

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.

SAFEMED SUPPORTING THE 2022 PUBLIC PROCUREMENT CYCLE

Despite Russia's invasion of Ukraine, the Central Procurement Agency (CPA) has successfully started procuring medicines and medical devices under the MOH centralized program public funds of 2022. CPA is authorized to procure 810 INNs under [30 streams](#) for this budget year. Prior to the war, CPA was scheduled to also procure public health medicines such as HIV and TB commodities; however, the MOH later decided to cancel these procurements as donor funding has stepped in to provide emergency commodities. According to the temporary legal changes introduced under martial law, the tendering processes are now conducted through market consultations rather than open tenders. CPA, with SAFEMed support, continues to engage with potential local and foreign suppliers and prepare contract documents to be in line with new procurement protocols. The CPA anti-corruption policy continues to operate under martial law. The set of anti-corruption measures is more intensive than in the pre-war period and includes: conducting anti-corruption inspections in accordance with the CPA SOP "Anti-Corruption Inspection of Business Partners"; implementation of draft sanctions on suppliers, their founders, beneficial owners and producers of their products and restrictions on being on the sanctions lists of the United States and OFAC, Great Britain, the EU, the UN Security Council, the National Security and Defense Council of Ukraine; application of the Four eyes principle, which excludes possible situations in which the decision is made alone.

The CPA-contracted logistics provider, Business Center Farmacia, was not accessible while the Russian forces were still in the Kyiv region. The CPA had full access to its facilities in mid-April, when Russian forces pulled away from the capital city. As a result, CPA was able to accelerate acceptance and distribution of goods procured with 2021 state budget funds. To date, 4 million UAH which is 52% from the procured items have come to the country and an additional 39,14% have been distributed to most regions. SAFEMed is assisting CPA in finalizing the 2021 monitoring report, expected to be completed in late May.

Throughout this unstable period, CPA coordinated closely with all stakeholders, balancing, and optimizing procurement procedures and delivery efforts to regional health authorities while continuing to strengthen its operational capacity to meet the growing procurement and distribution demand of the country during war time.



SEC HTA DEPARTMENT PUBLISHED CONCLUSIONS ON THE HTA EXPERTISE

After a period of inactivity as a result of the war, HTA Department of the State Expert Center (SEC) completed and published conclusions on two industry submitted requests, and submitted their recommendations to the MOH on April 12, 2022.

The medicines are both oral anticoagulants that are used for the prevention of stroke and systemic embolism in select patient groups:



TN - Pradaxa (INN dabigatran etexilate) — capsules 110 mg, 150 mg; (from Boehringer Ingelheim);



ELIQUIS (INN apixabane) — tablets 2.5 mg and 5 mg (from Pfizer).

Both medicines are recommended for inclusion into the national Essential Medicines List (EML) as both are considered within the cost-effective limits compared to available alternatives. The recommendation states that the MOH should consider further epidemiological data to estimate patient numbers and adapt the budget accordingly.

SAFEMed is currently working with its legal partner, Legal Alliance, and the SEC to explore how to make legal amendments to facilitate HTA submissions during the war.

SAFEMed has been supporting the full implementation of HTA in Ukraine for several years and continues to support the improvement of the HTA function technically, legally, and capacity-wise.

SAFEMED CONTINUES TO MONITOR CHANGES IN THE LEGISLATION DURING THE WAR

Key government stakeholders recognized early on the need to adapt the National Reimbursement Program to the context of the war. SAFEMed and its legal partner, Legal Alliance, supported the MOH and the National Health Service of Ukraine (NHSU) to prepare of several legal amendments to reflect wartime needs. These include the following:

DELAY OF EXPANSI

This order states that, *"On approval of the rules for prescribing medicines and medical devices, the procedure for dispensing medicines and medical devices from pharmacies and their structural units, Instructions on the procedure for storage, accounting and destruction of prescription forms (as amended)"*.

ON OF EPRESRIPTION:

to ensure access to medicines for people even as they are displaced or as pharmacies are not fully operational, the MOH delayed a planned introduction of required electronic prescription for all prescribed medicines originally scheduled to launch April 1. An amendment on March 18, 2022 to the MOH order of 19.07.2005 N 360, terminated this requirement.

ENSURE MARKET ACCESS TO MEDICINES:

a Decree of the Cabinet of Ministers decree simplified a number of procedures and requirements for the state registration and circulation of medicines in Ukraine under martial law, as well as approved a number of provisions, which were established on February 14, 2022, by MOH.

The Decree approved on April 15, 2022, №471 states that *"[There are] some issues [with the] of emergency state registration of drugs, medical immunobiological drugs, blood products produced or supplied to Ukraine during martial law, under obligations"*.

The resolution came into effect on April 21, 2022 and will be valid for six months when the end of martial law is declared.



SAFEMed will continue to support any legislation amendments needed to ensure timely access to quality medicines for Ukrainian citizen.

STAY TUNED FOR THE NEXT DIGEST