

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

MONTHLY
NEWS
DIGEST



OVERVIEW

Our work in Ukraine aims to bolster pharmaceutical governance and financing, contribute to a longer-term plan for pharmaceutical financing, and strengthen rational pharmaceutical management and the pharmaceutical supply chain, ultimately leading to better availability and use of essential medicines, particularly for those living with TB, HIV and AIDS, and noncommunicable diseases. We support the Government of Ukraine in responding to COVID-19 through technical assistance in implementing its national vaccination plan.

THE RUSSIAN INVASION OF UKRAINE DISRUPTED THE LIVES AND WORK OF EVERY UKRAINIAN AND UKRAINIAN INSTITUTION.

The Ministry of Health of the Government of Ukraine and its counterparts quickly adapted to their new reality of meeting the emergency health needs of its population while ensuring continuity of health services. SAFEMed also regrouped and sought to rapidly update its operational mode to provide essential support to key counterparts in line with the project's goals and objectives. The effort of the government and civil society leaders to ensure access to medicines and medical supplies during wartime has been nothing short of astounding. SAFEMed continues to provide technical and logistics support, especially around helping the government be able to safely assess needs and rapidly store and deliver medicines and commodities where they are needed most.

To honor the important work that was underway prior to the War, SAFEMed is sharing this newsletter as a reminder of the Ukrainian Government's deep commitment to establishing transparent, democratic, and equitable health institutions that are in line with European standards and to ensuring access to high-quality, affordable medicines to all Ukrainians. Several important initiatives were underway in February.

Below, we are reporting on the Central Medical Procurement Agency (CPA) work to meet international recognized standards for anti-corruption and several key legislative reforms that are designed to ensure more Ukrainians can access high-quality medicines at an affordable price.

The important work of meeting the health needs of Ukrainians is even more critical in these tragic times and SAFEMed will endeavor to continue offering its technical assistance and sharing important developments in the coming months.



SAFEMED HELPS TO STRENGTHEN ADHERENCE TO ANTI-GRAFT REQUIREMENTS IN MEDICAL PROCUREMENT

SAFEMed is proud to launch the development of anti-corruption feedback system within the framework of its support to the Central Medical Procurement Authority (CPA). The relevant Ethic Control Platform is to become a 24/7 online service designed to send, transfer, process and store signals about potential violations of anti-corruption legislation or ethical norms in the process of implementation of pharmaceutical products procurement procedures with public funds.

Implementation of best international practices and high professional activity standards, in particular, in the area of combating corruption and compliance is one of the CPA's key strategic priorities for 2021-2023. This is the foundation for building effective, transparent, and trust-based partnerships with suppliers, health authorities, and patients.

Anti-corruption mechanisms are reflected in all business processes of the CPA including sourcing and recruitment, due diligence, internal training, approval, and monitoring procedures. Thus, supported by SAFEMed, the CPA started preparing for external certification audit of compliance with the international standard of anti-corruption measures management, ISO 37001:2016.

These anti-corruption initiatives will enable the creation of an effective internal control system, minimize corruption risks within the CPA activities, and contribute to building a transparent and effective medical public procurement system in Ukraine that saves taxpayers' money. This work continues.

STRENGTHENING THE LEGISLATIVE FRAMEWORK FOR ENHANCED PRESCRIBING PRACTICES

SAFEMed, with legal backing from our partner Legal Alliance, is supporting the Ministry of Health of Ukraine (MOH) and the National Health Service of Ukraine (NHSU), in the drafting of new legislation designed to enhance oversight of proper dispensing of prescription medicines in Ukraine and reduce inappropriate self-medication.

The Cabinet of Minister's Decree, "On amendments to License provisions for business activity related to pharmaceuticals"

manufacture, wholesale and retail sale except for active pharmaceutical ingredients" and MOH Orders No.360 and No.490 aim to gradually introduce e-prescribing for pharmacies' dispensing of prescription medication, including antibiotics from April 1, 2022.

These draft regulations are currently available on the MOH official website for public consultation. *(Note: due to the War, these legislative changes have been put on hold)*

FURTHER STEPS TO FORMALIZE HEALTH TECHNOLOGY ASSESSMENT DECISION-MAKING

On January 27, 2022, the Ministry of Justice registered the MOH Order No. 95/37431, "On approval of Procedure for inclusion (exclusion) of medicines in (from) National Essential Medicines List and/or in (from) Nomenclature of medicines procured from national budget for implementation of programs and centralized health measures, applying state health technology assessment health measures, applying state health technology assessment." The order, drafted with the support of SAFEMed together with its partner Legal Alliance, is a major step towards completing full cycle of HTA assessment, appraisal and decision making with respect to access to medicines through public funds. It is based on the Cabinet of Minister's Decree in December 2020, "Procedure for conducting the state health technology assessment", that formalized the use of HTA in Ukraine.

SPECIFICALLY, THIS ORDER APPROVES THE FOLLOWING:



Creation of Expert Committee under the MOH State Expert Center, which will hold the appraisal function.



Establishment of a unified single process, that includes HTA Assessment and Appraisal, for building both the National Essential Medicines List and the nomenclature. Further, it allows for the use of previous year nomenclature as basis and only assesses new inclusions or exclusions to the list.



All medicines procured as part of the 2023 Fiscal Year Nomenclature will be subject to the requirements of this Order.



The MOH will establish a working group to receive recommendations from the SEC (HTA authorized body) and to review and submit final recommendations to the Minister.

When conditions allow, SAFEMed, together with our legal partner Legal Alliance, is ready to support the MOH to draft orders related to the creation, functioning, and membership of the working group. MOH also asked SAFEMed support to amend other relevant orders impacted by these new regulators to ensure a consistent, robust legal framework.

STAY TUNED FOR THE NEXT DIGEST