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SAFEMed
Technical Brief

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LEGAL REFORMS TOWARD GREATER PATIENT-ACCESS TO ESSENTIAL MEDICINES

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)*** *Activity (2017-2025) is supporting this effort by applying health system strengthening best practices and evidence-based interventions that 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. SAFEMed is managed by Management Sciences for Health.* ***LA Law Company (LA Law Firm),*** *a Ukrainian firm, serves as the technical lead for legal support.*

BACKGROUND

Over the last decade, the Government of Ukraine (GOU) has been on a journey of reforming its health sector, with critical advances achieved in making health services and medicines more affordable and accessible. Well-elaborated laws, policies, and regulations based on sound evidence and broad-based consultation serve as the foundation of these reforms. For these reasons, as the key GOU technical support project in the pharmaceutical sector, SAFMEed and its partners focus on advancing Ukraine's legal and regulatory reforms, through analyzing policy options, drafting legal acts, facilitating stakeholder dialogue and broad-based review of policies, and supporting their implementation.

Health reforms in Ukraine face several obstacles. Stakeholders often have differing perspectives on priorities and limited awareness and information regarding policy options and successful examples from other countries with similar objectives to increase access and affordability. Political instability, leading to frequent changes in the leadership of the Ministry of Health of Ukraine (MOH) and its subordinated technical agencies, slow regulatory reforms. Further, the COVID-19 pandemic and then the February 2022 Russian invasion of Ukraine and the necessary institution of martial law hindered some reform processes while also serving as catalyst to other reform efforts that had previously been stalled.

UKRAINIAN LEGAL CONTEXT

Over time, Ukraine has made progress in aligning its pharmaceutical legislation with international best practice. The work in legal reforms continues. Updated laws and regulations are needed to address gaps, further clarify inconsistencies, and address evolving challenges. The following key milestones achieved in the last five years lay the foundation for addressing these gaps and further advancing health sector reforms:

- The successful adoption on July 28, 2022 by the Verkhovna Rada (the Ukrainian Parliamentary body), of the new law on medicinal products, set to take effect 30 months after the end of martial law[1], outlines an ambitious agenda of reforms, many of which SAFEMed advocated for over the previous five years as well as those currently underway and further described below.
- The granting of Ukraine candidate status by the European Union[2] in June 2022 cleared the way to start formal negotiations as a member state. Gaining this status renewed the push to advance health sector regulatory reforms. As a result, many stakeholders, including Parliament, the Cabinet of Ministers of Ukraine (CMU), MOH, pharmaceutical industry, patient organizations, and others, committed to aligning Ukrainian institutions and regulations with the rest of Europe and beyond.
- Continuous GOU-approved increases in the national state budget for health and associated reforms as well as improving efficient use of available funds. The budget for health nearly doubled from 2017 (112 B UAH/equivalent 4.8 M USD) to 2022 (200 B UAH/equivalent 6.66 M USD). The exchange rate of the hryvnia against the dollar has changed over time, increasing by 1.5 times due to the war processes. At the beginning of the project in 2017, the rate was 27.8 UAH/USD due to the economic impacts of the war. By 2025, it had already risen to 41.7 UAH/USD. This explains the more modest increase in the budget in dollar terms compared to the more significant growth reflected in UAH. Further, the impacts of the war resulted in a drop in the amount of the overall state budget dedicated to health from 2024 to 2025, although investments in flagship medicine programs such as the Affordable Medicines Program (AMP) and the state procurement body, Medical Procurement of Ukraine (MPU) grew in 2023 and 2025.

Table I. Dynamic national health expenditure in local currency and USD equivalent using annual exchange rates

Year	State budget		Exchange rate[3]
	UAH, billion	USD equivalents, million	
2017	112.00	4.18	26.77
2018	120.00	4.43	27.06
2019	143.00	5.59	25.6
2020	173.00	6.47	26.73
2021	164.00	6.06	27.06
2022	215.30	6.66	32.35
2023	217.40	5.95	36.56
2024	238.70	5.98	39.92
2025	210.70	5.05	41.7

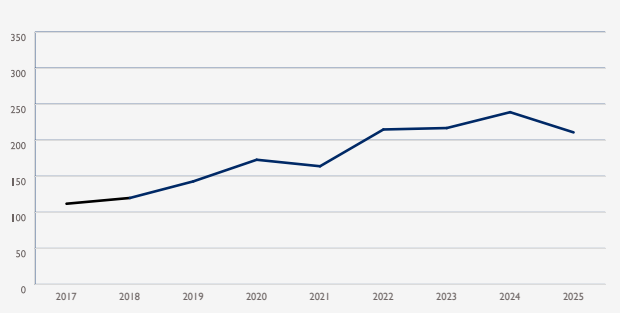


Figure I. Value of the state budget for health from 2017 through 2025 (in UAH).

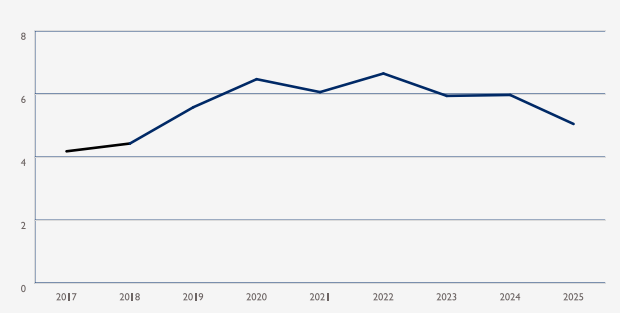
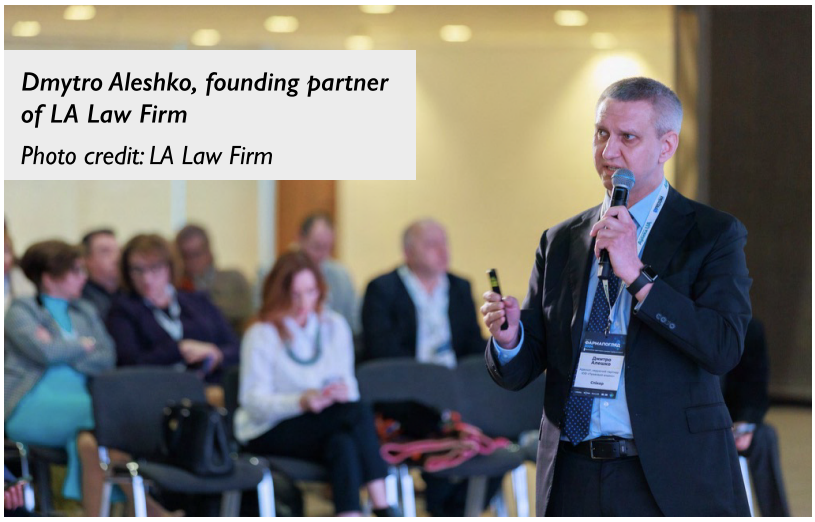


Figure II. Value of the state budget for health from 2017 through 2025 (in USD).

[1] The Law "On Medicinal Products" comes into legal force from the date of its publication and is enacted on January 1, 2027, except for certain articles that are enacted within the terms specified in Section XI (FINAL PROVISIONS).
[2] Ukraine - Consilium
[3] As exchange rate used the annual average of monthly rates, used for comparative demonstration. It is not weighted.

SAFEMED'S APPROACH

Since its launch in 2017, SAFEMed has supported the GOU to update and develop new laws and associated legal acts, also referred to as bylaws, that lay the legal foundation for improvements in the safety, quality, affordability, and accessibility of medicines in Ukraine. In addition to enhancing efficient use of budget expenditure for medicines and medical products, the GOU priorities for health sector reform have included the following:



Dmytro Aleshko, founding partner of LA Law Firm

Photo credit: LA Law Firm

- Create and institutionalize a process to ensure transparent criteria for selecting medicines for reimbursement, including introducing the internationally recognized practice of health technology assessment (HTA), which helps make evidence-based decisions about which medicines offer the best value for patients and the health system.
- Create and build a transparent national medicine procurement agency for centralized procurement and supply chain management to buy medicines in a more efficient, cost-effective, and accountable way, thus reducing waste and improving access. Through this agency, managed entry agreements (MEAs) were implemented as key tools to develop a transparent, efficient, and cost-effective national medicine procurement system, helping to further improve access and reduce waste.
- Establish and continue to grow the essential medicines list, and other relevant lists of medicines based on HTA to ensure the most needed and effective medicines are prioritized for public funding.
- Introduce effective mechanisms for regulating medicine prices to help prevent overpricing and ensure that essential medicines remain affordable.
- Expand and strengthen distribution and supply chain systems to ensure consistent availability of essential medications across all regions, supporting their appropriate and timely use.

The MOH, with support from SAFEMed, prioritized these initiatives and began making the necessary legislative changes. Our approach to build local buy-in and ownership, increase transparency and trust, and support sustainability involved working with stakeholders at every stage of the process. This includes engagement with state agencies involved in the pharmaceutical sector, such as the State Expert Center of the MOH (SEC), the State Medicines and Drug Control Service (SMDC), the National Health Service of Ukraine (NHSU), MPU, and the Center for Public Health (CPH). From industry, stakeholders include representatives of the American Chamber of Commerce, the European Business Association, the Association of Pharmaceutical Research and Development (APRaD), the Association of Manufacturers of Medicines of Ukraine, and the Association of Organizations of Employers of Medical and Microbiological Industry of Ukraine. And importantly, organizations representing patients are included.

PATHWAY TO LEGAL AND REGULATORY REFORM IN UKRAINE

The legislative reform process in Ukraine, as in many democratic societies, is multi-staged, lengthy, and complex, requiring coordination across various levels of government. Often, legal changes are considered when there is sufficient support (either from the government, the public, or other influential stakeholders) to introduce or amend a legal act at the level of Parliament. Draft legislation is submitted and registered, considered by the relevant committee, undergoes a series of public readings; and, once approved by Parliament, is sent to the President for signature.

Once a law is in force, the GOU must pass associated legal or normative acts, that guide implementation of the law. These may be official decrees passed by the President or the CMU, or an order passed by the responsible ministry or other governmental body.

The major types of legal acts and the responsible governmental body are described below. Over the life of the project, SAFEMed has contributed across all aspects in the development of these law and policy-making processes by facilitating the analysis, drafting, public comment, and review by government bodies. Examples of this work and the outcomes of these initiatives are described in the following section.

LAWS OF UKRAINE	CABINET OF MINISTERS OF UKRAINE DECREES	ORDERS OF THE MINISTRY OF HEALTH
■ Adopted by the Verkhovna Rada ■ Signed by the Head of Verkhovna Rada and the President	■ Adopted by the Cabinet of Ministers of Ukraine ■ Designed to implement laws of Ukraine	■ Adopted by the Ministry of Health of Ukraine ■ Forms and implements state policy in the sphere of healthcare

IMPACT

As of December 2024, SAFEMed's lawyers of the LA Law Firm and technical experts have worked with the GOU and stakeholders to help pass 48 legal acts (see Figure III). Table II presents some notable pieces of legislation and their effect on the health system. Throughout the life of the project, SAFEMed contributed to more than 200 legal acts, including laws, decrees, orders, and other normative documents. The reform process is dynamic and requires flexibility and adaptation as the landscape evolves, political commitment for a given legal act ebbs and flows, and as new challenges are confronted.

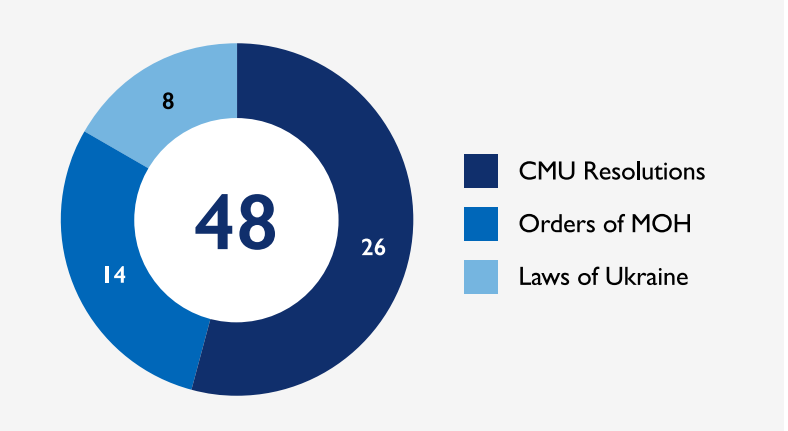


Figure III. Number of SAFEMed-supported legal acts

Table II. Major legal acts approved by GOU with SAFEMed support

MAJOR ACT	ACTION
CMU Decree "On reference pricing for certain medicinal products purchased with budget funds" No. 426, April 3, 2019	Introduces state regulation of prices for certain medicinal products from the National List based on prices in reference countries
Amendment to the Law of Ukraine "On Amendments to some laws of Ukraine aimed at increasing affordability of medicinal products, medical devices and their accessories, purchased by a person authorized to procure in the healthcare sector" No. 531-IX, March 17, 2020	Introduces definitions and basic requirements for managed entry agreements
CMU Decree "On approval of the procedure for conducting health technology assessment" No. 1300, December 23, 2020	Includes/excludes medicines in/from the national List and other lists based on HTA
CMU Decree "Some issues regarding managed entry agreements suspension of the first paragraph of clause 12 of Resolution of the Cabinet of Ministers of Ukraine No. 333 of March 25, 2009" No. 61, January 27, 2021	Approves the procedure for negotiating or concluding managed entry agreements
CMU Decree "Some issues of reimbursement of medicinal products and medical devices under the program of state guarantees of medical care for the population" No. 854, July 28, 2021	Legal mechanisms for reimbursement of insulin within the national Affordable Medicine Program (AMP)
MOH Order "On the approval of amendments to certain normative legal acts of the MOH" No. 1284, July 21, 2022	Introduces electronic prescriptions for all prescribed medicines, not only those in the AMP
MOH Order "On amendments to certain normative legal acts of the MOH on dispensing of medicinal products and medical devices on prescription" No. 494, March 15, 2023	

IMPACT ON THE HEALTH SYSTEM AND OUTCOMES

In addition to supporting legislative processes, SAFEMed works to ensure that legislative and regulatory reforms are implemented and have a positive impact on the health system and, ultimately, the users of the health system: patients and providers. These efforts led to substantive and measurable changes in multiple priority areas of the health system.

HEALTH TECHNOLOGY ASSESSMENT (HTA)

Ukraine adopted tools widely used in Europe, including health technology assessment, designed to ensure the rational use of budget funds for medicines covered by the state. According to preliminary data from December 2020 to November 1, 2024, the HTA Department of the State Expert Center processed 83 applications from companies for health technology assessment and 55 requests from the MOH, while 110 opinions with relevant recommendations were issued.

NATIONAL PROCUREMENT: MANAGED ENTRY AGREEMENTS (MEAs)

Managed entry agreements are an innovative procurement instrument whereby pharmaceutical manufacturers enter agreements with the government for innovative, high-priced items that would not otherwise be available for public coverage. This allows patients to benefit from promising new treatments sooner, while giving governments more time to gather evidence. The use of confidential pricing along with three-year agreements achieved budget savings of up to $10 million in the 2022 state budget alone[4]. While the HTA ecosystem and the MEA model require continual adjustments and improvements based on the implementation experience in the first years, these tools have made significant progress in ensuring patients receive effective and cost-efficient medicinal products.

ACCESS TO ESSENTIAL MEDICINES: AFFORDABLE MEDICINES PROGRAM

The implementation of a medicine reimbursement system based on best practices, known as the AMP, has improved patient access to medicines for conditions such as cardiovascular and cerebrovascular diseases, diabetes, chronic lower respiratory tract diseases, mental and behavioral disorders, and others. SAFEMed helped create the AMP, and in 2021, SAFEMed supported the necessary legal acts to add insulin to the list of medicines covered. As a result, the estimated 220,000[5] people with insulin-dependent diabetes are getting their treatment at low or no cost.

ELECTRONIC PRESCRIPTIONS IN ACCORDANCE WITH THE AMP

5.4 million patients

73 million prescriptions processed

156.4 million packages of medicines dispensed

16.1 billion UAH reimbursed to pharmacies

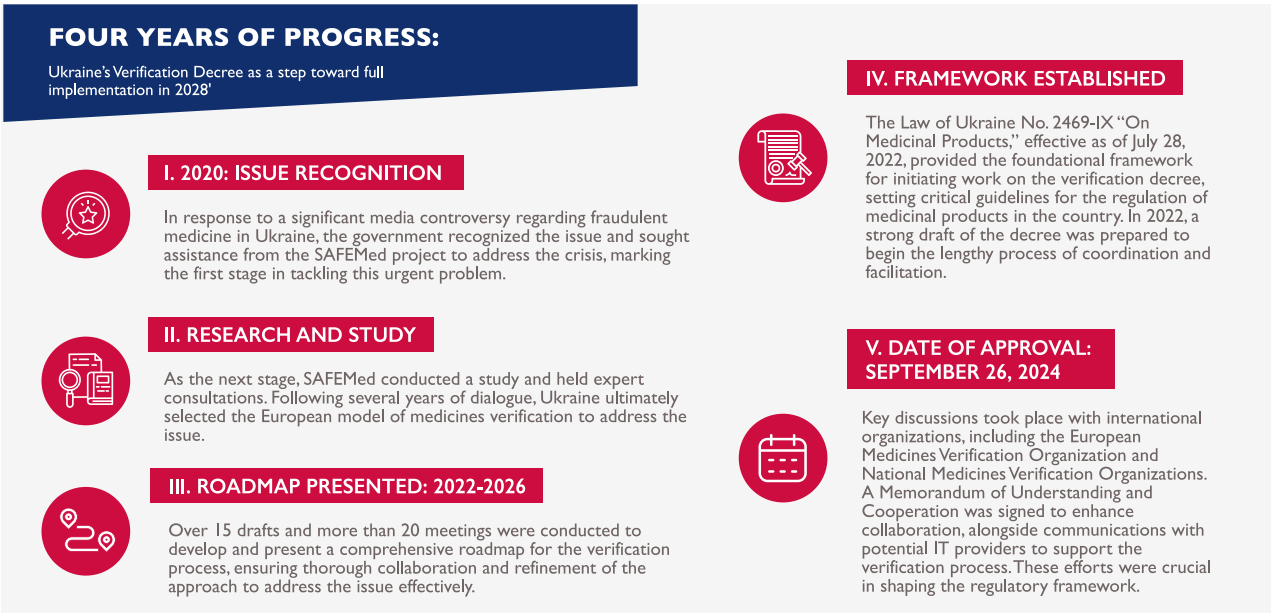
Limited control over dispensing prescription medicines without a prescription, which leads to overuse, self-medication, and is an urgent issue in Ukraine and a contributing factor to antibiotic resistance. In the MOH Order No. 634 of March 22, 2019, SAFEMed supported the introduction of electronic prescription (ePrescription) for the AMP. Given its success in this program, in 2023, the Ukrainian government decided to transition ePrescriptions for all prescription medicines to strengthen oversight of use of prescription medicine. Since the introduction of the ePrescription practice in 2019 until the end of March 2025, 89.4 million prescriptions were issued to Ukrainian patients, including those both within and outside the AMP, surpassing expectations[6].

[4] ITTA Editorial Team. (2022, December 14). МОЗ очікує в 2022 році економію близько $ 10 млн від використання механізму ДКД при закупівлі ліків: Itta Info. itta.info. https://itta.info/moz-ochikuye-v-2022-roci-ekonomiyu-blizko-10-mln-vid-vikoristannya-mexanizmu-dkd-pri-zakupivli-likiv/
[5] The quantity is estimated and provided by the Ukrainian data firm Support in Market Development (SMD).
[6] Source: NHSU's dashboards, through the end of March 2025

ONGOING EFFORTS IN LEGISLATIVE REFORM

VERIFICATION OF MEDICINAL PRODUCTS

One of the most challenging initiatives undertaken by the MOH was developing a model and drafting regulations for a national medicine verification system, aligned with international best practices. This system is essential to combat counterfeit medicines and improve medicine quality in Ukraine. SAFEMed played a critical role in helping the MOH to convince Ukrainian stakeholders to use the European model of serialization and verification. SAFEMed helped broker engagement among local and international medicine manufacturers to reach consensus on establishing the national system, including hosting meetings with the European Verification Organization and similar entities in EU countries. The CMU passed the resolution in September 2024. The approach of delegating system management to a non-profit organization established by manufacturers is unprecedented in Ukraine. The MOH, with its partners, continues to work toward the eventual launch of the system scheduled for early 2028.



ACCESS TO LIFESAVING MEDICINES FOR HIV

At the request of the CPH and MOH, SAFEMed legal experts drafted amendments to the Law of Ukraine "On counteracting the spread of diseases caused by the Human Immunodeficiency Virus (HIV) and the legal and social protection of people living with HIV." As a result of this collaborative effort and strong advocacy across civil society and HIV experts, Parliament adopted Law No. 2869-IX on January 12, 2023, which amended the application of modern approaches to the prevention, testing, and treatment of HIV infection to align with WHO guidelines. The Law enabled antiretroviral (ARV) medicines funded by the government and donors to be dispensed through pharmacies. The mechanism still requires further legislative changes at the level of bylaws and amendments to other laws. However, its implementation will significantly simplify patients' access to ARVs and create a more person-centered model of care.

A TRANSPARENT PHARMACEUTICAL REGULATORY BODY

Adapting Ukrainian legislation to international standards is a complex and multifaceted process requiring collaboration among all stakeholders. This adaptation includes restructuring the system that controls the pharmaceutical market through the establishment of a single, transparent regulatory body (i.e., the State Control Authority) and better aligning the system of manufacturers, importers, distributors, and pharmacies with the practices of the US and European countries. This effort requires drafting or revision of more than fifty legal acts, many of which are being updated with SAFEMed support. Key documents still need to be drafted and passed to establish a highly functioning regulatory body and to strengthen the broader ecosystem in which it will operate. These reforms are considered of the highest priority across all the key stakeholders in the pharmaceutical sector and are expected to be in place by 2027 when the new body is officially launched.

LESSONS LEARNED

Over seven years of experience in supporting legal reforms has provided SAFEMed with important lessons to share and build upon.

Time frames for reform: Depending on bandwidth, momentum, and available policy windows, some legislation can be very quick and others very slow. For instance, the process of agreeing on the CMU Verification Decree took over two years, from July 2022 when SAFEMed drafted a national roadmap for the establishment of a national verification system to the passage of the September 2024 Decree, with reviews of experience from other countries, extensive revisions of the concept and the legal acts, and many market-wide stakeholder consultations. This lengthy process created further support for the initiative while at the same time expanding the number of stakeholders across Ukraine who fully understand the rationale for the new system and how it would function.

Undue influence: Not everyone stands to benefit from a given policy reform. It is very important for SAFEMed to constantly map stakeholders to be aware of the positions of different market players, understand their interests, anticipate actions they may take to protect their interests – either in support of or against a given policy priority. Uniquely, SAFEMed worked to create environments to share perspectives openly – ultimately leading to the drafting of more responsive legal acts, that once adapted would be fair and prioritize the population of Ukraine.

Grassroots advocacy: SAFEMed was able to engage patient organizations, such as the leading non-governmental organizations Patients of Ukraine and the Rare Disease Organization of Ukraine, to advocate for patients' rights and show support for legislation that improved medicines access and quality. With the involvement of these influential organizations, SAFEMed could advance the adoption of legislation that may have been otherwise mired in bureaucracy.

An honest broker: SAFEMed's role as a technical assistance provider allowed the project to serve as an honest broker trusted by all parties. By not being influenced by any one group or interest, the project can focus on bringing expertise and exposure to global best practices while creating forums for exchange. This allows country stakeholders to focus on the long-term vision of increased access, transparency, and efficiency of a market with growth opportunities in Ukraine.

Holistic view: The project's strategic position and its communication with all elements of the healthcare system enable a comprehensive understanding of various perspectives and aspirations, and their interconnectedness. Through constant high-level dialogue with the country's leadership and the ability to present recommendations in the form of analytical materials, comparisons, and modeling, SAFEMed can visualize the overarching landscape of reforms and the nation's ambitions for change. As a result, this approach can save time and resources, allowing the country to progress more confidently and effectively.

CONCLUSION

SAFEMed, together with its legal partner LA Law Firm, has made substantial contributions to advancing legal and policy reforms in Ukraine, including direct support to 48 adapted legislative acts. These legal reforms served as the foundation for the establishment of many of the flagship pharmaceutical reforms in the country including implementation of the Affordable Medicine Program, the use of managed entry agreements, formal creation of the HTA function for selection of medicines for public coverage, and others.

There is still more to accomplish. Further reforms will always be needed to refine and improve programs based on analysis of their impact and to advance other health sector policy priorities not yet achieved, such as the creation of a strong regulatory body. Under the leadership of the GOU and in close collaboration with all stakeholders, these reforms will continue to improve the access, affordability, and safety of medicines for the Ukrainian population.

Learn more at msh.org/projects/safe-affordable-and-effective-medicines-for-ukrainians/

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