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SAFEMed Technical Brief

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STRENGTHENING THE SUPPLY CHAIN SYSTEM FOR THE COVID-19 RESPONSE AND IMMUNIZATION PROGRAM

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.

BACKGROUND

On March 3, 2020, Ukraine confirmed its first case of COVID-19 followed by a countrywide quarantine. The National Headquarters on the COVID-19 Response was launched to organize the country's response measures, including countrywide vaccine rollout. Yet, the Ukrainian public-sector health care and supply chain systems did not have the cold chain and especially ultra-cold chain (-70°C) infrastructure required to store and distribute the Pfizer/BioTech COVID-19 vaccines. Moreover, the Government of Ukraine (GOU) needed reliable information about how many vaccines were being used and how many were needed, which demanded real-time data on immunization rates and vaccine consumption. International partners helped strengthen the COVID-19 supply chain infrastructure and personnel capacity; however, Russia's full-scale invasion of Ukraine in February 2022 seriously curtailed the COVID-19 response, so international partners stepped in to increase support for both COVID-19 and routine vaccine distribution. Central to these efforts was the network of Regional Centers for Disease Control and Prevention (rCDCs), established by the Ministry of Health (MOH) in 2021 as part of a broader move to decentralize government functions to regional administrative units. One critical function of these newly formed regional entities is management of the national immunization program at regional level.

SAFEMED'S APPROACH

As the GOU's medicines and health supply chain-strengthening partner, SAFEMed was perfectly placed to provide immediate technical support to help establish and maintain the programs for COVID-19 and routine vaccinations. Our approach included the following activities:

- Participate in the work of the Ukrainian National COVID-19 Response Task Force
- Engage with the private sector to support COVID-19 vaccine distribution
- Support deliveries of routine vaccines, particularly to war-affected areas
- Strengthen rCDCs' capacity to manage the immunization program supply chain
- Develop a legislative framework to improve vaccine logistics and the immunization program
- Support COVID-19 and routine vaccine data management and use

PARTICIPATE IN THE UKRAINIAN NATIONAL COVID-19 RESPONSE TASK FORCE WORK

As the major government structure responsible for organizing and overseeing the country's COVID-19 control strategy, the National COVID-19 Response Task Force, in its advisory and policy development role, was guided by evidence-based medicine and the latest international recommendations.

During its collaboration with the Task Force, SAFEMed provided the following support:

- Contributed to drafting of the national COVID-19 Vaccination Roadmap.
- Analyzed major COVID-19 epidemic indicators, reported through a regular analytical note to the MOH, and treatment technologies (4 evidence summaries prepared for the MOH).
- In 2020-2021, worked with 645 hospitals in 24 regions and Kyiv city to collect and report data on health product stock levels and needs (mainly personal protective equipment [PPE], essential medicines, and oxygen-related equipment) through the MedData system.
- Supported daily supply chain data monitoring and analysis and prepared information for centralized Cabinet of Ministries (CMU) COVID-19 dashboards (see figure 1) including available stock of PPE, essential medicines, and oxygen-related equipment; hospital bed occupancy; and number of COVID-19 cases (both new and currently managed in hospitals).
- Coordinated the national- to regional-level COVID-19 vaccine supply chain including demand quantification, forecasting, deliveries to regional hubs, and monitoring stock reporting.
- Promoted the effective use of real-time logistics data for decision-making that ensured that vaccines were distributed where they were most needed.
- Provided legislative support related to all COVID-19 activities and contributed to the development of important COVID-19 documents.
- Worked with all national and international counterparts to coordinate humanitarian and supply chain activities, including the US government, COVAX, UNICEF, and the World Bank.
- Collaborated with GOU counterparts to ensure timely deliveries of essential health commodities, including COVID-19 medicines, PPE, and medical equipment such as oxygen concentrators, and later, vaccine supplies across the country.

Moreover, SAFEMed Deputy Project Director, Sergey Strashuk, was appointed as co-chair of the Task Force logistics subcommittee. SAFEMed also facilitated other activities linked to the vaccination campaign, including supporting development of the logistics scenarios that informed the national COVID-19 Vaccination Roadmap

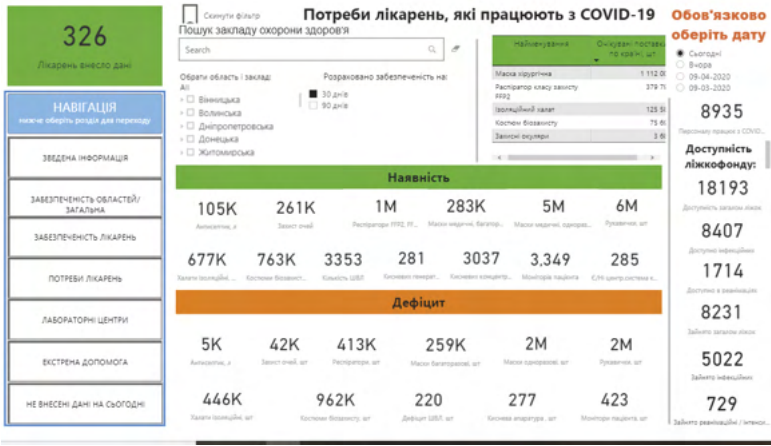


Figure 1. Screenshot of CMU COVID-19 dashboard that used data collected with SAFEMed's support

IMPACT: From June 2020 to March 2021, SAFEMed supported the Medical Procurement of Ukraine (MPU) to procure and deliver 6.15M USD worth of PPE to the regions at a cost of 143,000 USD for logistics services (figure 2).

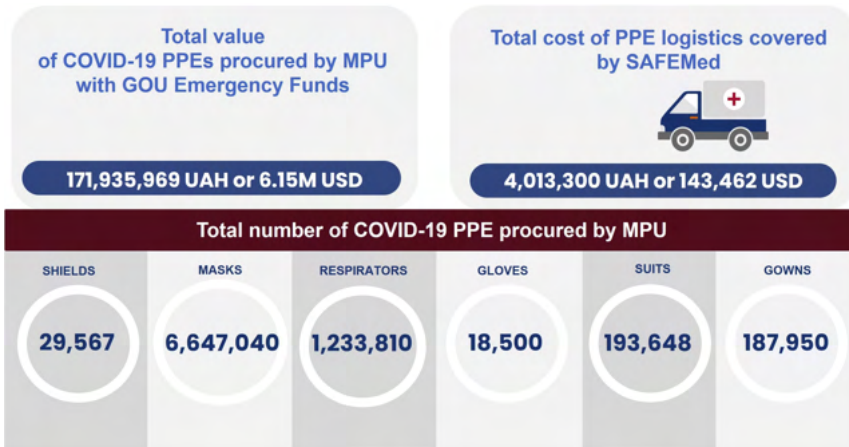


Figure 2. COVID-19 PPE procured and distributed with SAFEMed support: June 2020–March 2021

ENGAGE WITH THE PRIVATE SECTOR TO DISTRIBUTE COVID-19 VACCINES

Due to limited government capacity in the storage and distribution of products that require ultra-cold supply chain conditions, SAFEMed supported the MOH in distributing COVID-19 vaccines, especially those with strict temperature requirements. In 2021, SAFEMed contracted Farmasoft, a private logistics company, to provide warehousing and distribution services from central to regional level for the Pfizer/BioNTech COVID-19 vaccine. SAFEMed in collaboration with Farmasoft and UNICEF trained staff of the regional warehouses in the primary ultra-cold supply chain requirements and operational steps to manage this type of vaccine, and following that, contributed to the development of a standard operation procedure (SOP) for distributing COVID-19 vaccine with ultra-cold supply chain requirements. Subsequently, the GOU was able to cover logistics expenses to distribute the majority of COVID-19 vaccines, even those supplied by donors.



Airport staff unload a shipment of vaccines at the Kyiv international airport in May 2021

Photo credit: UNICEF/Ukraine

IMPACT: Since the beginning of SAFEMed’s vaccination distribution support from April 2021 through September 2024, SAFEMed ensured logistics services for 4,813,338 doses of COVID-19 vaccines.

Further, the logistics procedures that SAFEMed and Farmasoft developed for use in project-supported deliveries later became the standard approach used to distribute the Pfizer/BioNTech COVID-19 vaccine procured by state funds, a demonstration of the institutionalization of the project’s support.

DELIVER ROUTINE VACCINES DURING WARTIME

Following Russia’s full-scale invasion of Ukraine in February 2022, the MOH tapped SAFEMed with Farmasoft to support the storage and delivery of routine vaccines. To maximize distribution efficiency and cost-effectiveness, SAFEMed and partners developed a regular vaccine delivery schedule, combining several products in one shipment — and most importantly — created a national safety stock requirement to quickly deliver vaccines to regions in critical need and minimize the need for redistribution.

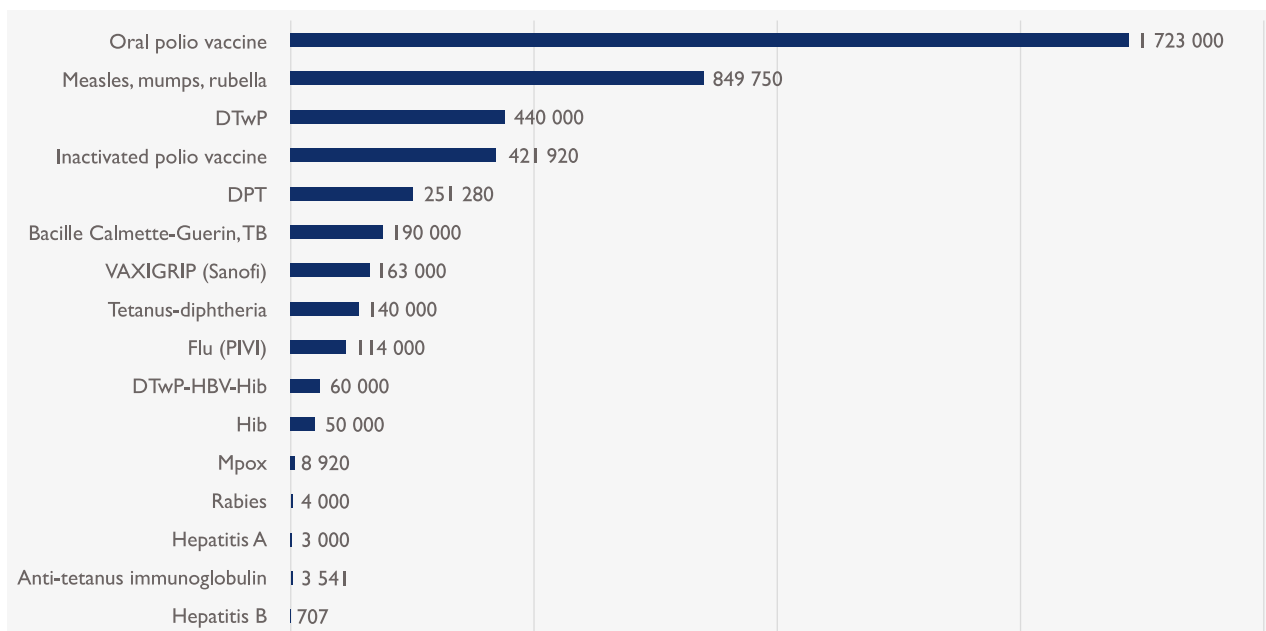


Figure 3. Delivery of routine vaccines to regions (N of doses): February 2022–September 2024

IMPACT: In addition to delivering COVID-19 vaccines that required an ultra-cold supply chain, SAFEMed’s support enabled the distribution of 4,877,848 routine vaccines from February 2022 to September 2024; for instance, urgently needed MMR vaccines were distributed as part of a catch-up campaign in July 2023 that covered more than 153,000 children who missed their vaccination due to the war. See figure 3.

STRENGTHEN RCDCS' CAPACITY TO MANAGE THE IMMUNIZATION PROGRAM SUPPLY CHAIN

With the establishment of 25 rCDCs in 2021 and the MOH decision to shift immunization responsibilities to them from regional departments of health, the government prioritized efforts to strengthen their ability to conduct this new mandate. SAFEMed began its capacity strengthening support for the broader immunization program in 2022.

ASSESS RCDCS' READINESS TO ASSUME IMMUNIZATION PROGRAM FUNCTIONS

Working closely with the MOH and Center for Public Health (CPH), SAFEMed drafted a checklist to assess the rCDCs' readiness to take over the immunization program with valuable inputs from the State Expert Center, World Bank, and the USAID/Public Health System Response and Recovery (PHS R&R) Activity. The checklist, which the rCDCs used for self-assessments, had a section to track the transition progress and a section on warehousing and logistics. Responses from all rCDCs were collected through an online platform in December 2022 achieving a 100% response rate. A follow-up assessment took place in March 2023 to track rCDC progress.

The results of the second assessment revealed that overall, the average score for transition progress increased from 5 to 7 out of 12, but that four regions still needed more preparation to take on immunization functions (figure 4). After additional efforts on the part of rCDCs to address remaining gaps, by September 2023, all 24 rCDCs reported to the MOH that they had fully operational immunization departments and warehouses to store and distribute vaccines at regional level.

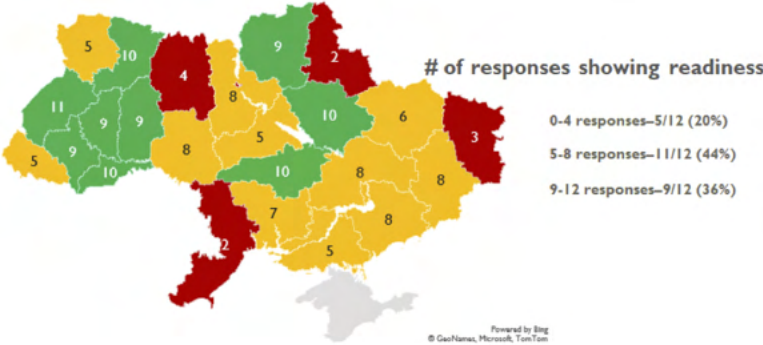


Figure 4. rCDC immunization readiness scores for follow-up self-assessment by region: March 2023 (n=24)

The initial rCDC assessments indicated weaknesses specifically in cold-chain storage; therefore, in April-May 2023 SAFEMed coordinated with UNICEF to support the MOH and CPH to determine cold-chain equipment capacity at 24 rCDCs and 2 national warehouses. The goals were to define rCDCs' capacity to store at least six months of vaccine stock and identify investments needed in the regional and national cold supply chain infrastructure to store vaccines safely. SAFEMed used demand quantification data to estimate the number of months' worth of vaccines needed to meet the projected need and compared it with available cold-chain equipment at the rCDCs and warehouses. Figure 5 shows that all but two rCDCs had adequate cold-chain equipment to store six months of stock.

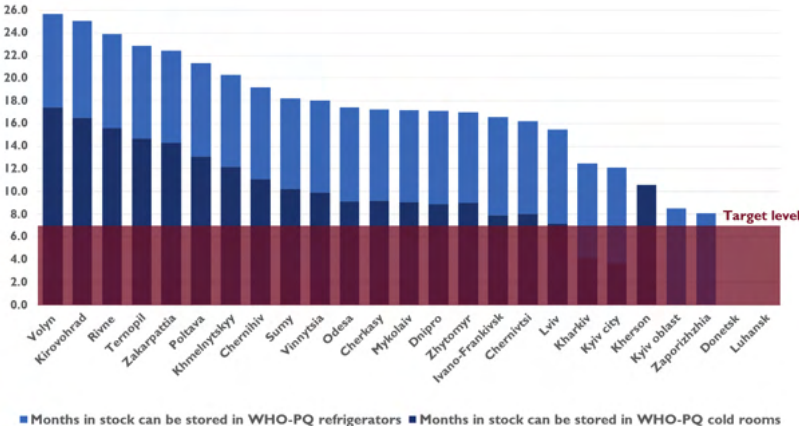


Figure 5. Adequacy of cold-chain equipment to meet estimated vaccine storage needs (n=25) as of May 2023

DETERMINE RCDCS' COMPLIANCE WITH NATIONAL DISTRIBUTION LICENSING REQUIREMENTS

As rCDCs took on this new function, the MOH needed to understand if rCDC warehouses could appropriately store and distribute vaccines given the existing strict distribution licensing requirements in the country. SAFEMed supported the MOH and the State Medicines and Drug Service to conduct a detailed analysis of the warehousing licensing conditions designed to inform amendments to CMU Decree No. 929 regulating license conditions to accommodate rCDCs' unique functions.

After the extensive assessment of rCDC compliance, research on current legislation, and consultation with other stakeholders, the MOH decided that rCDCs' warehouses can store and distribute vaccines effectively by following different regulations that detail the storage practices requirements for health facilities. Consequently, the MOH tapped SAFEMed to draft SOPs and a checklist to provide rCDCs with robust instruments to establish a proper quality control system, and to regularly assess their compliance.

Drawing from existing SOPs from several rCDCs, the national good storage and distribution practice guidelines, and those of a certified logistics provider with extensive experience in vaccine distribution, SAFEMed prepared the following SOPs:

- Accepting and dispatching vaccines
- Storing vaccines
- Transporting vaccines from rCDC warehouses to subregional hubs and health facilities
- Following an action plan during emergency situations

SUPPORTING CAPACITY-STRENGTHENING ACTIVITIES AT THE REGIONAL LEVEL

In 2021, SAFEMed partnered with regional authorities to recruit and support 24 logistics coordinators for up to one year to work within small regional response teams established to coordinate the scale-up of COVID-19 vaccine distribution at regional and subregional levels. SAFEMed provided technical assistance and supervision to the coordinators on vaccine distribution and designed capacity-building activities to bolster their pharmaceutical management skills.

In August 2023, SAFEMed presented at a two-day national training on cold-chain equipment and vaccine management hosted by UNICEF to equip rCDC personnel with additional knowledge and skills to manage the vaccine supply chain. SAFEMed also joined UNICEF-supported regional one-day training in October and November 2023 for relevant health care professionals on types of cold-chain equipment, temperature monitoring, vaccine handling, data management, and the related legislative framework.



Cold storage room at a Zhytomyr rCDC

Photo credit: SAFEMed

At the same time, SAFEMed experts visited regional warehouses used for vaccine distribution to explore how rCDCs equipped their warehouses and used new equipment. The main concerns arising from these visits include the following:

- Regions used cold-chain equipment for storing and transporting vaccines differently.
- Many health facilities lacked sufficient cooling bags and data loggers.
- Some health facilities still use household refrigerators for storing vaccines, which does not follow World Health Organization (WHO) and UNICEF recommendations.
- Regions struggled with maintenance and repair for newly supplied cold-chain equipment.
- rCDCs tracked vaccine stock levels using Google sheets, which resulted in poor data quality and hampered supply planning.

DETERMINING OPTIMAL MODELS FOR LAST MILE DELIVERY OF VACCINES

In line with the GOU's vision for decentralization and building on the rCDCs' new role in managing vaccine distribution, the MOH and CPH tapped SAFEMed to design an 11-month pilot to test alternative logistics services models to determine the optimal and cost-efficient model to institutionalize last-mile delivery and protect vaccine quality and safety. In June 2024, SAFEMed, the MOH, and CPH launched the pilot program in 13 regions. As figure 6 illustrates, Model 1 (six regions) delivers vaccines from the rCDC warehouse directly to the service delivery point and Model 2 (seven regions) delivers vaccines from the rCDC warehouse to a subregional warehouse and then to the service delivery point. SAFEMed will analyze the different financing options and make recommendations to the CPH to ensure better budget planning and more accurate estimates of the country's expenses when it introduces new vaccines.

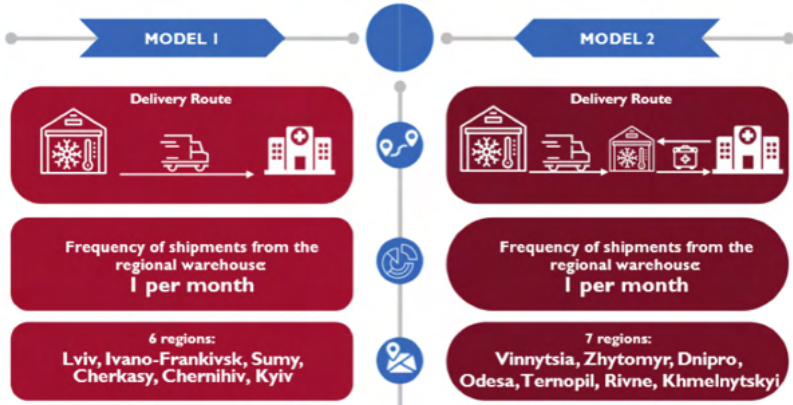


Figure 6: Design of last-mile vaccine distribution pilot study

Joint Implementation Across USAID Implementation Partners

SAFEMed and the PHS R&R project joined efforts to develop and deliver a training for trainers' program for rCDCs and health facility staff on managing the national immunization program. SAFEMed designed and led the pharmaceutical and cold-chain management modules. The project partners developed a set of educational materials that included program briefs describing key learning objectives, learning methods, and content outline and guides for trainers with instructions and a step-by-step approach to delivering training on cold chain and pharmaceutical management and prepared a slide deck for regional trainers to use during cascade training in the regions. The trainers' training took place in October 2024.

IMPACT: In 2023, SAFEMed supported training and monitoring visits to five regions (Cherkasy, Khmelnytskyi, Kyiv city, Ternopil, and Zhytomyr) with approximately 220 participants.

DEVELOP LEGISLATIVE FRAMEWORK TO IMPROVE VACCINE LOGISTICS AND IMMUNIZATION PROGRAM

From the beginning of the COVID-19 pandemic, SAFEMed supported the analysis and development of policies, protocols, standards, and legal acts needed to improve regulation of the vaccine supply chain and increase patient access to effective and safe products. For example, SAFEMed took a leading role in the development and approval of the MOH order that introduced the COVID-19 Vaccination Roadmap. This document outlined key approaches to efficiently provide COVID-19 vaccines to the Ukrainian population. In addition, SAFEMed worked with the MOH to draft amendments to the Ukrainian law on medicines allowing the GOU to indemnify vaccine producers from potential adverse events related to receiving the vaccination.

SAFEMed focused its legal assistance on the transfer of immunization responsibilities to the rCDCs by helping to draft a CMU decree passed on May 12, 2023 that codified the transfer and was a critical milestone in making rCDCs fully functional in the vaccine supply chain area and an MOH order that specified the process, roles, and responsibilities of distributing vaccines from the national level to service sites. Additionally, SAFEMed helped the MOH and CPH to draft an MOH order that defines and regulates vaccine management functions other than supply chain management. SAFEMed also made efforts to ensure a strong legal framework for vaccine data management.

IMPACT: *By June 2024, SAFEMed’s assistance in the development and adoption of eight legal acts created an effective legislative framework for improving the vaccine supply chain system. In addition, the new legal acts will crystalize national- and regional-level stakeholders’ responsibilities in vaccine data management including reporting and analyzing information on vaccination coverage, stocks, and consumption; and training health care staff on vaccine and cold-chain management. These comprehensive changes will strengthen the GOU’s overall coordination of the National Immunization Program and reinforce efforts to control vaccine-preventable diseases.*

SUPPORT COVID-19 AND ROUTINE VACCINE DATA MANAGEMENT AND USE

Since the beginning of the COVID-19 pandemic, SAFEMed has assisted the MOH and CPH in promoting quality data management and effective data use, relying on the national MedData system (developed and managed by MPU with SAFEMed’s support), to ensure access to real-time information that is crucial to make good decisions on the health commodity supply chain.

MEDDATA: MedData, a national demand-planning tool for collecting real-time stock information, was adapted to support the COVID-19 program. The system was used to track daily stock of PPE, essential medicines, and medical equipment from 645 hospitals that managed COVID-19 patients across all 24 regions of Ukraine and Kyiv city. Later, SAFEMed supported the development of the COVID-19 vaccine stock monitoring module. The system made high-quality information available to support decisions on demand and supply planning, minimize human error during data entry in facility-level management information systems, and streamline data exchange between the eHealth central database, DIIA¹, and other electronic services.

COVID-19 VACCINE REGISTRY: Before the national COVID-19 vaccination campaign began, the GOU authorized the creation of a national electronic registry of information about COVID-19 vaccines in Ukraine that was used to issue internationally recognized vaccination certificates and ensure data flow among government agencies. It includes information such as manufacturer, dosage and administration, authorization for use in Ukraine, and WHO/US Food and Drug Administration/stringent regulatory authority approvals. In May 2024, MPU with SAFEMed’s support upgraded the COVID-19 Vaccine Registry and modules for monitoring stock data, which are part of MedData, to incorporate other immunobiological products. This update enables interoperability with the WHO Global Health Records Trust Network, which allows the MOH to confirm citizens’ and noncitizens’ vaccination status and minimize the risks of fraud and medical record falsification. Additionally, the new modules to track vaccine stock at all levels of the supply chain system will facilitate more effective demand quantification and forecasting for vaccines that will lead to better use of scarce budget resources.

UKRVAC DATABASE: In November 2022, the MOH asked SAFEMed to analyze the functionality and effectiveness of the CPH UkrVac database that is used to collect routine immunization supply chain and vaccination rate data. The analysis revealed several major drawbacks including an imprecise data collection method, lack of online availability, and

¹ A mobile application for Ukrainians to access digital documents, such as their COVID-19 vaccination certificates.

incompatibility with other MOH systems. Therefore, SAFEMed proposed expanding the COVID-19 Vaccine Registry within MedData to include vaccines for routine immunizations, modifying MedData’s stock reporting module, and developing new reporting templates for monitoring vaccination rates. The MOH supported these recommendations, and SAFEMed consulted with MOH, CPH, and WHO representatives in December 2022 to discuss the new modules’ functions and general barriers to effective vaccine data management as well identified priority activities, resources needed to implement them, and their expected results.

ANALYTICAL DASHBOARDS: In 2024, SAFEMed developed analytical dashboards that make vaccine procurement and distribution decisions by national and regional health managers easier by providing useful insight into vaccine consumption, forecasting, and availability at the regional and facility levels (figure 7). The dashboards give users high-quality information that enables them to identify changes, outliers, and trends; make better use of vaccine stock; and quickly mitigate stock-out risks.

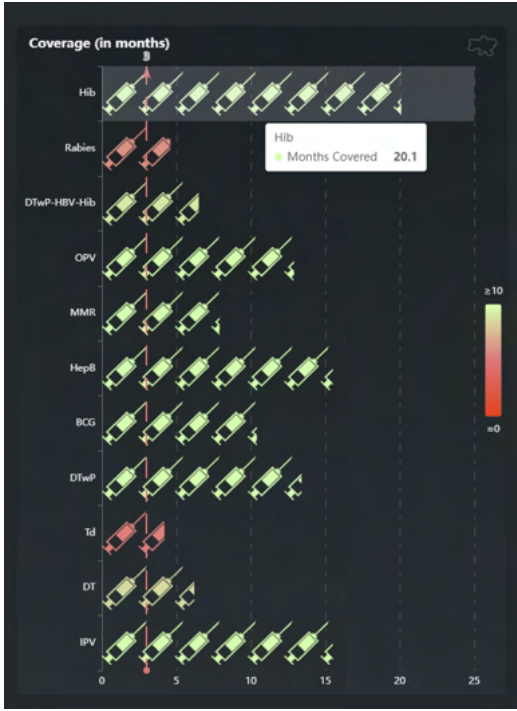


Figure 7. Example of dashboard with information on vaccine use and availability

IMPACT: SAFEMed helped lay the foundation for an effective vaccine data management system with increased availability of quality information that can empower stakeholders to make better decisions on supply planning for COVID-19 and routine immunizations. These data management enhancements made it possible to achieve in-country and international system interoperability and streamlined data exchange with EU countries, preparing Ukraine to meet EU information system interoperability requirements and roll out vaccine management global best practices.

Timely Data to Make Lifesaving Vaccines Available

SAFEMed routinely provided information that the MOH and counterparts used to follow the National Vaccine Roadmap and ensure access to lifesaving COVID-19 vaccines by:

- Preparing and regularly updating analytical notes and presentations for the MOH that visualized up-to-date information on stock availability, demand quantification results, the supply pipeline, and critical logistics issues requiring immediate action.
- Bolstering the MOH’s communication with the donor community and helping to generate solutions to avoid vaccine stockouts and optimize vaccine consumption.

In November 2022 and August 2023, when vaccination rates dropped—producing an overstock of Pfizer/BioNTech vaccines at risk of expiration—SAFEMed initiated and supported the MOH in communicating with the Pfizer office in Ukraine about extending vaccine shelf-life for 12 months.

More than a million COVID-19 vaccine doses were saved from expiration.

NEXT STEPS

SAFEMed continues to support the MOH and the CPH to build a sustainable supply chain system for COVID-19 and routine vaccines as well as to develop proper business processes in managing the immunization program. In 2025, SAFEMed will focus on the following activities:

- Roll out the new modules for monitoring vaccine stock levels and consumption rates at the regional and facility level and develop final versions of analytical dashboards that will inform CPH's decision-making in procuring and distributing vaccines.
- Conduct a national landscape analysis of cold-chain equipment capacity.
- Provide financial support for private logistics services for COVID-19 vaccine distribution.
- Complete the pilot for last-mile vaccine distribution and recommend the most cost-effective model to institutionalize logistics services that deliver vaccines to service delivery points.

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

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