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# SAFEMed Technical Brief

SEPTEMBER 2023



## STRENGTHENING SUPPLY CHAIN TO ENSURE ACCESS TO LIFE-SAVING HIV/AIDS SERVICES

### BACKGROUND

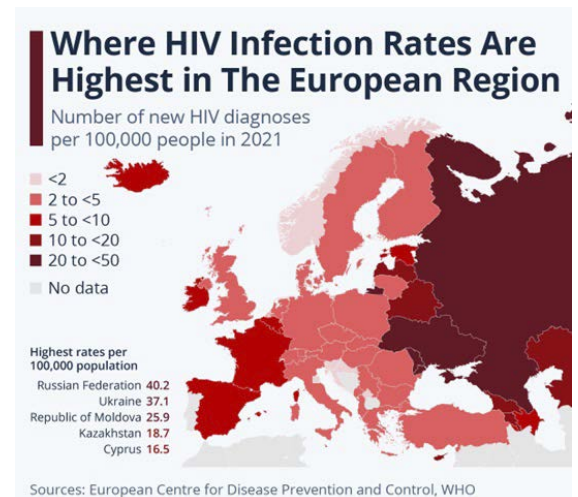
With one of the highest HIV prevalence rates in Eastern Europe and Central Asia, Ukraine has been significantly affected by the HIV epidemic. Approximately 240,000 people are living with HIV, with 150,000 on life-saving antiretroviral treatment (ART)<sup>1</sup>.

Collaboration among government agencies, international organizations, civil society, and affected communities is crucial to ending Ukraine's HIV epidemic, and Ukraine's Center for Public Health (CPH) plays a key role in coordinating and implementing HIV prevention, care, and treatment programs. They work closely with regional AIDS centers, which provide comprehensive care, treatment, and support to people living with HIV (PLHIV), including ART. These centers also offer counseling, testing, prevention services, and harm reduction programs for at-risk populations at the regional level.

Successful HIV treatment depends on a stable supply of antiretroviral drugs (ARVs). Historically, the Government of Ukraine (GOU) contracted international organizations to procure and provide ARVs. However, there has

### 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.



Graphic credit: Statista, 2022

<sup>1</sup>UNAIDS data. <https://www.unaids.org/en/keywords/ukraine>

been a gradual shift toward state procurement by the Medical Procurement of Ukraine (MPU), which is the national agency responsible for procuring medicines and medical supplies that started procuring ARVs in 2021. The primary objective of this transition was to enhance operational efficiency and address previous issues related to inadequate planning and forecasting, which often resulted in frequent emergency delivery requests; additionally, the transition was intended to reduce reliance on external funding sources.



*Health care facility destroyed during the war  
Photo credit: MOH*

As elsewhere, the COVID-19 pandemic disrupted Ukraine’s health care systems and services, including HIV testing and other prevention and treatment efforts. In response, the government’s and partners’ activities in Ukraine have focused on ensuring the continuity of services through telemedicine; home delivery of ARVs; adaptation of prevention programs, such as awareness campaigns shifted online to avoid large gatherings and free pre-exposure prophylaxis (PrEP) delivered directly to the patient; and other innovative approaches. Furthermore, Russia’s full-scale invasion on February 24, 2022 has damaged health care infrastructure; displaced populations; limited access to essential services; and increased reliance on donors to cover the cost of HIV commodities, testing, treatment, and care for affected populations, including those living in conflict zones.



*Joint Ukraine PEPFAR COP23 Co-Planning Meeting and Global Fund National Dialogue (March 13-17, 2023, Warsaw)  
Photo credit: CPH*

## **SAFEMED’S APPROACH**

With funding from the US President’s Emergency Plan for AIDS Relief (PEPFAR), through the US Agency for International Development (USAID), the Safe, Affordable, and Effective Medicines (SAFEMed) for Ukrainians Activity has been working to enhance the GOU’s stewardship of the public supply chain using legal and regulatory reforms; institutionalizing policies and practices; digitalizing public supply chain functions for efficient, transparent decision-making; and reinforcing government health agencies’ technical and operational excellence. SAFEMed’s strategic approach supports the GOU’s and PEPFAR’s priorities by strengthening the health system’s capacity to identify, select, forecast, procure, and distribute health commodities effectively, including for HIV.

## ENSURING THE AVAILABILITY OF RECOMMENDED ARVS

PEPFAR's Country Operational Plans from 2019 to 2023 and updated World Health Organization (WHO) recommendations indicate dolutegravir (DTG)-based regimens as the preferred first-line and second-line treatment for all populations in all countries; SAFEMed has supported the CPH to scale the use of tenofovir/lamivudine/dolutegravir (TLD) to follow the latest recommendations.

### ENGAGING QUALIFIED SUPPLIERS TO ENSURE COMMODITY SECURITY

In 2019, the CPH conducted a joint meeting with PEPFAR, the US Centers for Disease Control and Prevention (CDC), UNICEF, USAID, MPU, SAFEMed, Global Fund, and others about Ukraine's insufficient ARV stock levels, where participants reached a consensus on the need to bring additional generic TLD suppliers to the country. To expedite progress, we supported the GOU to extend the terms of existing fast-track registration certificates for TLD. These actions involved mapping the market and collaborating with TLD manufacturers to promote the registration of ARV medicines as a crucial component of treatment optimization and the TLD transition plan.

Following the mapping and an in-depth analysis of the suppliers, in February and March 2020, SAFEMed contacted three manufacturers who met the selection criteria, namely (1) representative offices in Ukraine; (2) WHO prequalification and US Food and Drug Administration approval; and (3) a local brand portfolio and interest in expanding market share in Ukraine. Individual meetings with two out of three manufacturers took place to encourage accelerated TLD registration in Ukraine and participation in public tenders through the national procurement system, ProZorro.

**IMPACT:** *As a result of these outreach activities, Mylan Laboratories Ltd has registered TLD 30 (30 tab bottles) through the fast-track procedure; moreover, in February 2021, Hetero Labs Ltd received registration of TLD 30 for five years. This was a major milestone in bringing in more options to supply TLD to the country.*

### STRENGTHENING DATA-DRIVEN DECISION-MAKING FOR THE TLD TRANSITION

High-quality supply chain data and product visibility are crucial for accurate planning and forecasting. In Ukraine, supply chain stakeholders participate in the Procurement and Supply Management (PSM) Coordination Group, which is led by the CPH and includes MPU, Ministry of Health (MOH), CPH, Global Fund, USAID, penitentiary sector, 100% Life, Alliance for Public Health, SAFEMed, and other partners. The group, which meets regularly, synchronizes the procurement and supply of pharmaceuticals and health products for HIV and TB funded by both the government and donors. SAFEMed supported the CPH to prepare dashboards and other high-quality materials (e.g., market and legal analysis and solutions) for group members. Dashboards and other visualization tools present the latest data on stock levels, consumption rates, and procurement schedules at PSM meetings, so group members can monitor procurement and supply chain-related risks. Special emphasis was dedicated to the TLD transition to ensure that the process was going as planned and that more patients received the recommended treatment. As visualized in Figure 1 below, the number of patients taking TLD increased significantly from January 2020 (7,125) to December 2021 (84,888), which reflects the successful transition of patients previously on alternate treatment regimens.

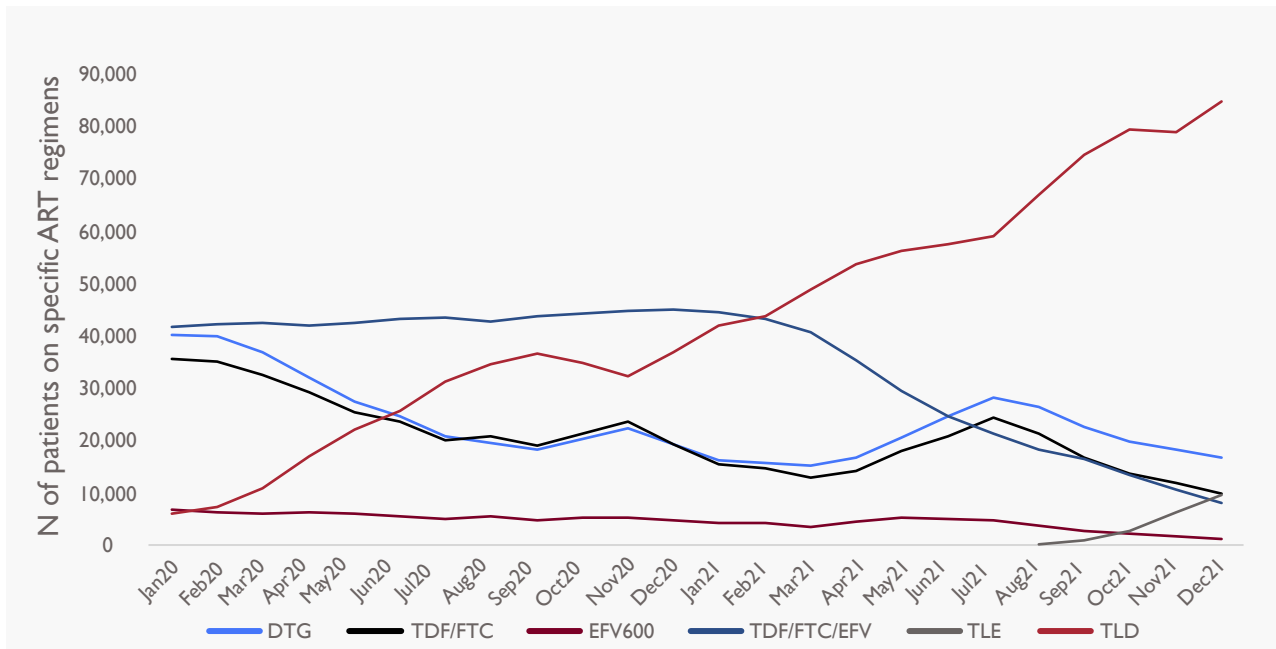


Figure 1. Number of patients transitioning to TLD: 2020-2021

We further triangulated and analyzed logistics and patient data monthly to track the TLD transition and trigger resupply actions to prevent stock imbalances. This helped to guide supply planning for the TLD transition and ensure continuous treatment for patients. Figure 2 shows the estimated number of patients transitioning to TLD, which closely followed the actual number from January 2020 to December 2021.

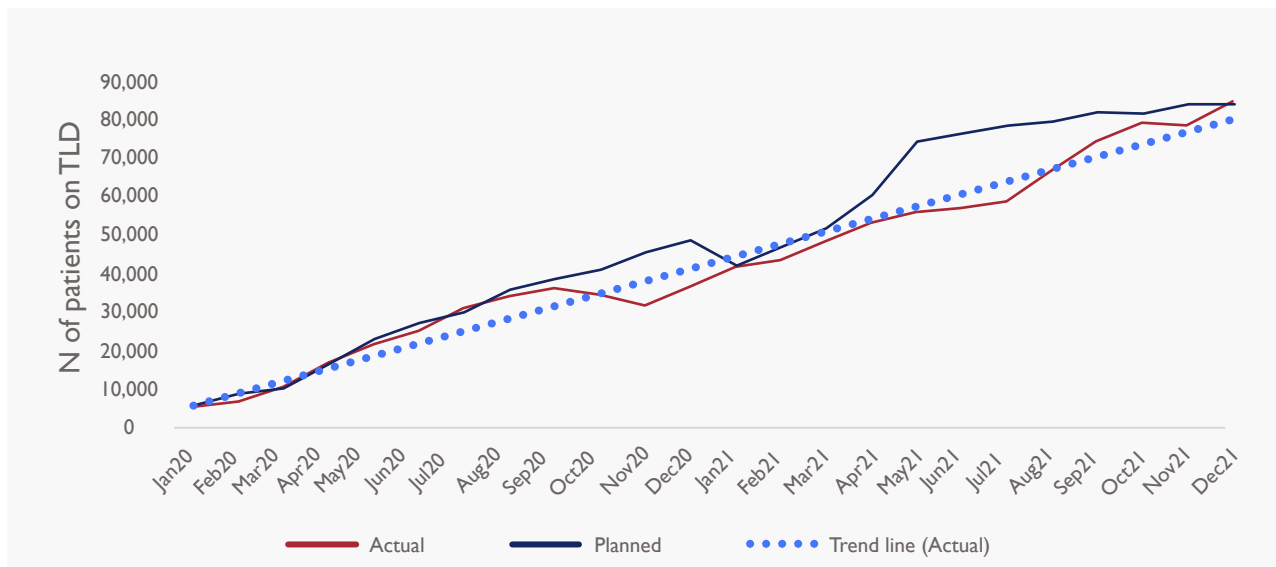


Figure 2. TLD actual vs planned transition progress: 2020-2021

**IMPACT:** By January 2022, all eligible PLHIV undergoing treatment had switched from previous ART regimens to TLD.

## INFORMING DONORS ABOUT HIV COMMODITIES PROCUREMENT

Leveraging our expertise and up-to-date knowledge of procurement and supply chain management for ARVs, SAFEMed frequently offers valuable information and recommendations to donors. These inputs primarily focus on ensuring the accurate quantification of ARV needs and regular stock monitoring at all levels so that adequate quantities are available. By actively engaging with the donors and sharing our expertise, we contribute to the development of robust and responsive procurement and supply chain strategies for ARVs. This collaborative approach prompts the actions needed to meet the treatment needs of PLHIV, especially during the ongoing war in Ukraine. This mainly relates to ensuring the accuracy of country demand calculations to effectively allocate the budget, while donors take care of ARV procurement.

## IMPROVING HIV COMMODITY FORECASTING

Expanded access to rapid HIV testing is essential to improve case-finding and increase patients' access to ART. However, the rapid test kit (RTK) supply chain is fragmented and poorly coordinated, leading to expired kits as well as shortages and stock outs. As a pivotal enabler of improvements to the HIV and TB supply chain continuum, SAFEMed forged intensive collaborations with local counterparts from the MOH, CPH, and MPU that focused on bolstering the CPH's capacity to quantify and forecast ARVs and RTKs. The overarching aim was to rectify ongoing technical problems that had plagued this process and tackle the complicated challenge of collecting accurate data for precise regional calculations.

## DEVELOPING AN ARV QUANTIFICATION TOOL

To rectify the persistent issue of inaccurate demand calculation for ARV supply planning, SAFEMed provided technical assistance to develop a modern e-tool to quantify ARV demand with the potential to add TB, hepatitis C, and medication-assisted therapy commodities. The MOH established a working group in March 2021 to create a roadmap to design and launch the updated ARV quantification tool (Figure 3). MedData, the commodities information and analytical system managed by MPU, was selected to be the master system for the e-tool, ensuring its smooth integration and sustainability. Subsequently, we facilitated a data-exchange agreement between MPU and CPH that included patient regimens, ARV names, stock levels, and drugs dispensed to enable data triangulation for better supply chain planning and risk assessment.

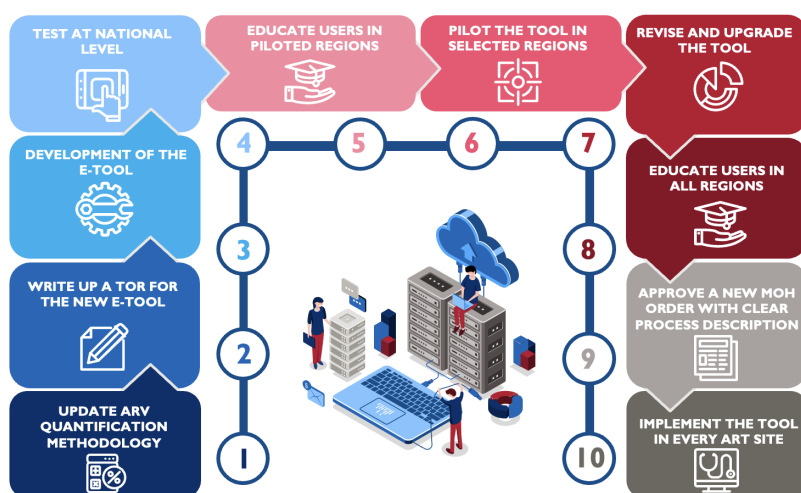


Figure 3. ARV quantification roadmap

The MPU and CPH, supported by SAFEMed, organized two orientations on the tool for six representatives from three regions to gather their feedback on how to make the tool more customer oriented before conducting a final test at the national and regional levels. Crucial next steps are working group approval and a legal framework to support the tool's nationwide use, for which SAFEMed is providing the appropriate legal assistance.

Lastly, we are conducting regional educational events and providing resources to facilitate the adoption of the quantification tool, thereby improving medication management and health care planning.

## ENHANCING ACCESS TO HIV RAPID TEST KITS

To characterize RTK supply chain issues and identify opportunities for improvement, we supported the CPH to assess the tools, processes, and actors involved in RTK demand collection, forecasting, procurement, distribution, and consumption monitoring (Figure 4). The assessment included all RTK suppliers and involved input from all funders and implementing partners including USAID, PEPFAR, CDC, Global Fund, AIDS Healthcare Foundation Ukraine, 100% Life, Alliance for Public Health, and other organizations that provide HIV testing services. SAFEMed interviewed 26 RTK supply and distribution stakeholders and compiled a comprehensive report with important findings and recommendations.

To discuss the assessment results, the CPH and SAFEMed held an online event in October 2022 for more than 25 participants from national and international stakeholders. A major recommendation was to quickly finalize and implement the recently drafted methodology for RTK forecasting. Other recommendations included strengthening routine communication among partners involved in RTK procurement and distribution, conducting a national mapping of the source of HIV RTKs, and unifying reporting of RTK movement in the supply chain.



Figure 4. Objective of HIV RTK assessment

- Assessment of the HIV RTK supply chain system in Ukraine
- Assessment report highlighting best practices, weaknesses and recommendations for improving and strengthening systems.

In line with the recommendations, the CPH carried out a three-month pilot of the methodology in three regions to garner valuable user feedback prior to launching it nationally. We embedded a consultant in each of the three regions to master the methodology, conduct trainings with staff at the pilot health care facilities, and summarize the information they received. The CPH and SAFEMed will analyze the results to determine ways enhance the tool for nationwide use.

## DISTRIBUTING HIV AND TB MEDICINES TO THE LAST MILE

Access to safe essential medicines is critical to an effective health care system. Medicines for several priority health programs, including HIV/AIDS, TB, and viral hepatitis, procured by central government programs, are transported from national warehouses to regional distribution centers where they are stored until last-mile distribution to public health facilities. The distribution of medicines from the regional level to service delivery points (SDPs) is highly variable. To better understand the drivers of this variability, SAFEMed conducted a regional-level landscape analysis of the supply chain systems in 2019, which revealed the following challenges:

- Lack of a systematic approach to distribution.
- No specialized vehicles to transport medicines.
- No budget for logistics in the local budget programs.
- Trips to regional facilities to pick up national program medicines combined with other purposes.
- Compliance with cold chain requirements not monitored – no temperature recording or tracking.
- Substandard warehousing functions, often without qualified personnel to support basic operations.

We identified a way to address these challenges by leveraging the Ukrainian private sector logistics market and supporting the GOU to transition from operating the supply chain to overseeing supply chain services.

## DEPLOYING A PRIVATE SECTOR LOGISTICS SOLUTION

To overcome regional distribution challenges and improve overall supply chain systems for ARVs and TB medicines, SAFEMed initiated an innovative last-mile logistics pilot in Odesa region in 2019. This region was chosen because it had the highest HIV burden. The pilot's goal was to attract the private sector to provide high-quality, cost-effective logistics services to transport HIV and TB commodities from the regional level to SDPs in compliance with Good Distribution Practice (GDP) standards. Figure 5 summarizes the initiative.

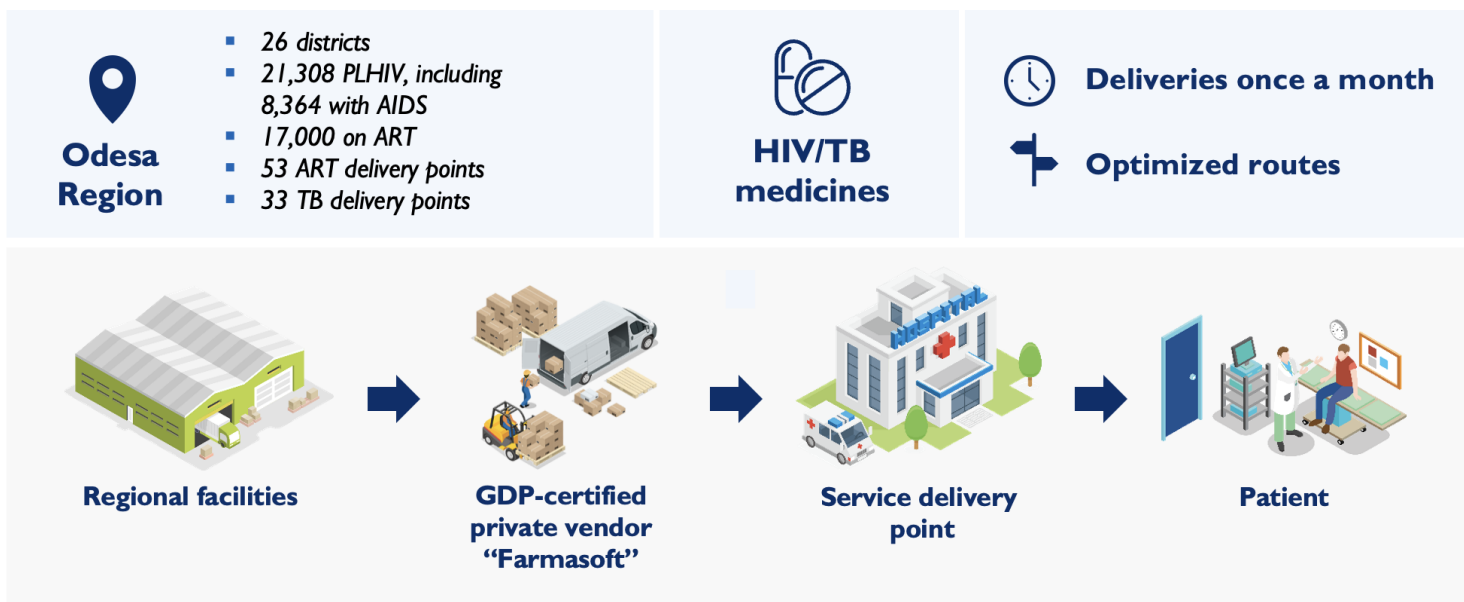


Figure 5. Summary of SAFEMed's last-mile distribution pilot

Fourteen months of deliveries in Odesa region demonstrated the following:

- Transportation quality improved significantly by using specialized transport.
- Supply chain-related workload of specialists in regional health care facilities was reduced.
- Frequency and regularity of HIV and TB commodity deliveries to health care facilities within the region increased.
- Stock levels were optimized because stock outs at the subregional level decreased.
- High level of satisfaction among end-users.

Considering these positive results, the MOH and CPH requested expansion of the pilot to all 25 regions of Ukraine and the addition of viral hepatitis medicines. The private sector logistics companies made their first deliveries in March 2021 in Dnipro, Mykolaiv, and Odesa regions. The following month, Chernivtsi and Luhansk regions received commodities under the extended last-mile activity. The number of regions grew gradually and by the February 24, 2022 attack, 16 regions had been included. Overall, 232 and 174 SDPs received ART and TB commodities, respectively, at least once during the pilot period.

Russia's full-scale invasion of Ukraine has limited the last-mile delivery efficiency, highlighting that while this approach works well during peacetime when planning and delivery schedules are more predictable and frequent, disruptions to logistics services during unrest are significant. However, even in such catastrophic circumstances, nine regions continue to use private sector delivery services for ART and TB commodities (Figure 6).

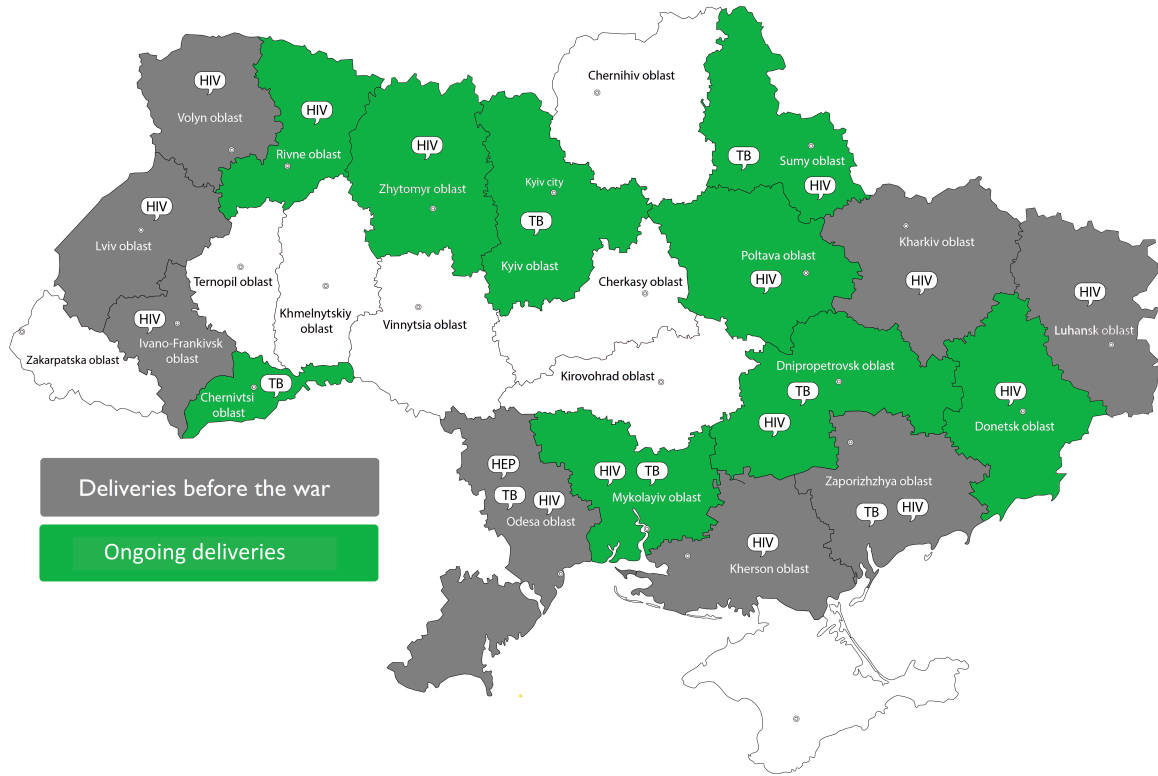


Figure 6. Regions participating in the private sector last-mile delivery program before and after the war

Even with these hurdles, SAFEMed made sure that vital drug supplies were available by making deliveries more frequently than once a month, if required. In frontline regions, local contacts provided invaluable information that was essential in establishing secure and efficient routes to SDPs. During the initiative, the pricing model assumed a fixed price per kilometer and fixed rate per distribution point. Figure 7 shows how the war has affected the average delivery cost per SDP over all engaged regions. We are looking for sustainable transportation models at fair prices for ongoing last-mile delivery services.

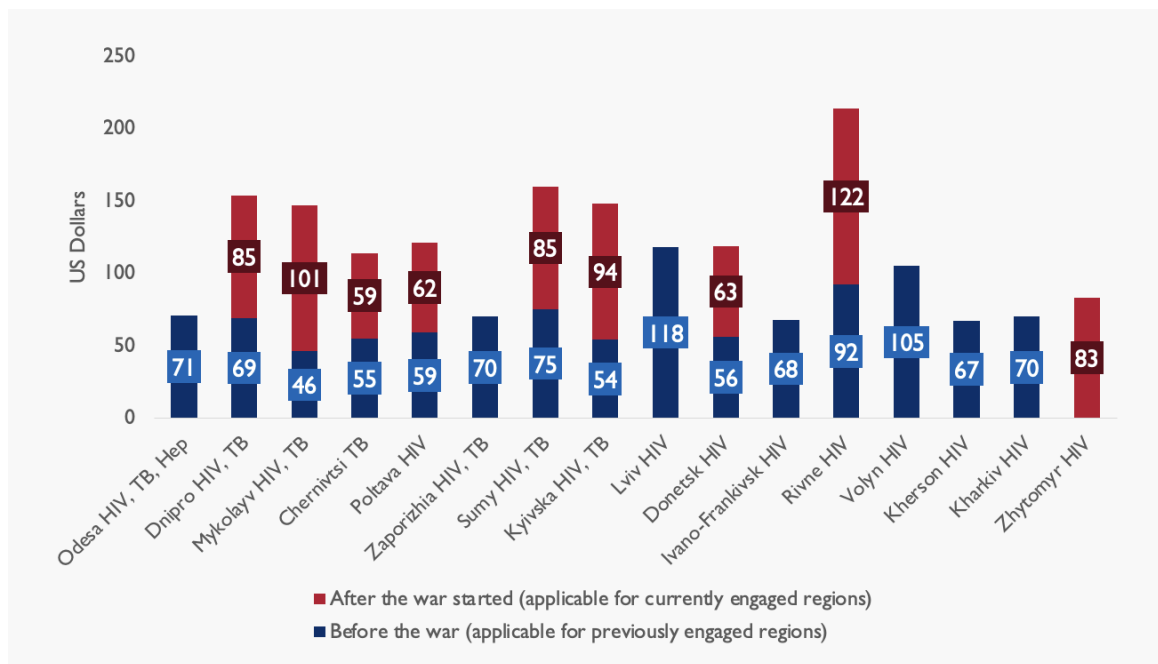


Figure 7. Average delivery cost per SDP (USD) before and after the war



The GOU relies on SAFEMed to support continuous deliveries in the participating regions and to expand to other regions, even during the ongoing war, to ensure that patients access vital medications. The intervention's ultimate objective is to establish a government-funded, sustainable, last-mile delivery system that meets GDP standards. The MOH will likely prioritize the institutionalization of private-sector last-mile logistics for essential commodities once the war is over; therefore, we will continue to evaluate various models for cost-effectiveness. This initiative will provide lessons to develop efficient last-mile logistics services for other critical commodities procured with the state budget.

The last-mile project was recognized globally—the Council of Supply Chain Management Professionals named this intervention as the winner of the 2021 Supply Chain Innovation Award.



**IMPACT:** *The last-mile supply chain solution contributed to the following improvements:*

- *Compliance with GDP requirements along the last-mile distribution route to participating health facilities (i.e., logistics partner meeting GDP standards).*
- *Frequency and consistency of ARV and TB commodity deliveries (mostly monthly) to health care facilities in the region.*
- *Stock levels optimized at regional and subregional levels based on delivery schedule.*

## ENHANCING REGIONAL WAREHOUSE CAPACITY



In November 2020, the MOH asked us to support an independent assessment of how well regional distribution centers' storage of medicines for HIV/AIDS, TB, and viral hepatitis treatment complied with Ukrainian legislation and Good Storage Practice. The findings identified weaknesses in distribution centers' capacity and formed the basis of recommendations for the MOH, CPH, and regional health departments.

SAFEMed and CPH drafted terms of reference, and through an open tender, we selected Kreston GCG to assess Ukraine's 79 regional distribution centers. The CPH, SAFEMed, and Kreston GCG developed a comprehensive checklist to use during onsite visits.

During April and May 2021, Kreston's auditors visited all the distribution centers and reported on their findings and recommendations for improvement. The assessment revealed significant discrepancies in some of the distribution centers' adherence to Ukrainian regulations (Figures 8 and 9).

*Kreston auditor at a regional distribution center in 2021*

*Photo credit: SAFEMed*

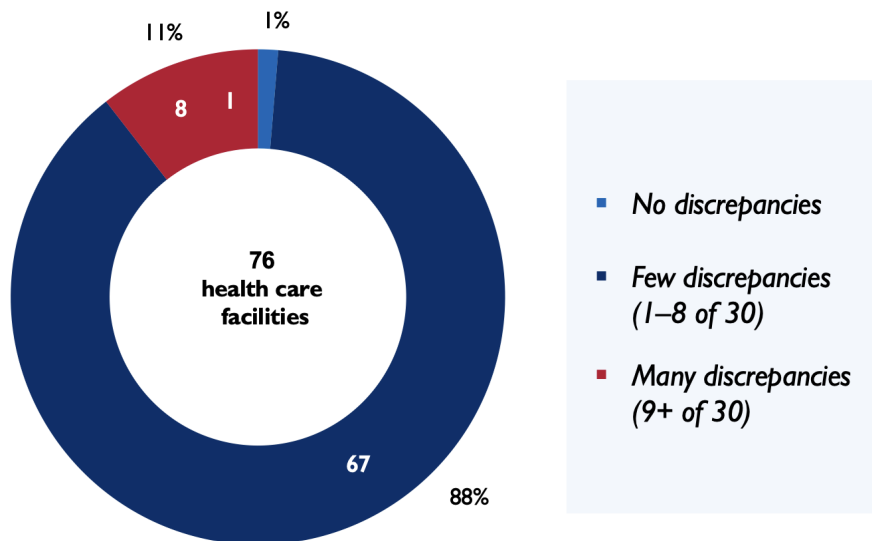


Figure 8. Number of health care facilities by number of discrepancies

**Main findings included the following:**

1. Some centers were not set up to store drugs and were sometimes overloaded.
2. The appearance of surfaces and auxiliary equipment, such as wiring, wall coverings, and ceilings at the drug storage premises did not meet requirements. As a result, these locations could not be cleaned properly.
3. When funding was limited, distribution centers were forced to use obsolete and worn-out equipment, such as household refrigerators and hygrometers.
4. The systems for tracking the shelf life of drugs during storage and shipment according to the FEFO (first expiry, first out) principle were inadequate.

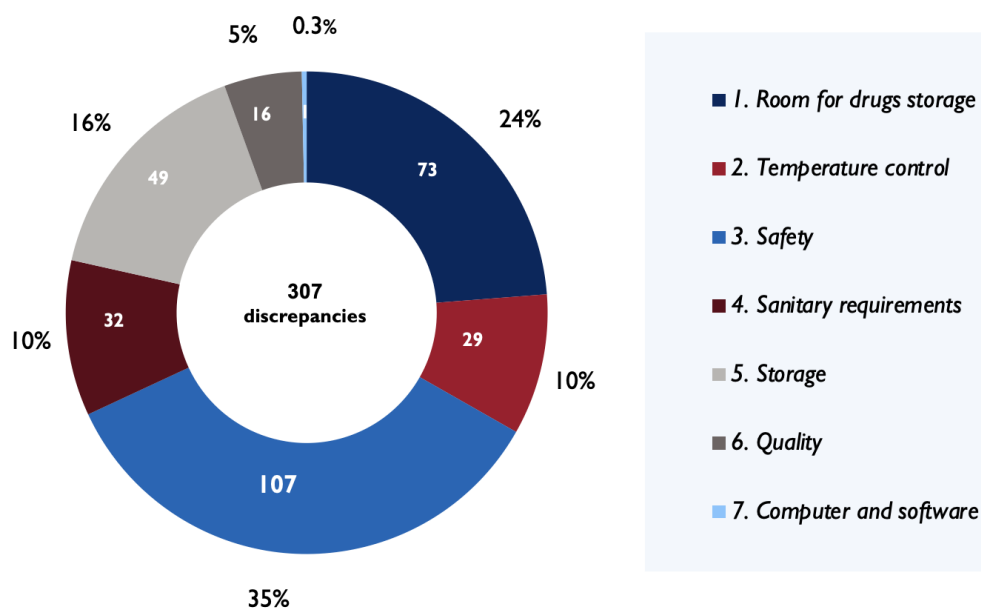









Figure 9. Distribution of centers' discrepancies by criteria.

In September 2021, SAFEMed organized a stakeholder event to disseminate the assessment and plan next steps, then the MOH, with our support, sent the results to the regional health departments and requested that they tackle the deficiencies and report back on their efforts.

**IMPACT:** *The assessment prompted enhancements to regional-level warehousing; according to regional health department reports, actions taken included the following:*

- *Protect medicines from direct sunlight — 10 regions* 
- *Create a schedule for measuring equipment verification in health facilities — 2 regions* 
- *Attain service-measuring equipment — 8 regions* 
- *Equip storage rooms with durable reinforced doors — 6 regions* 
- *Allocate quarantine zones for medicines — 10 regions* 
- *Prepare documentation on security and fire alarm systems — 6 regions* 
- *Equip a center with a computer — 1 region* 

## EXPANDING ACCESS TO ARVS THROUGH PHARMACIES

The initiative to design an innovative distribution model for ARVs and PrEP through private and municipal pharmacies started in early 2020 as a way to promote client-centered differentiated service delivery. SAFEMed's major efforts, including initiating legislative changes and obtaining political support, demonstrated an inventive approach to overcoming barriers and creating a supportive environment for ARV and PrEP dispensing. This initiative will improve geographic access to treatment for PLHIV, increase treatment adherence, decrease patients' financial risk, and in the long term, reduce the burden on the health care system.

The MOH formed a working group to design this new initiative with representatives from the CPH, MPU, National Health Service of Ukraine (NHSU), 100% Life, SAFEMed and others, and the MOH approved the roadmap to develop different models for pharmacies to dispense ARVs and PrEP by e-prescription (Figure 10). SAFEMed is providing significant technical inputs into creating and piloting this new system. A legal analytical note that we supported described two models, with either MPU or NHSU as the process owner; consequently, the working group gave the responsibility to MPU.

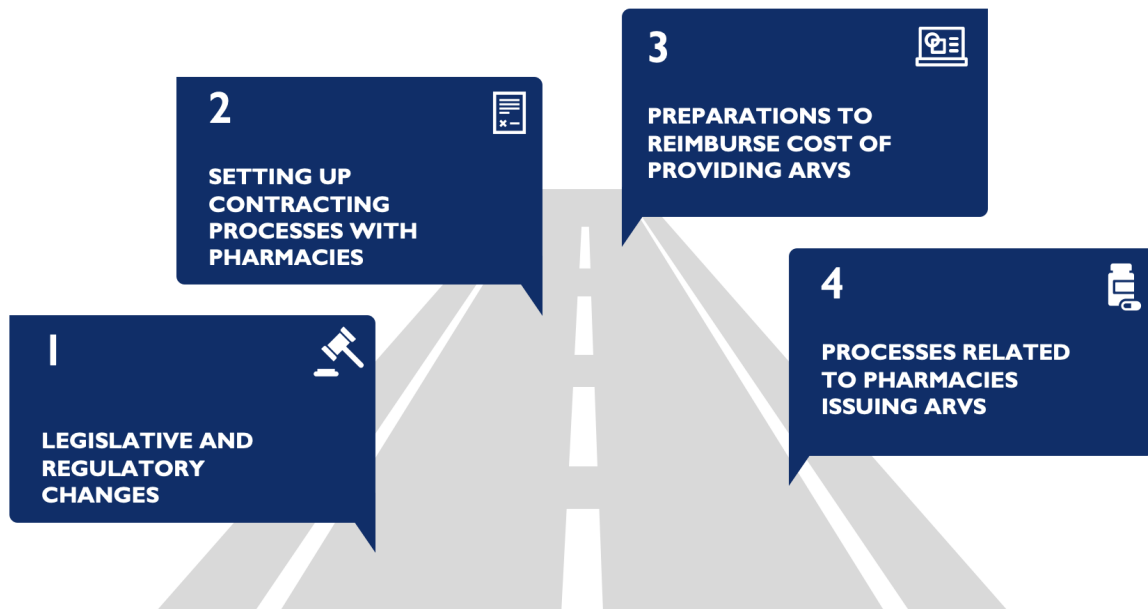
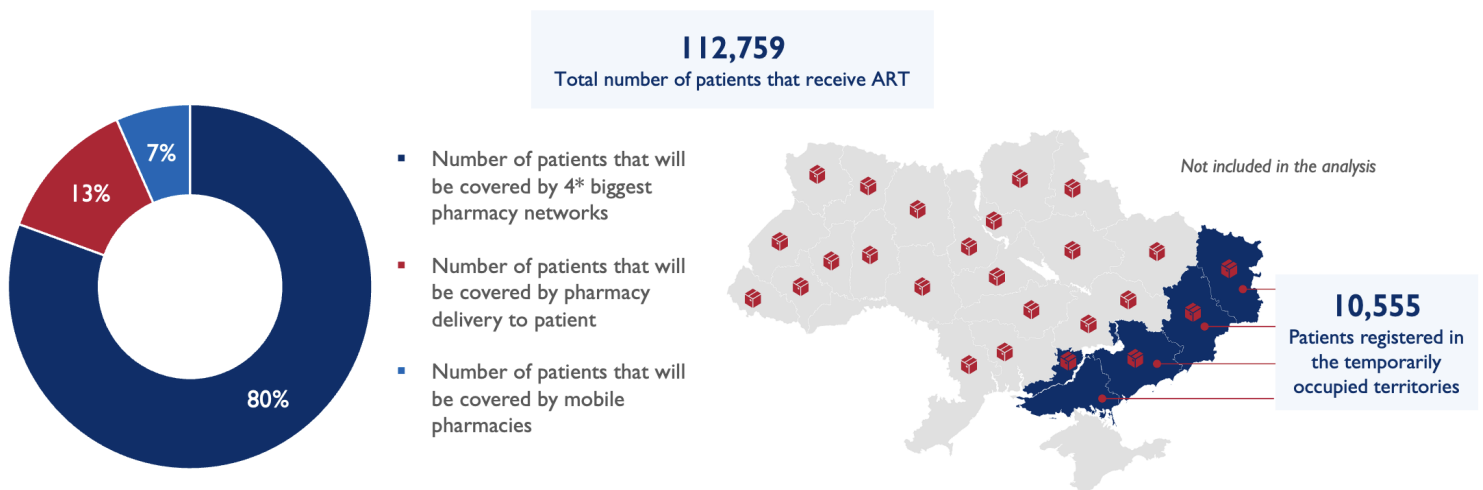


Figure 10. Summary of the roadmap to provide HIV commodities through pharmacies

A pharmacy mapping exercise on patient dispensing within the regions showed the tremendous potential of reaching PLHIV through this dispensing method (Figure 11).



\*. Based on the information provided by Morion, their sales represent over 50% of the total

Figure 11. Results of pharmacy mapping for ART delivery

Besides being an innovative alternative to increase access to these life-saving commodities, this initiative may also serve as a client-centered model to dispense other state-procured (or donated) commodities via new channels that could be especially useful in emergency situations such as an epidemic and the ongoing war.

**IMPACT:** The New Law of Ukraine on HIV lays the legal foundation for dispensing ARVs and PrEP through pharmacies, which is a differentiated service-delivery model that potentially can be applied to improve access and uptake to other life-saving commodities.

## WAY FORWARD

Combating HIV/AIDS and supporting the GOU in achieving the 95-95-95 global goal (i.e., diagnose 95% of PLHIV, provide ART for 95% of those diagnosed, and achieve viral suppression for 95%) by 2030 is one of our top priorities. For this reason, we plan to continue and expand our activities in the following ways:

- Further support the GOU in building a sustainable supply chain and institutionalizing the last-mile delivery model.
- Finalize the electronic quantification tool to collect ARV demand data, legitimize it, ensure that all levels of users are educated on its use, monitor the national rollout, and follow up with regions underutilizing the tool.
- Assist the CPH to pilot, refine, and scale the RTK quantification methodology nationwide.
- Assist the MOH and CPH in developing, piloting, and legitimizing the distribution of ARVs and PrEP through pharmacies.

In partnership with the GOU, SAFEMed will continue to contribute its expertise and resources during the ongoing war and as part of the health care system's recovery plans. For sustained impact, we will continue to leverage our knowledge in areas such as procurement, supply chain management, and capacity building to strengthen Ukraine's HIV program and the health care system overall.

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

*This publication is made possible by the support of the American people through the United States Agency for International Development (USAID), under the terms of contract number AID-121-C-17-00004. The contents of this report are the sole responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government.*

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