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SAFEMed Technical Brief

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HEALTH TECHNOLOGY ASSESSMENT FOR EVIDENCE-BASED DECISION MAKING

BACKGROUND

Coming out of a heavily centralized Soviet health system, over the last 30 years, Ukraine has worked to reform its pharmaceutical policies to be able to provide its population with greater access to high-quality medicines. As of 2020, the World Bank estimated that the Government of Ukraine (GOU) was spending 8.2% of the state budget on health with citizens paying for nearly half (47.9%) of expenses out-of-pocket.¹ In comparison, the world averages for these figures in 2020 were 10.9% and 16.4%, respectively,² illustrating the shocking proportion of health care expenses that Ukrainians must bear.

Given these resource constraints, Ukraine needed a transparent process to decide which health technologies provide the best value for the health care system—a method called health technology assessment—or HTA. HTA is considered “best practice” to review technologies, which can range from a medicine to a medical device, in a systematic and clear way and use the strongest evidence related to clinical effectiveness, safety, costs, and other economic and cultural implications.

Ukraine committed to introducing HTA as a way to optimize the country’s health resources. The process to institutionalize an HTA function began in 2017, when the Ministry of Health (MOH) established a working group to explore the options, and remarkably, in less than five years, the MOH and the Cabinet of Ministers of Ukraine (CMU) with support from SAFEMed had established and institutionalized a fully autonomous, sustainable HTA function. Even more remarkable was that this achievement came despite the devastating COVID-19 pandemic and Russia’s invasion of Ukraine in 2022.

About SAFEMed

*Improving access to safe and affordable medicines for the Ukrainian population is one of the Government of Ukraine’s top priorities, with ambitious health reforms underway to ensure that access. The **United States Agency for International Development (USAID) Safe, Affordable, and Effective Medicines for Ukrainians (SAFEMed) project (2017-2025)** is supporting this effort by applying health system strengthening best practices and evidence-based interventions — working to institutionalize rational medicine selection; systematize public procurement of pharmaceuticals and commodities; support sustainable public-sector pharmaceutical financing; and strengthen the pharmaceutical supply chain in collaboration with the government, civil society, and the private sector.*

¹ World Bank data sheets

² <https://data.worldbank.org/indicator/SH.XPD.OOPC.CH.ZS>

This technical brief describes the comprehensive approach that the country and its partners took to create an HTA system, some of the results, and potential actions needed to continue strengthening Ukraine’s HTA function and establish an independent HTA agency within the GOU.

UKRAINE’S HTA JOURNEY

Important to HTA is a national essential medicines list (EML), which comprises products that meet a country’s priority health needs and that a health system should have available at all times. The medicines on the list are chosen based on evidence of safety, efficacy—how well they work—and comparative cost-effectiveness.³ A national EML streamlines product procurement and distribution, promotes more appropriate prescribing and use, and lowers costs for health care systems and for patients. In 2017, as part of the government’s health reform, the GOU established a national EML based on the World Health Organization (WHO) model list. This important work, which was initiated by SAFEMed’s predecessor project and completed under the current project, was a fundamental precursor for Ukraine to establish a vision and begin its journey to create a fully functional HTA agency.

Figure I summarizes the process for developing HTA in Ukraine from the MOH creating an HTA Department in 2019 embedded within the MOH’s State Expert Center (SEC), then moving to the establishment of the full legal framework for HTA to function in the country.

Why HTA?

*As universal health coverage expands, and the introduction of new treatments, diagnostics, and other health technologies increases exponentially, countries need to prioritize how they allocate limited resources to maximize health impact. Selecting health technologies for use in the public health care system greatly affects both quality of care and cost of treatment; however, health priority setting in many low- and middle-income countries typically lacks transparency and fails to fully address the competing interests of governments, donors, and other stakeholders.**

Health technology assessment is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its life cycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system.**

*Glassman A, Chalkidou K, Giedion U, et al. Priority-Setting Institutions in Health: Recommendations from a Center for Global Development Working Group. *Glob Heart*. 2012 7:13–34.

**O'Rourke B, Oortwijn W, Schuller T. The new definition of health technology assessment: a milestone in international collaboration. *Int J Technol Assess Health Care*. 2020; 1-4

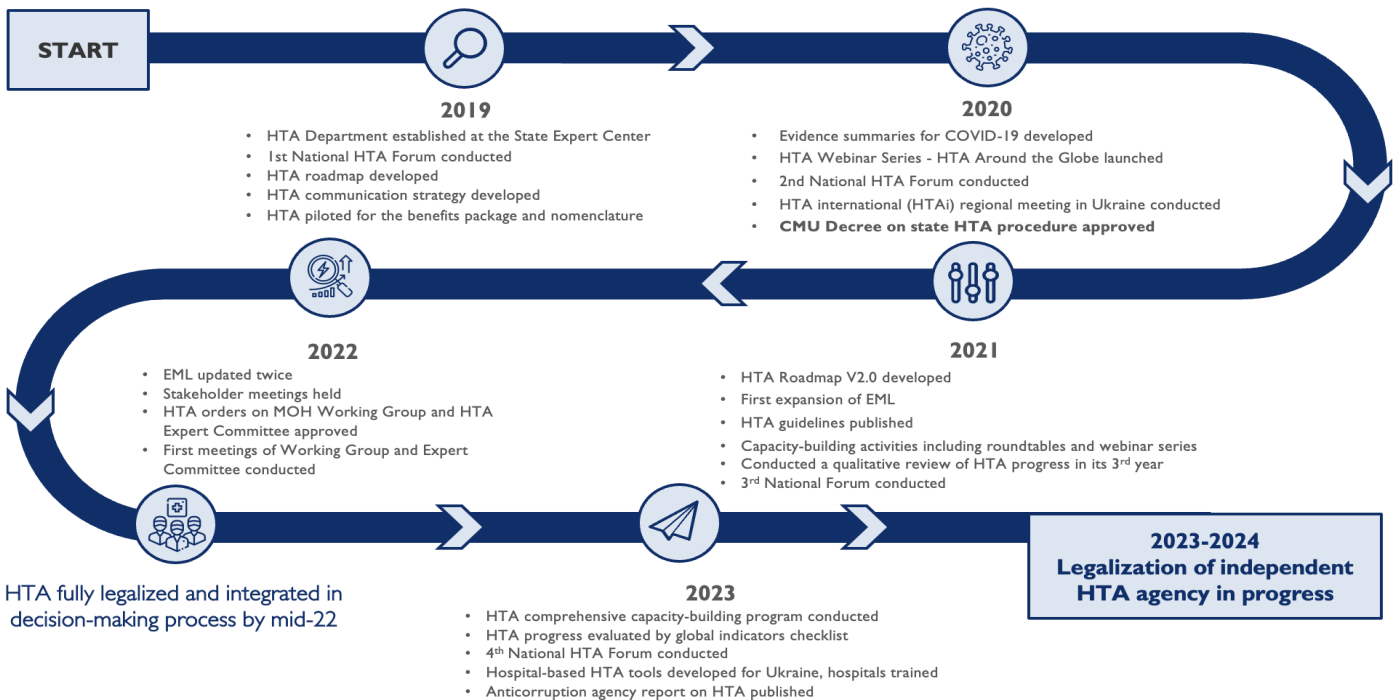


Figure I. Development of the HTA function in Ukraine

³ World Health Organization: Essential medicines and health products. WHO Model Lists of Essential Medicines at the end of 2017. Available at: <https://www.who.int/medicines/publications/essentialmedicines/en/>

TECHNICAL APPROACH

The lynchpin and guide to SAFEMed's technical approach to help the government establish an HTA system is the HTA roadmap for Ukraine, developed through SAFEMed-supported stakeholder collaboration in 2019:

- Provide legal support for resolutions and orders
- Support the MOH to create a functioning HTA agency by strengthening capacity in HTA
- Help implement practical priority-setting tools
- Facilitate engagement, knowledge sharing, and dialogue with key actors in the health system at international and domestic events

The goal is an HTA function integrated into the health system that has qualified staff who are operating in a transparent, evidence-based decision-making ecosystem. Figure 2 illustrates how Ukraine currently conducts its HTA process; however, it is evolving all the time to reflect the country's increasing capacity and experience.

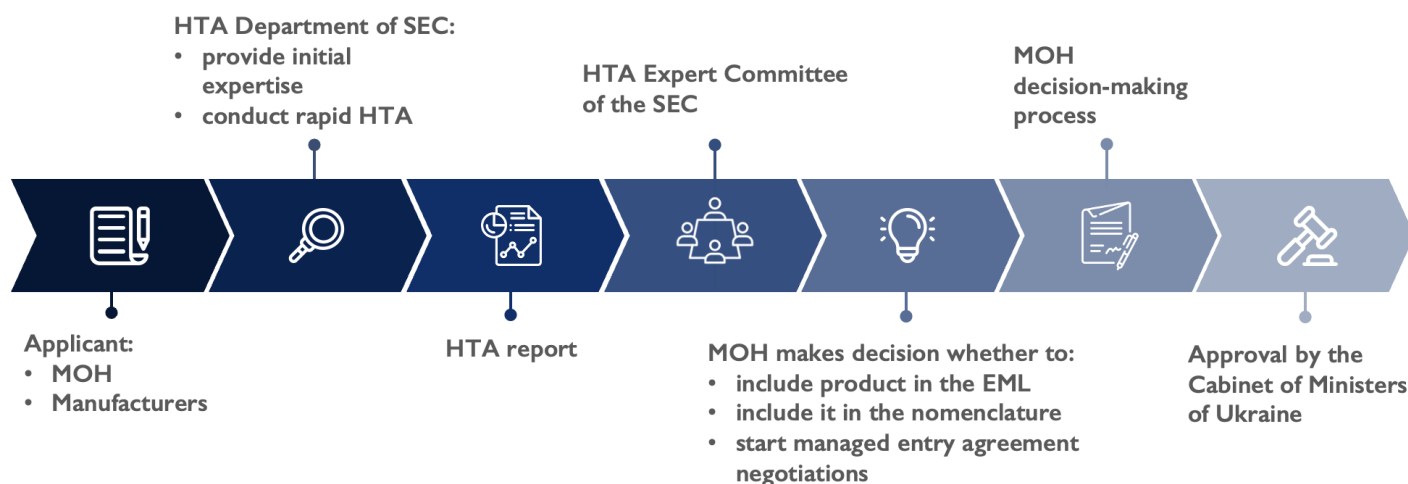


Figure 2. Current HTA process in Ukraine

UKRAINE'S HTA ROADMAP

To develop a robust HTA roadmap, SAFEMed analyzed the MOH's activities related to the national EML and HTA to characterize achievements, challenges, opportunities, and areas of improvement. Armed with this information, SAFEMed held a series of meetings with a broad group of stakeholders to support the MOH and SEC to draft an initial HTA roadmap in 2019. The MOH and SEC, with SAFEMed support, also created a roadmap activity plan. Following further legislative changes in 2019 and 2020 and successful implementation of the initial roadmap activities, SAFEMed supported the HTA Department to update the HTA roadmap and activity plan to version 2.0, which was approved in 2021. The original roadmap had five strategic objectives, and a new roadmap added a sixth objective (Figure 3).

By defining stakeholders' roles and responsibilities and steps to take, the HTA roadmap has clearly guided the construction of the HTA systems and structures needed to achieve its six objectives. It is a living document that can be continuously updated as Ukraine's HTA process evolves. The following sections describe SAFEMed's support to the GOU in achieving the six strategic objectives.

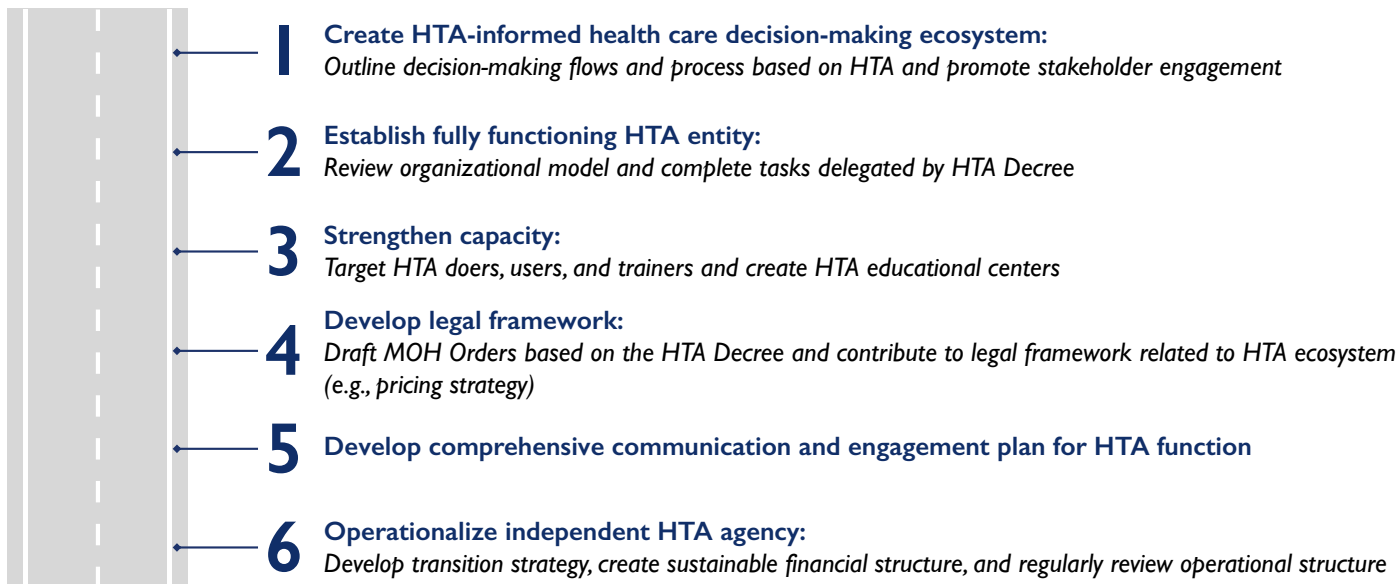


Figure 3. HTA Roadmap v 2.0

I. CREATE AN HTA-INFORMED HEALTH CARE DECISION-MAKING ECOSYSTEM

The MOH, with support from SAFEMed, organized stakeholder meetings and engaged with diverse perspectives, including those of clinicians, patient groups, hospitals, manufacturers, health sector decision-makers, and academics. While this initially helped raise awareness, it also increased stakeholders’ support for the HTA function through exposure to international examples of best practices. Another important step to build an HTA foundation was to clarify the roles and functions of the HTA Department and other public authorities, define the actual decision-making flows between them, and create methods for each process; SAFEMed also supported the legislative acts and procedures that the Ukrainian system required to allow these steps to be taken. Fortunately, the HTA Department, which has now grown to employ 24 full-time SEC personnel with a dynamic and accomplished director, quickly proved its worth by conducting many assessments and contributing to the HTA ecosystem, which in turn, helped accelerate HTA’s institutionalization in the country.

2. CREATE A FULLY FUNCTIONING HTA ENTITY

Once a 2020 CMU Decree made HTA a mandatory process for publicly purchased medicines, SAFEMed moved forward with helping to establish an independent, sustainable HTA entity. Activities included working with the HTA Department to improve their methods such as document management and define new HTA roles and functions within the context of Ukraine’s continuing health reforms. This involved updating the HTA organizational model and identifying needs, including human resource capacity and expertise; in addition, SAFEMed helped to develop HTA guidelines for medicines, which the MOH approved in early 2021. Even in its nascency, the HTA Department conducted many rapid assessments requested by the MOH and many full assessments requested by the manufacturers whose results fed the national EML expansion.



HTA Department team

Photo credit: SEC

3. IMPROVE CAPACITY FOR HTA

Over the project's life, SAFEMed has supported capacity-strengthening activities for MOH staff members and stakeholders who will either do, use, or be affected by HTA. SAFEMed also trained people from the MOH and academia to create a pool of experts who can be trainers but also make sure that HTA capacity building continues. In the project's first six years, 250 to 500 participants a year attended SAFEMed-facilitated trainings or engagement opportunities. These include representatives from government institutions such as the National Health Service of Ukraine (NHSU), Center for Public Health (CPH), Medical Procurement of Ukraine (MPU), SEC, ministries of health, finance, economic development and trade, education, and others; nongovernmental and international organizations; health care providers; academia and research organizations; patient organizations; and the pharmaceutical sector. Other capacity-building and engagement activities included webinars, policy dialogue events, and many one-on-one meetings with stakeholders to brainstorm or exchange knowledge.

Around the World Webinar Series

 **50-75**
participants
each time

 **15**
webinars

From 2020-2021, SAFEMed supported a series of webinars inviting international experts to present various aspects of HTA implementation. Topics ranged from country examples (such as UK or Poland) as well as specific HTA themes such as patient engagement, ethics in HTA, or hospital-based HTA. Pre/post webinar quizzes showed that participants gained new knowledge on HTA with scores increasing from an average of 64% to 82%. More than half of the information received during the webinars was new for more than 90% of all respondents and 74% could make immediate use of it.

Annual national forums

Since 2019, SAFEMed has organized national forums bringing together stakeholders from across all levels of the health sector to share experiences, generate new ideas, and reach agreement on thorny issues related to HTA. Forums began in person, then transitioned to virtual and then hybrid formats due to COVID-19 and later, Russia's invasion. The first forum had 130 participants and the fourth, in 2023, had 174. SAFEMed arranged for international experts to host several interactive workshops in conjunction with the forums, and in some years, there were roundtables with up to 200 participants to advance a specific policy issue, such as pharmaceutical pricing or creation of a single positive list of health products procured with public funds. After the Third National HTA Forum, a SAFEMed-led survey showed participants' high satisfaction with the event with the following scores (out of 5): overall satisfaction 4.6, agenda 4.6, speakers 4.4, topics 4.5, and technical 4.6 with 98% of the participants saying they would join the next forum.

International best practices

As described, Ukrainian national fora, webinars, workshops, and roundtables hosted over 20 well-known international speakers, thereby exposing Ukrainian counterparts to global best practices. In the same vein, the SEC HTA Department joined three global HTA professional bodies, HTAi, the International Network of Agencies for HTA (INAHTA), and the European Network for HTA (EUnetHTA). Ukraine also contributed regularly to national joint HTA assessments through EUnetHTA.

Comprehensive capacity-strengthening program

In 2022, SAFEMed selected Radboud University Medical Center of the Netherlands to work with Ukrainian colleagues to create a comprehensive training program for HTA doers and users that also has a train-the-trainers component. As a first step, Radboud assessed HTA capacity and training needs and reviewed HTA curricula from other countries to draft a model curriculum for Ukraine. SAFEMed, together with Radboud, proposed a set of minimum requirements that local HTA education centers would need to meet based on other effective country programs. Based on this, SAFEMed and

Radboud conducted a virtual course, which 75 HTA doers and users and 13 trainers have taken, comprised of 160 hours of instruction plus the train-the-trainer component as well as coaching and supervision for the trainees. A formal evaluation of the course showed that participants gained knowledge, were very satisfied with the course overall, and reported that the program contributed to their professional growth.

Trainings on hospital-based HTA

Because hospitals also have their own budgets to procure pharmaceuticals, SAFEMed is working with the MOH to introduce HTA to help hospitals use their resources more wisely. Consequently, SAFEMed identified hospital-oriented HTA tools in use in other countries and conducted a workshop with over 50 experts from 9 hospitals at different levels to raise awareness and provide basic training about HTA and to adapt the hospital-based HTA tools to the Ukrainian context. SAFEMed held webinars to present the Ukraine-specific tools to the hospitals, which are being piloted in one Kyiv national hospital to determine their usefulness in a real-life setting and make revisions as needed, before SAFEMed supports rollout.

4. DEVELOP A ROBUST LEGAL FRAMEWORK FOR A WELL-FUNCTIONING HTA STRUCTURE

To create a comprehensive HTA legal framework, SAFEMed and its local partner, Legal Alliance, focused on drafting the legislative documents necessary to fully govern the country's HTA assessment procedures and use HTA conclusions for decision-making. Between 2018 and 2023, SAFEMed and Legal Alliance supported the creation of a new law and amendments to two laws, three new decrees along with three amendments to existing decrees, and, four new MOH orders. In addition, the SEC approved three orders. Table 1 summarizes the major legal steps taken to institutionalize HTA in Ukraine.

Table 1. Major HTA legalization milestones

MILESTONE	DATE
<i>Law introduces the HTA term in Ukraine</i>	<i>October 2017</i>
<i>MOH develops national strategy (2018-2025) to guarantee provision of safe, effective, and quality medicines including “using HTA for decision making”</i>	<i>December 2018</i>
<i>HTA Department was established under the MOH State Expert Center until an independent HTA agency is formed</i>	<i>January 2019</i>
<i>CMU makes HTA mandatory for any medicine to be publicly covered and requires HTA guidelines to be published and actions taken to establish an independent HTA* agency</i>	<i>December 2020</i>
<i>MOH approves HTA guidelines</i>	<i>March 2021</i>
<i>CMU allows the EML to be updated for the first time in four years; seven medicines were added, providing opportunity to expand the medicine guarantee program</i>	<i>April 2021</i>
<i>CMU approves use of managed entry agreements (MEAs) that are first recommended after going through an HTA procedure; MOH approves MEA working group and establishment of negotiations group and MEA regulations</i>	<i>January 2021 – November 2021</i>
<i>MOH outlines the HTA process starting with the HTA Department and then going to the HTA Expert Committee and mandates creation of a working group to recommend which medicines to include under state coverage</i>	<i>January 2022</i>
<i>MOH approves the process for the working group to oversee EML formation and recommend which medicines the MOH should include/exclude from it</i>	<i>June 2022</i>
<i>MOH approves the creation of HTA Expert Committee with 11 experts with diverse backgrounds, including clinical practice and hospital management</i>	<i>August 2022</i>
<i>Parliament approves the new Law on Medicines, which lays the foundation for creating a positive list</i>	<i>July 2022</i>
<i>CMU approves legislation for external reference pricing of the national EML</i>	<i>October 2022</i>
<i>HTA guidelines revised and go through public discussion as a draft</i>	<i>August 2023</i>

*The CMU Decree passed in December 2020 continues to serve as the main legislative document in the Ukrainian HTA ecosystem.

Full legalization and institutionalization of HTA in Ukraine was completed by mid-2022, providing a clear-cut, stakeholder-engaged, and evidence-based process to decide which medicines and other technologies will be purchased with state funds. An independent HTA agency remains a government commitment; however, the war changed immediate priorities, and while the establishment of an HTA agency was not a focus during the war's first year, the HTA Department's process has continued to support decision-making that has made a visible impact on improving access to medicines in the country. The government has since re-established the creation of an independent HTA agency as a priority and is taking steps to make it happen.

5. DEVELOP A COMPREHENSIVE AND ROBUST COMMUNICATION AND ENGAGEMENT PLAN FOR THE HTA FUNCTION

Developing a credible and sustainable HTA function requires comprehensive, understandable communication to diverse audiences. Throughout the project, SAFEMed has supported the MOH and the SEC HTA Department to share HTA implementation successes through media products, such as infographics and short videos, as well as with the international HTA community. For instance, SAFEMed promoted Ukraine's experience through many international platforms, such as conferences sponsored by HTAi, Professional Society for Health Economics and Outcomes Research, WHO, HTAsiaLink, and the Drug Information Association. HTAi, in fact, held its regional meeting in 2020 in Ukraine to highlight Ukraine's outstanding performance in advancing HTA. Also, in June 2022 in the Netherlands, HTAi invited Ukrainian representatives to share the country's progress in developing HTA despite the war—the audience of over 300 gave a standing ovation. The Ukraine HTA experience was also shared through three presentations and posters at the 2023 HTAi annual meeting. Overall, since the HTA Department was launched, Ukrainian HTA experts have presented over 40 abstracts at international conferences and have been invited speakers at 11 international in-person events and many virtual events.

6. CREATE A FINANCIALLY AND OPERATIONALLY SUSTAINABLE, INDEPENDENT HTA STRUCTURE WITH A WELL-DESIGNED TRANSITION PLAN

The roadmap laid out a plan to create an independent HTA agency by 2022 initially, then postponed to 2024, with three main objectives:

- Develop a strategy to smoothly transition from the current HTA Department to an independent HTA agency
- Analyze the HTA function's financial needs and develop options for creating a sustainable financial structure
- Analyze the current operational structure and continue to regularly review it for sustainability

Ukraine's ambition to continue reforms needed for EU integration prompted the GOU to revisit the roadmap, update the options analysis and budget that SAFEMed had developed for the MOH, and draft a plan for legal actions. A transition strategy will need to provide a step-by-step approach to independence and beyond.

IMPACT

SAFEMed has provided continuous technical assistance to the MOH and the SEC HTA Department and worked with other government entities and stakeholders to ensure that evidence-based policies are shaped and conducted so that Ukrainians receive medicines at the best value to the health system. SAFEMed’s advocacy and technical support has yielded impressive results in this area, despite the pandemic and ongoing war.

Practical Application of HTA Methodology

The HTA Department’s assessment of two medicines used to treat kidney cancer, sunitinib and pazopanib, found them to be safe and effective, and the MOH approved them for public procurement. Two manufacturers competed for the order from MPU, which led to significant savings of **UAH 156M (USD 4.2M)**. Moreover, this collaboration between the HTA Department, MOH, and MPU allowed the government to cover **100%** of patients with kidney cancer who were eligible for the treatment for the first time. This illustrates how using HTA to make decisions about medicine procurement can expand access while bringing additional value to Ukraine and its patients.

ROBUST ACHIEVEMENTS AGAINST GLOBAL BENCHMARKS

WHO uses several indicators to measure HTA use in different parts of the world; overall, they emphasize having a strong policy framework for HTA, supported by legislation, and the capacity for using HTA in policymaking.^{4,5} Table 2 shows Ukraine’s remarkable HTA advancement—meeting 75% (9/12) of global HTA indicators—with the remaining three partially met; for example, Ukraine’s HTA process formally links the HTA Department and the MOH, who is mandated to consider the Department’s recommendations in its policies (green), and although HTA training is available domestically, it needs additional academic input (yellow). No indicators lack any progress at all.

Table 2. Ukraine’s progress compared with global indicators

INDICATORS	PROGRESS
Formal link between the HTA unit and policy-makers	Green
Statement on willingness to use HTA in policy decision-making	Green
Use of HTA results in policy implementation	Green
Implementation roadmap	Green
Full-time group of HTA researchers	Green
Legislation on the HTA’s role in decision-making	Green
Appointment of an HTA focal point agency	Green
Allocation of annual budget for HTA activities by the government	Yellow
Collaboration with local stakeholders in conducting HTA research	Yellow
Domestic HTA training	Yellow
Availability of HTA method guidelines	Green
Availability of HTA process guidelines	Green

⁴WHO Regional Office for the Western Pacific, Asia Pacific Observatory on Health Systems and Policies. 2015. Factors conducive to the development of health technology assessment in Asia: impacts and policy options.

⁵Bertram M, Dhaene G, Tan-Torres Edejer T, editors. 2021. Institutionalizing health technology assessment mechanisms: a how to guide. Geneva: World Health Organization.

STRONG HTA PERFORMANCE

According to the standard process, manufacturers submit HTA dossiers to the HTA Department on a rolling basis, and HTA conclusions are published according to designated timelines. A second channel to request HTA is through the MOH, whose priorities are assessed in a shorter time frame. Most industry submissions for HTA have been for oncology medicines, while the MOH is prioritizing orphan or rare disease treatments in its fast-track requests.

As Figure 4 illustrates, from December 2020's approval of the HTA CMU Decree until September 2023, pharmaceutical companies made 59 submissions to the HTA Department, of which 36 received HTA conclusions. The HTA Department also received and finalized 52 MOH fast-track requests.

Among the 36 conclusions for industry submissions, 19 medicines were recommended for negotiations with industry for price discounts through MEAs, 8 were rejected, 7 were recommended to be included on the EML, and 2 were to be included in the nomenclature for state-covered reimbursement. Among these, three oncology medicines are under negotiation with manufacturers for lower prices.

Among the 52 MOH fast-track conclusions, 11 medicines were recommended for industry price discounts, 26 were recommended to be included on the EML, and 11 in the nomenclature. Also, four HTA conclusions recommended that medicines be excluded from the nomenclature based on inadequate data on the drugs' cost-effectiveness.

Due to these strong HTA practices, Ukrainians can be confident that the medicines that they access are of assured quality and efficacious and demonstrate the best value for them and the health system; in addition, the medicines that go through MEA negotiations with manufacturers would often not be available at an affordable cost, especially for rarer health conditions.

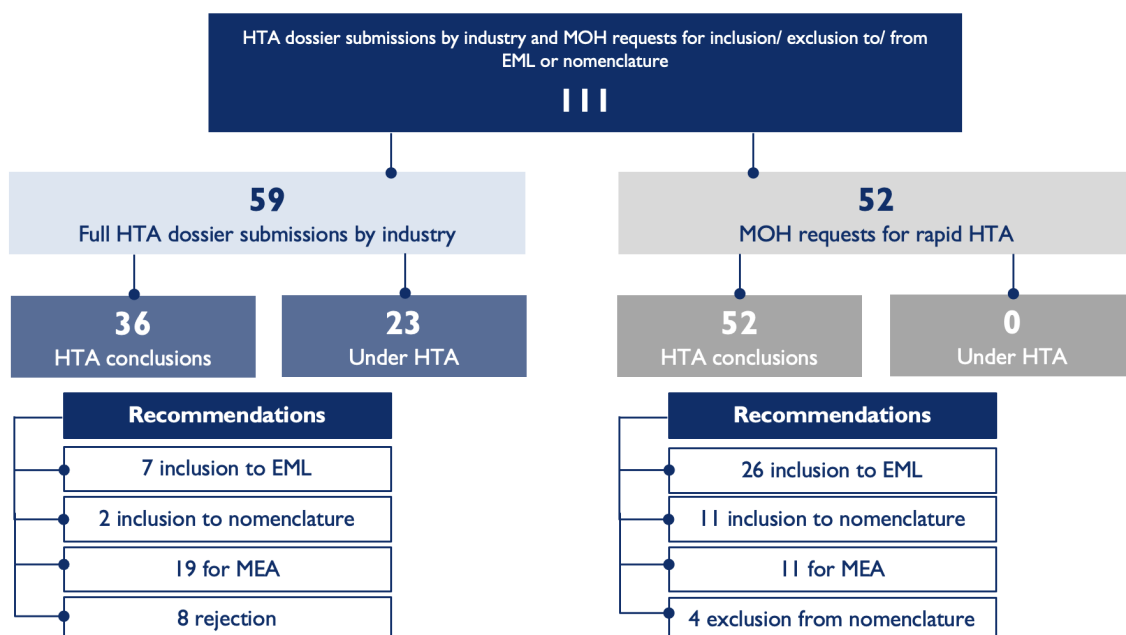


Figure 4. Impact of HTA implementation: first half of 2023

HTA role in MEA

A MEA is a risk-sharing arrangement that health care payers, government departments, or national authorities responsible for coverage, pricing decisions, or HTA negotiates with the firm that sells a health technology. MEAs reduce the consequences of making a poor decision about what products to cover when the effects of a new treatment on health outcomes and health care budgets are uncertain. Covering treatments that end up being ineffective or denying coverage for treatments that later are seen as cost-effective can negatively affect health outcomes or waste resources; therefore, to bolster such decisions, HTA is an essential step that the GOU must take before pursuing a MEA.

Source: Wenzl M, and Chapman S, 2019. Performance-based managed entry agreements for new medicines in OECD countries and EU member states: How they work and possible improvements going forward. OECD Health Working Papers, No. 115. <https://doi.org/10.1787/6e5e4c0f-en>.

WAY FORWARD

Ukraine has established a robust foundation for transparent, evidence-based decision-making regarding the adoption of cost-effective health products, including medicines. With renewed government commitment and political momentum, SAFEMed will continue its support to the GOU to establish an independent HTA agency by drafting the necessary legislative framework and a proposed organizational structure for the new agency, which is mandated to be established by January 2024. SAFEMed's focus will remain on building the HTA Department's organizational and staff capacity through interactions with global HTA experts and by expanding their scope, for example, by introducing HIV technology horizon-scanning to routine practice and building the private sector's trust in HTAs' fairness and transparency to increase industry dossier submissions.

With its powerful aspiration to join the European Union, Ukraine will also need to continue fine-tuning HTA implementation by further strengthening the appraisal and decision-making process and expanding to include medical devices, such as diagnostics and equipment. Equally important will be instituting parallel reforms such as finalizing the positive list and harmonizing different pricing strategies. The positive list will combine the nomenclature, national EML, and public reimbursement list—all medicines covered by public funds—into one single list based on HTA.

The National Agency on Corruption Prevention published a report that emphasized the need to move quickly on these improvements, demonstrating HTA's value to the GOU and recognition that the nascent processes need close monitoring to maintain transparency and continue to meet patient needs.

CONCLUSION

Ukraine's MOH has invested a tremendous amount in health reforms founded on new structures, visible processes, and the international best practices, including the use of HTA in health sector decision-making. With catalytic support from USAID through SAFEMed, a clear, systematic HTA mechanism with a strong legal framework is in place. The remaining challenges are to align processes under the guidance of an independent HTA entity, make sure institutions work in harmony, and galvanize the use of HTA to feed into a single list of medicines covered by public funds, each with a fair and transparent price. Ukraine has mostly completed what it needs for a robust, sustainable HTA function, and with minimal continuing effort, will be an outstanding example of HTA success in a lower middle-income country.

[Learn more at msh.org/projects/safe-affordable-and-effective-medicines-for-ukrainians/](https://msh.org/projects/safe-affordable-and-effective-medicines-for-ukrainians/)

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