



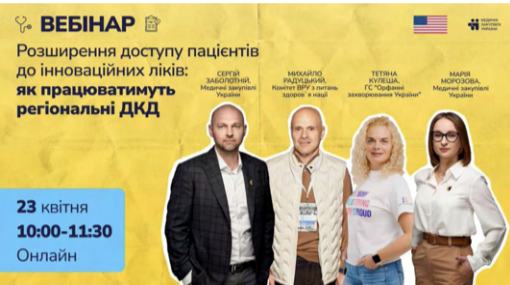
SAFE, AFFORDABLE, AND EFFECTIVE MEDICINES FOR UKRAINIANS (SAFEMed) ACTIVITY

MONTHLY NEWS DIGEST

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UKRAINE SCALES MANAGED ENTRY AGREEMENTS TO EXPAND ACCESS TO INNOVATIVE MEDICINES



The webinar brought together representatives of Medical Procurement of Ukraine, policymakers, and patient organizations to discuss the rollout of MEAs at the regional level.

On April 23, Medical Procurement of Ukraine (MPU), with the support of SAFEMed, convened a national **webinar** on implementation of Managed Entry Agreements (MEAs) at the regional level. The session brought together hospitals, regional health authorities, patient organizations, and policymakers to discuss how the updated model will work in practice, including the legal framework, co-financing mechanisms, and practical steps for regional participation. More than 450 participants joined the session, reflecting strong interest in expanding the mechanism beyond the national level.

Managed Entry Agreements enable governments to negotiate confidential pricing arrangements with pharmaceutical manufacturers, improving access to high-cost innovative medicines while strengthening

financial sustainability. Since the mechanism was introduced in Ukraine in 2022, 24 agreements have been concluded, covering treatments for rare and complex conditions, including hemophilia, spinal muscular atrophy, Gaucher and Fabry diseases, as well as some cancers.

The model has already demonstrated measurable impact. Medicines procured through MEAs reduced projected procurement costs significantly, from an estimated UAH 7 billion (approx. \$175 million) to roughly UAH 3 billion (approx. \$75 million), while expanding patient access to treatment.

The expansion of MEAs to the regional level marks an important evolution in Ukraine's pharmaceutical financing model. Moving beyond a fully centralized approach, the updated framework enables national, regional, and healthcare facility budgets to jointly support access to treatment through shared financing arrangements. The webinar aimed to support the rollout of the new policy by preparing regional stakeholders to apply the mechanism and participate in co-financed procurement. It also highlighted the role MEAs can play in reducing financial barriers to innovative treatment, particularly for patients with complex and high-cost conditions.

As a next step, MPU and SAFEMed will conduct targeted regional visits to assess implementation readiness and provide hands-on technical support.

ADVANCING THE ESTABLISHMENT OF THE UKRAINIAN PHARMACEUTICAL AGENCY THROUGH HIGH-LEVEL TECHNICAL SUPPORT

Ukraine continues advancing the establishment of the Ukrainian Pharmaceutical Agency (UPA), the future national regulator expected to become operational in early 2027 and consolidate key pharmaceutical regulatory functions under a single authority.

The reform is being supported through the European Union Twinning Project, launched last year to help establish the new agency and strengthen alignment with European regulatory standards. Within this framework, SAFEMed continues to provide targeted technical expertise and operational support to advance implementation.

To support the process, SAFEMed established a dedicated multidisciplinary support team embedded within the Ministry of Health. Working closely with national stakeholders, the team supports both institutional development of the agency and advancement of the regulatory framework envisioned under the 2022 Law on Medicines.

Bringing together expertise across legal, coordination, communications, design, finance, and human resources functions, the team strengthens the Ministry's operational capacity to move multiple reform components forward simultaneously and in alignment. The approach combines strategic, technical, and operational support to help translate legislative reform into institutional practice.

A stronger and more predictable regulatory environment is expected to improve access to quality medicines, strengthen confidence in the system, and create more stable conditions for the pharmaceutical sector to operate in Ukraine. To support this process, SAFEMed also facilitates regular strategic Advisory Board meetings on the establishment of the state regulatory authority, creating a structured platform for dialogue among national and international experts. Together, these efforts are helping ensure that the development of the Ukrainian Pharmaceutical Agency is not only technically sound, but also operationally grounded and responsive to broader health system needs.



Deputy Minister of Health of Ukraine Maryna Slobodnichenko with SAFEMed experts and SAFEMed embedded experts that form the multidisciplinary Ukraine Twinning Team, April 2026.

About SAFEMed

The Safe, Affordable, and Effective Medicines (SAFEMed) for Ukrainians Activity is designed to support the Government of Ukraine in its ongoing efforts to reform its health care system and expand access to affordable and reliable medicines. With support from the U.S. Government, the MSH-led project provides technical and legal assistance to strengthen Ukraine's pharmaceutical sector. Our work in Ukraine aims to boost transparency, improve cost efficiency, and strengthen the pharmaceutical supply chain, ultimately leading to better availability and use of essential medicines and health commodities for TB, HIV and AIDS, COVID-19, and noncommunicable diseases. We support the Government of Ukraine in its ongoing efforts to reform its healthcare system in the wake of the war.

MONITORING VISITS IN VINNYTSLIA AND KHMELNYTSKYI SUPPORT ROLLOUT OF THE UPDATED IMMUNIZATION SCHEDULE



Monitoring team during a regional visit in Vinnytsia, assessing implementation of the updated immunization schedule, April 2026.

SAFEMed, in partnership with the Center for Public Health (CPH) and WHO, continues supporting the nationwide implementation of Ukraine's updated immunization schedule through a series of regional monitoring visits. In April 2026, monitoring visits were conducted in Vinnytsia (April 16–17) and Khmelnytskyi (April 23–24), bringing together national and regional stakeholders to review implementation progress and identify operational gaps requiring additional support.

The visits assessed coordination, readiness, and service delivery capacity at both regional and healthcare facility levels. Using a standardized monitoring checklist, teams reviewed implementation of the updated schedule, vaccine distribution systems, cold chain capacity, pharmacovigilance practices, and use of data for planning and decision-making. The visits included regional CDCs, vaccine warehouses, primary healthcare facilities, maternity hospitals, and perinatal centers, providing a system-wide view of implementation.

The monitoring process also identified areas requiring further strengthening, particularly around data management, consistency of implementation across facilities, and practical guidance for frontline health workers. Findings from the visits will inform ongoing rollout and targeted support, helping ensure more consistent implementation of the updated immunization schedule across healthcare facilities nationwide.

SAFEMED MET WITH THE AMERICAN CHAMBER OF COMMERCE (AMCHAM) HEALTH CARE COMMITTEE TO DISCUSS PHARMACEUTICAL REFORM PRIORITIES

On April 3, the SAFEMed team met with members of the American Chamber of Commerce (AmCham) Health Care Committee to discuss ongoing pharmaceutical reform priorities in Ukraine. SAFEMed was represented by Rebecca Kohler, Chief of Party, Serhii Strashuk, Deputy Chief of Party, and technical advisors Anastasiia Shevchuk and Viktoriia Nikulina.

Discussions focused on health technology assessment (HTA), pricing policy, the reimbursement program, the establishment of the Ukrainian Pharmaceutical Agency, medicines verification, and Managed Entry Agreements. Particular attention was given to recent developments in pricing and reimbursement, reflecting their significance for both market stability and the implementation of ongoing reforms.

The discussion provided an opportunity for representatives of the business community to exchange perspectives with the SAFEMed team and raise questions related to current reform processes. Participants expressed interest in continued engagement through upcoming technical discussions and events focused on Managed Entry Agreements and hospital-level implementation. They also emphasized the importance of a predictable regulatory environment for long-term planning, investment, and effective market functioning.

The meeting helped maintain an open dialogue between SAFEMed and private-sector stakeholders while supporting continued engagement around key pharmaceutical reforms shaping Ukraine's health sector.



The meeting took place in a shelter due to the security situation in Kyiv, underscoring stakeholders' continued engagement despite ongoing challenges.

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