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IMPLEMENTATION OF THE MANAGED ENTRY AGREEMENT FRAMEWORK IN UKRAINE: A NATIONAL ANALYSIS OF THE PATHWAY FROM HEALTH TECHNOLOGY ASSESSMENT TO CONCLUDED AGREEMENTS

Iryna Kostiuk, Zhanna Polova, Kostyantyn Kosyachenko, Dmytro Savchenko

The aim: *to conduct a comprehensive analysis of the implementation of the Managed Entry Agreement (MEA) framework in the public procurement of medicines in Ukraine and to identify the main trends in its development.*
Materials and methods: *a retrospective descriptive study was conducted using official, publicly available national data from the Medical Procurement of Ukraine and the State Expert Center of the Ministry of Health of Ukraine. During the study, a unified database was created that includes medicines under consideration for MEAs as of July 2026. The analysis covered 58 indications corresponding to 48 international non-proprietary names. Methods of content analysis, classification, structural analysis, comparative analysis and summarizing analysis were applied. Data analysis was conducted using descriptive statistics.*
Results*: oncology accounted for the largest share of indications considered for MEAs (31; 53.4%), followed by immunological and other systemic diseases (17; 29.3%) and rare and genetic diseases (10; 17.2%). All included medicines underwent the national Health Technology Assessment (HTA) procedure and received approval to begin negotiations. As of July 2026, MEAs had been signed for 23 indications (39.7%), a negative decision had been recorded for 1 indication (1.7%), and no final decision on conducting an MEA had been recorded for 34 indications (58.6%). Roche had the largest therapeutic portfolio (13 indications), while Takeda and Pfizer were represented in all three therapeutic areas. The number of national HTA recommendations supporting MEA consideration increased from 6 in 2021 to 21 in 2025, indicating a gradual expansion of the MEA framework in Ukraine.*
Conclusions*: the MEA framework is gradually being integrated into the mechanism for public financing of high-cost innovative medicines in Ukraine. National HTA is a key prerequisite for selecting medicines subject to the MEA. For 34 indications (58.6%), no final decision on conducting an MEA had been recorded as of July 2026. The findings provide the first systematic data on the implementation of the Ukrainian MEA framework and may contribute to the further optimization of negotiation procedures, policy development, and improved patient access to innovative medicines*
Keywords*: managed entry agreements, health technology assessment, innovative medicines, public procurement, pharmaceutical policy, access to medicines, reimbursement, negotiation process, pharmaceutical companies, Ukraine*

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1. Introduction

Patient accessibility to expensive innovative medicines remains one of the pressing issues in health care financing. Under martial law, this issue has become even more critical, as it's necessary to ensure an uninterrupted supply of medicines, adapt existing financing mechanisms and seek new ways to make innovative treatments more accessible to patients [1]. Decisions regarding government funding for innovative medicines are often made under conditions of uncertainty. At the time these medicines enter the market, there may be insufficient data on their long-term efficacy and safety. At the same time, the high cost of such drugs can significantly increase healthcare system expenditures. Therefore, when making decisions, it's important to consider both the state's financial capacity and patients' need for timely access to modern treatments [2]. To solve this problem, approaches that reduce financial risks and account for uncertainly regarding treatment outcomes are increasingly being considered. In particular, mechanisms for reimbursing the cost of drugs are being developed that involve risk-sharing between the government and pharmaceutical manufacturers [3, 4].

Managed Entry Agreements (MEA) have become one of the most common tools for addressing this issue. These agreements provide for risk-sharing mechanisms based on financial indicators or performance outcomes and are designed to facilitate patient access to innovative medicines while eliminating uncertainly regarding their clinical and economic value [3, 5]. Experience in European Union countries shows that MEAs are most commonly applied to oncology, orphan, and other high-cost medicines; however, their implementation varies significantly depending on the organization of national health care systems, health technology assessment (HTA) procedures, negotiation processes, and mechanisms for monitoring the implementation of concluded agreements [4, 6, 7]. Risk-sharing agreements are increasingly viewed as a logical extension of the HTA process, as HTA provides the evidence necessary to charac-

terize uncertainty, assess the clinical and economic value of new medicines, and determine the appropriateness of specific risk-sharing arrangements [2, 5, 8].

Ukraine is among the countries that have integrated MEAs into their public financing system for medicines in recent years [9–11]. The introduction of national HTA, amendments to legislation allowing for the use of MEAs [12, 13], and the establishment of official negotiation procedures have created a new framework for decision-making regarding the public procurement of expensive innovative medicines [14–16]. At the same time, the availability of open data from the State Expert Center of the Ministry of Health of Ukraine and the Medical Procurement of Ukraine has made it possible to assess the practical implementation of this system [17, 18]. However, most Ukrainian studies have focused on the legal and regulatory aspects of MEAs, international experience, or the conceptual development of the national HTA system, while comprehensive studies of the practical implementation of the MEA framework remain limited [9, 10, 15, 16, 19, 20].

Despite the active implementation of MEAs in Ukraine, no comprehensive study has yet been conducted to analyze the relationship between HTA findings, the negotiation process, concluded agreements, the therapeutic profile of medicines, and trends over time in the implementation of the MEA framework. Such as analyses allows us to move beyond an examination of the regulatory framework to an assessment of its practical implementation and provides insight into how MEA functions as a tool for translating HTA recommendations into decisions regarding public funding for innovative medicines.

The aim of this study was to analyze the implementation of MEAs in the field of public procurement of medicines in Ukraine and to identify the key trends in the development of this system.

2. Research planning (methodology)

This retrospective descriptive study was designed to evaluate the implementation of the MEA framework in Ukraine. The study methodology involved the development of a database of medicines for which, as of July 2026, the possibility of concluding an MEA was being considered, followed by a descriptive analysis. The general study design is presented in Fig. 1.

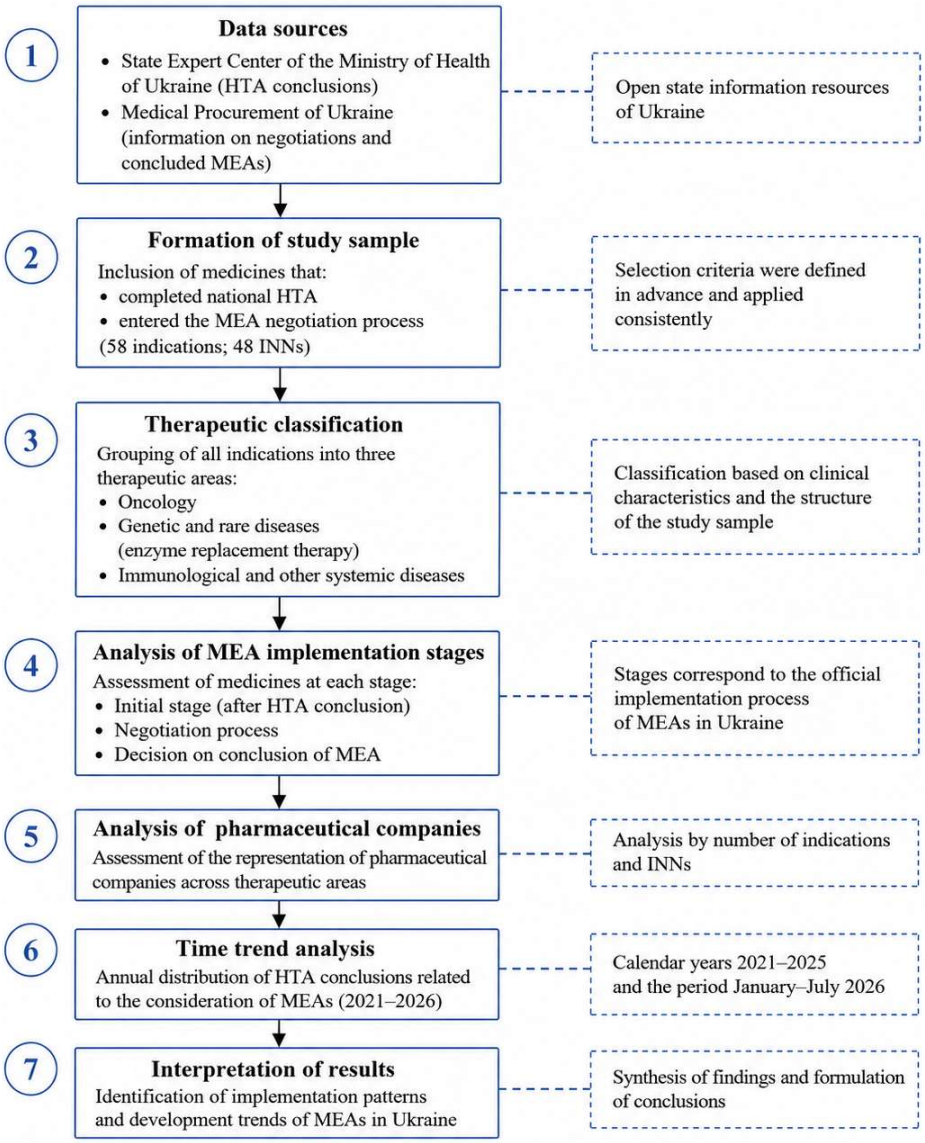


Fig. 1. Methodological framework of the study

In the first stage, the study cohort was formed by comparing the results of the national HTA with publicly available information on the implementation of the MEA framework. Medicines met the inclusion criteria if the national HTA had been completed and an official decision had been made authorizing negotiations to conclude a MEA.

In the second stage, a structural analysis of the study cohort was conducted. Medicines were classified according to their international non-proprietary names (INNs), approved indications, and therapeutic areas. To facilitate data interpretation, all indications were grouped into 3 therapeutic categories: oncology; rare and genetic diseases (enzyme replacement therapy); and immunological and other systemic diseases.

In the third stage the progression of medicines through the principal stages of the MEA framework was analyzed, from completion of the national HTA to the final decision regarding the conclusion of an MEA. In addition, the distribution of pharmaceutical companies by therapeutic area was examined, and temporal trends in the implementation of the MEA framework were analyzed based on the year in which national HTA conclusions were published.

3. Materials and methods

The study was based on officially available data from two national sources in Ukraine: the dashboard of the Medical Procurement of Ukraine, which provides information on the implementation of the MEA framework, and national HTA recommendations published on the official website of the State Expert Center of the Ministry of Health of Ukraine. By integrating data from these sources, a unified database was established comprising medicines for which the conclusion of the MEA had been considered as of July 2026.

The initial list of medicines considered for MEAs was obtained from the Medical Procurement of Ukraine dashboard. This list was subsequently supplemented with information on the assessed indications, assessment dates, and HTA procedures from the corresponding national HTA conclusions published on the State Expert Center website. Records from the two sources were matched by INN and the indication assessed in the corresponding national HTA conclusion.

The study sample included medicines that had completed the national HTA process and had subsequently been considered for the conclusion of an MEA. In total, 58 indications corresponding to 48 INNs were included in the analysis. Different indications for the same INN were counted as separate records, whereas each INN was counted once when calculating the overall number of unique INNs. Procedural statuses were extracted from the negotiation-status column, whereas decision outcomes were determined from the columns reporting the working group's decision on concluding an MEA and the agreement-signing status. These variables were analyzed separately because they describe different aspects of the procedure (the reported negotiation status and the outcome of the decision-making process). Indications with no recorded authorization to conclude an MEA, negative decision, or signed agreement were classified as having no recorded final decision.

The study employed general scientific and specialized research methods. Content analysis was used to collect and process information from official open sources, which allowed us to systemize and generalize the obtained data. Classification methods were applied to categorize medicines by therapeutic areas, stages of the MEA framework, and pharmaceutical companies. Structural analysis made it possible to determine the distribution of medicines across the selected categories. Comparative analysis was used to compare the representation of pharmaceutical companies across different therapeutic areas, as well as to study the distribution of medicines across the stages of the MEA framework. The generalization method was applied to interpret the results and identify the main trends in the development of the MEA framework in Ukraine. Statistical data analysis was performed using descriptive statistics. For categorical variables, absolute frequencies and percentages were determined. The results are presented in tables and figures.

4. Results

The first stage of the analysis examined the distribution of medicines for which the conclusion of MEAs had been considered in Ukraine. To facilitate interpretation of the findings, all indications included in the study were classified into therapeutic areas. Based on the clinical characteristics of the underlying diseases, three therapeutic categories were identified: oncology; rare and genetic diseases (enzyme replacement therapy); and immunological and other systemic diseases. The distribution of indications across these therapeutic categories is presented in Table 1.

As shown in Table 1, oncology medicines accounted for the largest proportion of medicines considered for inclusion in the MEA framework, comprising 31 indications (53.4%) corresponding to 25 INNs. This finding is consistent with international practice, where MEAs are most applied to innovative anticancer medicines because of their high treatment costs and substantial clinical uncertainty [7].

Table 1

Distribution of medicines in the MEA framework in Ukraine by therapeutic area

Therapeutic area	Number of INNs	Number of indications	Share of total indications, %
Oncology	25	31	53.4
Rare and genetic diseases (enzyme replacement therapy)	10	10	17.2
Immunological and other systemic diseases	14	17	29.3
Total	48*	58	100.0

Note: Each INN was counted once within each therapeutic category, regardless of the number of indications. Lanreotide was included in two categories for different indications. Therefore, the category-specific counts sum to 49, whereas the overall total comprises 48 unique INNs.

The second largest group comprised medicines for immunological and other systemic diseases, accounting for 17 indications (29.3%). These medicines covered a broad range of severe chronic conditions requiring long-term, high-cost treatment. Rare and genetic diseases, represented predominantly by enzyme replacement therapies, accounted for 10 indications (17.2%). Overall, these findings indicate that the MEA framework in Ukraine is primarily focused on improving access to innovative medicines in therapeutic areas associated with the greatest clinical and economic burden on the healthcare system.

The next stage of the analysis examined the procedural status and outcomes of decisions reported through the MEA system in Ukraine. All 58 indications included in the study underwent a national HTA and received approval to begin negotiations. Table 2 presents information on the procedures and outcomes of decisions in two separate sections.

Table 2

Distribution of indications across the stages of the MEA framework in Ukraine

Procedural status or decision outcome	Number of indications	Share, %
A. Reported procedural status		
Proposal submitted to the working group	24	41.4
Invitation to negotiations issued	1	1.7
Negotiations not initiated	10	17.2
Negotiations ongoing	17	29.3
Negotiations completed	4	6.9
Request submitted to the Ministry of Health to clarify procurement volumes	2	3.4
B. Decision outcomes		
MEA signed	23	39.7
No authorization granted to conclude an MEA (negative decision)	1	1.7
No final decision on concluding an MEA recorded	34	58.6
Total for decision outcomes	58	100.0

Note: sections A and B describe different dimensions of the procedure and should not be added together.

As shown in Table 2, all 58 indications included in the study received approval to begin negotiations after undergoing a national HTA. The largest share (41.4%) concerned proposals submitted to the working group, while 29.3% were reported as undergoing negotiations. These categories were considered separately and were not combined to estimate the proportion of indications awaiting a final decision. Negotiations were reported as completed for 6.9% of indications. While in 17.2% of cases they had not yet begun. For 2 indications (3.4%), requests had been submitted to clarify procurement volumes, and an invitation to negotiations had been issued for 1 indication (1.7%). These procedural statuses were distinguished from decision outcomes: as of July 2026, MEAs had been signed for 23 indications (39.7%), a negative decision had been recorded for 1 indication (1.7%), and no final decision on concluding an MEA recorded for 34 indications (58.6%). Among the 23 indications for which MEAs had been signed, the negotiation-status field showed «negotiations completed» for 4 and «proposal submitted to the working group» for 19. The number of signed MEAs was therefore determined from the agreement-signing field, separately from the reported negotiation status.

The next stage of the analysis examined the distribution of pharmaceutical companies participating in the MEA program by therapeutic area. All indications included in the study were classified according to the manufacturing pharmaceutical company and the three predefined therapeutic categories. Different legal entities belonging to the same corporate group were grouped under the name of a single company. The results are presented in Table 3.

Table 3

Distribution of indications included in the MEA framework in Ukraine by pharmaceutical company and therapeutic area

Pharmaceutical company	Oncology	Rare and genetic diseases (enzyme replacement therapy)	Immunological and other systemic diseases	Total
Roche	7	0	6	13
Takeda	3	3	2	8
AstraZeneca	5	0	0	5
MSD	3	0	2	5
Pfizer	3	1	1	5
Novartis	3	0	1	4
Sanofi	0	4	0	4
Ipsen	2	0	1	3
Astellas	2	0	0	2
BioMarin	0	2	0	2
Other companies	3	0	4	7
Total	31	10	17	58

The analysis demonstrated substantial variation in the representation of pharmaceutical companies across therapeutic areas within the MEA framework. Roche had the largest portfolio, with 13 indications distributed across oncology and immunological diseases. Takeda ranked second with eight indications. Both Takeda and Pfizer were represented in all three therapeutic areas, reflecting the most diversified portfolio among the manufacturers included in the study. In contrast, AstraZeneca, Astellas, Sanofi, and BioMarin were represented in only a single therapeutic area, indicating a more specialized portfolio.

Comparison across therapeutic areas revealed different levels of market concentration. Oncology involved the largest number of participating companies: however, 24 of 31 indications (77.4%) were accounted for by only six manufacturers (Roche, Takeda, AstraZeneca, MSD, Pfizer, and Novartis). In contrast, all indications for rare and genetic diseases were represented by only four companies (Takeda, Sanofi, BioMarin, and Pfizer), with Takeda and Sanofi together accounting for 70.0% of indications in this category. In the immunology and other

systemic disease category, Roche accounted for 6 of 17 indications (35.3%), followed by Takeda and MSD with 2 indications each (11.8% each). These figures describe the distribution of indications within the study cohort rather than market concentration.

To assess the evolution of the MEA framework in Ukraine, the distribution of national HTA recommendations was analyzed according to the year in which they were issued (Fig. 2). This temporal analysis illustrates the development of the MEA framework between 2021 and 2026 and reflects changes in the number of national HTA recommendations that served as the basis for considering the conclusion of MEAs.

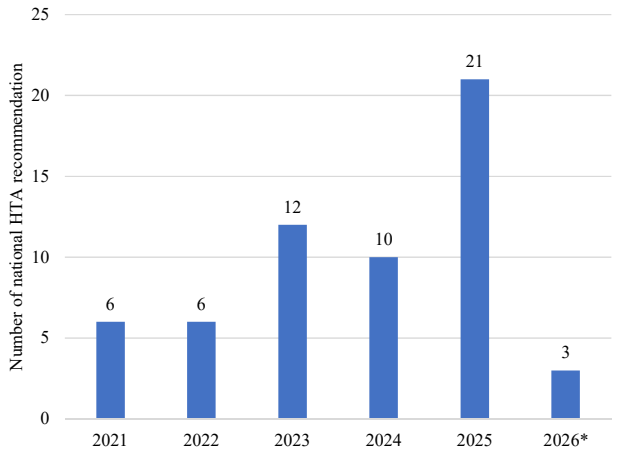


Fig. 2. Distribution of national HTA recommendations supporting consideration of MEAs in Ukraine, by year (2021–2026): * – data as of July 2026

As shown in Fig. 2, the number of national HTA recommendations supporting consideration of MEAs remained stable in 2021 and 2022, with six recommendations issued each year. From 2023 onwards, a clear upward trend was observed, suggesting a transition of the MEA framework from its initial implementation phase towards more systemic use within the public procurement of medicines. Although the number of recommendations declined slightly to 10 in 2024, the overall upward trend continued, reaching a peak of 21 recommendations in 2025. This pattern may reflect not only the expanding use of MEAs but also the increasing role of national HTA as a key component of decision-making for the public procurement of high-cost innovative medicines. As of July 2026, only three medicines had completed the national HTA process; therefore, the data for 2026 are not directly comparable with those of previous years.

Overall, the findings demonstrate the gradual expansion of the MEA framework in Ukraine between 2021 and 2026. Its application has been concentrated primarily in oncology, as well as in the treatment of immunological, systemic, rare, and genetic diseases. However, by July 2026, final decisions had been reached for fewer than half of the included indications: 23 resulted in signed MEAs, 1 received a negative decision, while 34 indications remained under consideration. The distribution of pharmaceutical companies reflected a combination of broad therapeutic portfolios among several manufacturers and a high degree of specialization among others within specific therapeutic areas.

5. Discussion

To our knowledge, this is the first comprehensive study dedicated to the implementation of the MEA framework in Ukraine. The study analyzes the medicines considered under this mechanism, their therapeutic areas, the stages of the procedure, and the involvement of pharmaceutical companies. It also examines changes in HTA recommendations over time. The results show that MEA is gradually becoming part of the system for public financing of expensive innovative medicines. At the same time, this mechanism is still in the implementation phase in Ukraine.

Most of the indications included in the study related to oncology – 31 out of 58, or 53.4%. This is consistent with findings from other countries, where MEAs are often applies to expensive oncology medicines. [7] documented their use across European countries, highlighting differences in agreement types and their application to different indications. Ferrario et al. [6] identified oncology and diabetes as prominent therapeutic areas for MEAs in Central and Eastern Europe. However, direct numerical comparisons are limited by differences in study populations and observation periods. In our study, 46.6% of the indications related to other diseases, including immunological, systemic, rare and genetic conditions. This indicates that the Ukrainian MEA framework covers several therapeutic areas in which patients require expensive innovative treatments.

All 58 indications included in the study completed the national HTA process and received approval to begin negotiations. This demonstrates the important role of HTA within the mechanism under consideration. Ferrario and Kanavos [3] also described the relationship between assessment, uncertainty management, and agreement implementation, while identifying significant differences in management systems and agreement types across countries. Their findings provide an international context for the Ukrainian algorithm, although this study did not assess whether specific HTA outcomes influenced the results of the negotiations.

As of July 2026, MEAs had been signed for 23 of the 58 indications (39.7%), and a negative decision had been recorded for 1 indication (1.7%). For the remaining 34 indications (58.6%), no final decision on concluding an MEA had been recorded in the publicly available data. Ferrario et al. [6] identified administrative requirements and the resources needed to implement and review conditions as current challenges in Central and Eastern Europe. These observations confirm the need for further study of organizational aspects in Ukraine. However, this study did not analyze the duration of individual procedures or the reasons for unresolved cases. Further research should determine which factors influence the duration of negotiations and how this process can be improved.

An analysis of pharmaceutical companies showed that their presence in various therapeutic areas varies.

Roche had the largest number of indications (13), while Takeda and Pfizer were represented in all three therapeutic areas. At the same time, medicines for the treatment of rare or genetic diseases were concentrated in the portfolios of a relatively small number of manufacturers. This may be explained by the specific characteristics of the orphan medicine market. The results indicate that companies' specializations and the composition of their portfolios can influence negotiation strategies, the level of competition, and the feasibility of applying various MEA models.

The number of national recommendations to consider entering into MEAs increased from 6 in 2021 to 21 in 2025. This indicates the gradual spread of this mechanism in Ukraine. These findings support the need for systematic monitoring of MEA procedures and agreement outcomes, including further assessment of negotiation duration.

Practical significance. The results of the study provide the first systematic overview of the implementation of the MEA mechanism in Ukraine based on open national data. They can be used by the Ministry of Health of Ukraine, the Medical Procurement of Ukraine, and other stakeholders involved in this process. The findings will help assess the current status of the mechanism′s implementation, identify the stages where the greatest delays occur, and improve the negotiation process. In addition, the results can be used when planning the procurement of innovative medicines, improving the regulatory framework for MEA, and developing indicators to evaluate the implementation of concluded agreements and the outcomes of their application.

Study limitation. This study was based on publicly available data from «Medical Procurements of Ukraine» and the State Expert Center of the Ministry of Health of Ukraine. Therefore, the comprehensiveness of the analysis depended on the volume and level of detail of the published information. These data did not allow for an assessment of the confidential financial terms of the contracts, budget savings, clinical outcomes. The results reflect the status of the MEA mechanism's implementation as of July 2026. Data for the incomplete year of 2026 are not directly comparable to data from previous full years.

Prospects for further research. Future research should focus on determining the duration of individual stages of the MEA procedure, examining the factors that influence the successful completion of negotiations, and evaluating the clinical, economic, and budgetary outcomes of concluded agreements. It's also important to compare Ukraine's MEA mechanism with the approaches used in European Union countries to determine the potential for applying their experience in Ukraine. Particular attention should be paid to evaluating the effectiveness of various MEA models and developing a system of indicators to monitor their implementation and determine their impact on patients' access to innovative medicines.

6. Conclusions

1. This study is the first comprehensive analysis of the implementation of the MEA framework in Ukraine, based on data from national HTA and the subsequent negotiation process. The analysis covered 58 indications corresponding to 48 INNs. Most indications were in oncology (31; 53.4%), followed by immunological and other systemic diseases (17; 29.3%) and rare and genetic diseases (10; 17.2%).

2. All 58 indications included in the study had completed national HTA and received authorization to initiate negotiations. As of July 2026, MEAs had been signed for 23 indications (39.7%), a negative decision had been recorded for 1 indication (1.7%), and no final decision on concluding an MEA had been recorded for 34 indications (58.6%).

3. The analysis demonstrates that the distribution of pharmaceutical companies varied significantly depending on therapeutic areas. Thus, Roche had the largest portfolio (13 indications), while Takeda and Pfizer were represented in all three therapeutic areas. The results reflect differences in therapeutic specialization among the pharmaceutical companies represented in the study.

4. The number of national HTA conclusions supporting consideration of MEAs increased from 6 in 2021 to 21 in 2025. Overall, the results provide the first systematic data on the current implementation of the MEA framework in Ukraine and may contribute to further policy development, the optimization of negotiation procedures, and improved access to innovative medicines.

Conflict of interest

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

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Data availability

Data will be made available on reasonable request

Use of artificial intelligence

ChatGPT (OpenAI, GPT-6) was used to check grammar, spelling, and punctuation in the Ukrainian and English abstracts and the English main text. The authors reviewed each suggested correction against the original wording to ensure that the scientific meaning, terminology, numerical data, and conclusions remained unchanged. Only corrections verified and approved by the authors were incorporated. This assistance did not affect the research findings or conclusions. The authors take full responsibility for the final manuscript.

Authors' contributions

Iryna Kostiuk: Conceptualization, Methodology, Formal analysis, Investigation, Visualization, Writing – original draft; **Zhanna Polova**: Formal analysis, Investi-

gation, Writing – review & editing; **Kostyantyn Kosyachenko**: Conceptualization, Methodology, Writing – review & editing; **Dmytro Savchenko**: Investigation, Writing – review & editing.

All authors have read and agreed to the published version of the article and are jointly responsible for the reliability, accuracy, and integrity of the data and research results presented in the article.

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