the institutional capacity of HTA management systems was carried out (availability of a special authorized body, level of centralization/decentralization, financing features, availability of a regulatory framework and personnel potential). The functionality and areas of activity of HTA bodies (organizations), the level of their accountability, openness and interaction with various interested parties were also analyzed. Based on the results of the study, a typological model was proposed, which provides for the selection of four types of HTA management systems (start-up, centralized, decentralized, balanced).

Conflict of interests

The authors declare that they have no conflict of interest in relation to this research, including financial, personal, authorship or other nature, which could affect the research, and its results presented in this article.

Funding

The study was performed without financial support.

Data availability

Data will be provided upon reasonable request.

Use of artificial intelligence

The authors confirm that they did not use artificial intelligence technologies when creating the presented work.

References

1. Tutuk, V., Nazarkina, V., Babenko, M., Nemchenko, A., Zhakipbekov, K. (2023). Assessment of medical technologies in the formation of government programs to assist patients with rare metabolic diseases. ScienceRise: Pharmaceutical Science, 5 (45), 99–108. https://doi.org/10.15587/2519-4852.2023.290218

2. Fontrier, A.-M., Visintin, E., Kanavos, P. (2021). Similarities and Differences in Health Technology Assessment Systems and Implications for Coverage Decisions: Evidence from 32 Countries. PharmacoEconomics – Open, 6 (3), 315–328. https://doi.org/10.1007/s41669-021-00311-5

3. Global survey on health technology assessment by national authorities (2015). WHO. Available at: https://www.who.int/publications/i/item/9789241509749

4. Akehurst, R. L., Abadie, E., Renaudin, N., Sarkozy, F. (2017). Variation in Health Technology Assessment and Reimbursement Processes in Europe. Value in Health, 20 (1), 67–76. https://doi.org/10.1016/j.jval.2016.08.725

5. Schuster, V. (2024). EU HTA Regulation and Joint Clinical Assessment – Threat or Opportunity? Journal of Market Access & Health Policy, 12 (2), 100–104. https://doi.org/10.3390/jmahp12020008

6. Health Technology Assessment and Health Benefit Package Survey 2020/2021. Available at: https://www.who.int/teams/health-systems-governance-and-financing/economic-analysis/health-technology-assessment-and-benefit-package-design/survey-homepage

7. Heryliv, D. Yu. (2013). Differentiation of typology and classification of state: problematic issues. Naukovyi visnyk Uzhhorodskoho natsionalnoho universytetu. Seriia Pravo, 22 (1), 19–23.

8. Nastasyak, I. (2015). Relationship of concept «typologization» with related concepts. Visnyk of the Lviv University. Series Law, 61, 37–44. Available at: http://nbuv.gov.ua/UJRN/Vlnu_yu_2015_61_8

9. Reibling, N., Ariaans, M., Wendt, C. (2019). Worlds of Healthcare: A Healthcare System Typology of OECD Countries. Health Policy, 123 (7), 611–620. https://doi.org/10.1016/j.healthpol.2019.05.001

10. Wendt, C.; Levy, A., Goring, S., Gatsonis, C., Sobolev, B., van Ginneke,n E., Busse, R. (Eds.) (2019). Health System Typologies. Health Services Research. New York: Springer, 927–937. https://doi.org/10.1007/978-1-4939-8715-3_21

11. Wendt, C.; van Ginneken, E., Busse, R. (Eds.) (2018). Health System Typologies. Health Care Systems and Policies. Health Services Research. New York: Springer. https://doi.org/10.1007/978-1-4614-6419-8_21-1

12. Burau, V., Blank, R. H., Pavolini, E.; Kuhlmann, E., Blank, R. H., Bourgeault, I. L., Wendt, C. (Eds.) (2015). Typologies of Healthcare Systems and Policies. The Palgrave International Handbook of Healthcare Policy and Governance. London: Palgrave Macmillan, 101–115. https://doi.org/10.1057/9781137384935_7

13. de Carvalho, G., Schmid, A., Fischer, J. (2020). Classifications of health care systems: Do existing typologies reflect the particularities of the Global South? Global Social Policy, 21 (2), 278–300. https://doi.org/10.1177/1468018120969315

14. Khomenko, V. M., Nemchenko, A. S., Kosiachenko, K. L. (2007). Typolohiia derzhavno-upravlinskykh vidnosyn u farmatsii: pytannia teorii ta praktyka. Farmatsevtychnyi zhurnal, 4, 3–9.

15. Evans, T. G., Ahmed, S. M.; Raviglione, M. C. B., Tediosi, F., Villa, S., Casamitjana, N., Plasència, A. (Eds.) (2023). Governance of Health Systems. Global Health Essentials. Sustainable Development Goals Series. Springer: Cham, 285–289. https://doi.org/10.1007/978-3-031-33851-9_43

16. Angelis, A., Lange, A., Kanavos, P. (2017). Using health technology assessment to assess the value of new medicines: results of a systematic review and expert consultation across eight European countries. The European Journal of Health Economics, 19 (1), 123–152. https://doi.org/10.1007/s10198-017-0871-0

17. Chamova, J. (2018). Mapping of HTA national organisations, programmes & processes in EU & Norway. EC, Directorate. General for Health & Food Safety, Publ. Office. https://doi.org/10.2875/5065

18. Kristensen, F. B. (2017). Mapping of HTA methodologies in EU and Norway. EC, Directorate-General for Health and Food Safety, Publ. Office. https://doi.org/10.2875/472312

19. Health Technology Assessment (HTA) in the Nordic countries. Introduction to and Status of HTA's Role in the Value Chain of Medical Technology (2017). Nordic Medtech Growth, 48.

20. Nazarkina, V. M., Nemchenko, A. S., Kosiachenko, K. L., Babenko, M. M.; Nemchenko, A. S. (Ed.) (2022). Metodolohiia tsinoutvorennia na likarski zasoby v systemi okhorony zdorovia. Kyiv: Farmatsevt Praktyk, 288.

21. Nemzoff, C., Shah, H. A., Heupink, L. F., Regan, L., Ghosh, S., Pincombe, M. et al. (2023). Adaptive Health Technology Assessment: A Scoping Review of Methods. Value in Health, 26 (10), 1549–1557. https://doi.org/10.1016/j.jval.2023.05.017

22. Kristensen, F. B. (2012). Development of European HTA: from vision to EUnetHTA. Michael, 9, 147–156. Available at: http://www.dnms.no/index.php?seks_id=149347&a=1

23. Henshall, C. (2012). Describe decision-making systems, assess health technology assessment reports. International Journal of Technology Assessment in Health Care, 28 (2), 168. https://doi.org/10.1017/s0266462312000177

24. Allen, N., Pichler, F., Wang, T., Patel, S., Salek, S. (2013). Development of archetypes for non-ranking classification and comparison of European National Health Technology Assessment systems. Health Policy, 113 (3), 305–312. https://doi.org/10.1016/j.healthpol.2013.09.007

25. WHA67.23 – Health Intervention and Technology Assessment in Support of Universal Health Coverage. WHA Resolution; Sixty-seventh World Health Assembly (2014). World Health Organization. Available at: http://apps.who.int/medicinedocs/documents/s21463en/s21463en.pdf

26. Allen, N., Liberti, L., Walker, S. R., Salek, S. (2017). A Comparison of Reimbursement Recommendations by European HTA Agencies: Is There Opportunity for Further Alignment? Frontiers in Pharmacology, 8. https://doi.org/10.3389/fphar.2017.00384

27. Kristensen, F. B., Nielsen, C. P., Panteli, D.; Busse, R., Klazinga, N., Panteli, D. et al. (Ed.) (2019). Regulating the input – Health Technology Assessment. Improving healthcare quality in Europe: Characteristics, effectiveness and implementation of different strategies. Copenhagen: European Observatory on Health Systems and Policies. (Health Policy Series No. 53). Available at: https://www.ncbi.nlm.nih.gov/books/NBK549272/

Received date 12.08.2024
Accepted date 01.10.2024
Published date 07.10.2024

Mykhailo Babenko*, PhD, Associate Professor, Department of Organization and Economy of Pharmacy, Bogomolets National Medical University, Tarasa Shevchenka blvd., 13, Kyiv, Ukraine, 01601, Director, State Enterprise «State Expert Center of the Ministry of Health of Ukraine», Antona Tsedika str., 14, Kyiv, Ukraine, 03057

Kostyantyn Kosyachenko, Doctor of Pharmaceutical Sciences, Professor, Head of Department, Department of Organization and Economics of Pharmacy, Bogomolets National Medical University, Tarasa Shevchenka blvd., 13, Kyiv, Ukraine, 01601

***Corresponding author:** Mykhailo Babenko, e-mail: babenko@nmu.ua*