SAFEMed Activity Quarterly Progress Performance Report

Safe, Affordable, and Effective Medicines for Ukrainians (SAFEMed) Activity PY4 Q1 Quarterly Report (1 October 2020–31 December 2020)

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I. ACRONYMS AND ABBREVIATIONS

ARV  antiretroviral drug
CMU  Cabinet of Ministers
CPA  Central Procurement Agency
CPH  Center of Public Health
DTG  dolutegravir
EML  essential medicines list
EMVO  European Medicines Verification Organization
EU  European Union
GDP  good distribution practices
HTA  health technology assessment
INN  International Nonproprietary Name
IT  information technology
MAT  medication-assisted therapy
MEA  managed entry agreement
MIS  management information system
MOH  Ministry of Health
MSH  Management Sciences for Health
NHSU  National Health Service of Ukraine
PEPFAR  President’s Emergency Plan for AIDS Relief
PPE  personal protective equipment
PPP  public-private partnership
PrEP  pre-exposure prophylaxis
PY  project year
SAFEMed  Safe, Affordable, and Effective Medicines for Ukrainians (Activity)
SEC  State Expert Center
SWG  small working group
TLD  tenofovir/lamivudine/dolutegravir
UAH  Ukrainian hryvnia
USAID  US Agency for International Development
WHO  World Health Organization
II. CONTEXT UPDATE

Ukraine has continued to experience political, security, and economic challenges this reporting period. The country has witnessed several momentous economic downfall events, including the rising prices for gas and the Ukrainian hryvnia (UAH) devaluation. The Government undertook key reforms, including carrying out significant fiscal consolidation, moving to a flexible exchange rate, reforming energy tariffs, and social assistance that enhances the transparency of public procurement, continue with health and pension reforms, and establish anti-corruption agencies.

The health care and procurement systems in Ukraine continue to undergo a variety of broad reforms aimed at breaking the status quo and fighting corruption. As part of the Ministry of Health’s (MOH) plan to transition the procurement of 28 centralized programs from international organizations, the newly established Central Procurement Agency (CPA) of Ukraine is in the spotlight as it races to procure and execute contracts for 14 of those programs, which account for 485 medicines and medical devices, in a timely manner. Even with more than 3 billion UAH in savings to date, changes to the MOH administration and its agencies bring uncertainties and shifting priorities. It will take additional time and effort to create a common understanding and vision among key stakeholders to pave a measurable path forward that will continue to build on and solidify health care reforms in Ukraine.

In late December 2020, the Ukrainian MOH published the “National plan for the introduction of a vaccine against the coronavirus disease COVID-19” and took steps to contract with available vaccine suppliers. On December 29, the CPA used some of the funds it had saved to contract with Sinovac Biotech for 1,913,316 doses of the COVID-19 vaccine, and the first shipment of 700,000 doses is scheduled to arrive before the end of March 2021. The first steps of the Ukrainian vaccination deployment campaign made in 2020 will have a tremendous social and political impact in 2021.

Ukraine’s fight against COVID-19 has resulted in a statement from the Office of the President that they are considering refocusing the medical reform as it currently stands bringing a halt to Phase 2 of the reform, namely the reform of the hospital sector. The lack of trust in public institutions remains a fundamental concern for most people, and surveys reveal that many individuals feel that corruption is widespread—from the financial sector to health care—and that oligarchs continue to dominate the economy.

Lastly, at the end of 2020 the State Expert Center saw a change in leadership as Tetiana Dumenko stepped down and Mykola Babenko was appointed as the new head of the organization. However, Mr. Babenko is also very supportive of health technology assessment (HTA) and has pledged to continue Tetiana Dumenko’s legacy of establishing an independent HTA agency in Ukraine.
III. EXECUTIVE SUMMARY

A. Key Narrative Achievements

SAFEMed is a five-year (September 2017–September 2022) US Agency for International Development (USAID) activity in Ukraine and is implemented by Management Sciences for Health (MSH), a US-based organization. It aims to improve transparency and cost-efficiency of pharmaceutical public procurement that will foster increased access to safe, affordable, and quality medicines for Ukrainians. In pursuit of our goal and through close collaboration with the MOH, National Health Service of Ukraine (NHSU), CPA, Center of Public Health (CPH), and State Expert Center (SEC), SAFEMed is guided by three project objectives:

1. Strengthen governance within the pharmaceutical sector of Ukraine
2. Optimize the financing of the pharmaceutical sector
3. Increase the availability and appropriate use of medicines in Ukraine

All project activities are implemented via technical, financial, and legal assistance in the work streams of procurement, reimbursement, priority settings, and supply chain as well as quality assurance with a focus on bioequivalence of generic medicines coupled with communication as a cross-cutting area. When combined, work streams and activities collectively strengthen the existing system from all angles, from selecting medicines for public coverage to forecasting and procurement and/or reimbursement, to establish a more effective, transparent, and corruption-free supply chain continuum in Ukraine.

1.0 Policy Priority Setting: Health Technology Assessment (HTA) and Essential Medicines List (EML)

Despite COVID-19 limitations, while building capacity of the HTA department at the SEC, SAFEMed has continued its efforts in promoting HTA to be included in all relevant processes to ensure evidence-based health policy making. To this end, during this reporting period, SAFEMed:

- Supported the approval of Decree №1300 “About the approval of the State Health Technology Assessment Procedure”. The decree is the main legislative document in the Ukrainian HTA ecosystem. It provides new opportunities in health care system development in accordance with best global HTA practices.
- Facilitated collaboration between the HTA Department of the SEC and the MOH on inclusion of medicines into nomenclature lists for central public procurement. Having this work done by the HTA Department in collaboration with the MOH and CPA allowed the government to cover 100% of patients with kidney cancer eligible for the treatment.

2.0 Advancing Public Procurement Instruments and Operations, Regionally and Centrally

SAFEMed continued to support the CPA to ensure that the newly formed agency continues to grow and perform adequately in its preparation for taking over the procurement of life-savings medicines from international organizations. To this end, SAFEMed:

- Continued to support in the recruitment, evaluation, selection, and funding of key personnel seconded at the CPA for business continuity, with 11 of the 15 agreed positions currently in place.
- Organized two regional events to help facilitate dialogue and increase communication between the CPA and regional health care departments. Two online training sessions were
held as a part of the course in which the CPA provided training on: CPA’s procurement cycle; supply chain and legal regulations; documentation requirements and management.

- Coordinated two high-level roundtable events to support a coherent and common vision among key stakeholders on managed entry agreement (MEA) and supported the development of two key legislative amendments:
  - The exclusion of MEA from the law on public procurement, which would enable confidentiality of contractual terms, including pricing, to maximize effective use of the tool in accordance with global best practices and
  - The law on “Basic principles of healthcare of Ukraine”, which will be amended with provisions that mandate the use of HTA before MEA and will publish general contractual information on MEA to the public, excluding pricing, for public awareness.

- Supported the CPA to set up an internal audit department and helped design the department structure, defined the controls to be audited, and assessed personal requirements in a manner that aligns with the CPA’s overall business strategy.

- Successfully added more than 600 products to the e-catalogue platform, with sales of about 7 million UAH. In 2020, 3,253 products were added to the system, more than 800 health care facilities are currently active on the tool, and total annual sales amounted to 20 million UAH.

- Continued to collect real-time stock information through MedData from 631 hospitals, 29 laboratories, and 25 emergency departments across the 24 regions of Ukraine for all COVID-19-related commodities.

### 3.0 Strengthening NHSU Pharmaceutical Policy

SAFEMed has provided continuous technical assistance to the NHSU to further advance its capacity in the management and promotion of the state reimbursement program. More specifically, SAFEMed:

- Supported the expansion of the reimbursement medicines list for the third time and added three medicines for the treatment of cardiovascular disease: warfarin, nifedipine, and acetylsalicylic acid. This is the most tangible reimbursement expansion since the program’s launch.

- Supported an NHSU working group on insulin reimbursement with endocrinologists where SAFEMed trained NHSU staff on previously developed pathways and updated categories. During these meetings, participants discussed proposed changes to the list of categories of patients who are eligible for insulin reimbursement, patient pathways, and ICD-10 codes for diagnosis categorization.

- Assisted the NHSU in further enhancing ePrescription’s protection functions through both internal and external interventions, SAFEMed continued to support the NHSU with two consultants in web design and business analytics.

### 4.0 Optimizing PEPFAR Supply Chain Contributions

During this reporting period, as part of the overall improvement of the HIV and TB supply chain continuum, SAFEMed and local counterparts at the MOH, CPH, and CPA:

- Produced a final report of the logistic pilot in Odesa region that contains an overview of 11 months of the PPP pilot in Odesa region with results of two surveys provided by sub-regional health care facilities, follow up recommendations, and further actions for stakeholders.
Worked towards an assessment of the existing distribution centers that store ARV, TB, and viral hepatitis therapies at the regional level by developing terms of reference for this activity for the potential vendor, determining the list of health facilities to be inspected, and developing a comprehensive checklist for the assessment.

Worked towards the development of a contemporary e-tool for ARV demand quantification with further inclusion of TB, Hep C, and medication-assisted therapy (MAT) commodities.

Participated in the work of Ukrainian National Headquarters on the COVID-19 response by:
- Analyzing key epidemic indicators and treatment technologies for COVID-19
- Working with 540 first-wave hospitals to collect information about current stock levels and needs
- Providing legislative support for all COVID-19-related activities and contributing to the development of key COVID-19-related documents (e.g., CMU decrees, decrees of chief sanitary doctor, orders of National COVID-19 HQ, MOH orders)
- Working with national and international counterparts and coordinating humanitarian and supply chain activities
- Supporting the MOH in collaboration with the CMU, President’s Office, Minister of Foreign Affairs, Ministry of Social Politics, customs authorities, and international donor platform headed by Vice Prime Minister to ensure timely deliveries of humanitarian aid to all 24 regions and Kyiv
- Signed an official memorandum of understanding and cooperation to strengthen efforts in the fight against HIV/AIDS, TB, and viral hepatitis and provide a basis for further coordination toward the achievement of common goals.

5.0 Quality of Medicines: Bioequivalence and Serialization
During this reporting period, SAFEMed continued moving forward with the roll-out of the bioequivalence strategy in Ukraine. In several meetings with the MOH, SAFEMed advocated for the importance of development and regulation in this field as bioequivalence is one of the key instruments in ensuring the quality of generic medicines that are included in the governmental programs or central procurements programs.

In addition, to work towards implementation of a 2D verification system in Ukraine, SAFEMed developed a concept note that consists of a review of previous attempts to implement verification systems in Ukraine, their legal components, and results. A comparison of 2D coding models and technical requirements for implementation are key points in the document. Based on this, SAFEMed proposed a description of the model, implementation stages, and funding mechanisms and regulatory changes that need to be made to current legislation.

6.0 Strategic Communications
This reporting period, SAFEMed communications activities included a variety of soundbites; one finalized success story; 12 media monitoring releases related to public procurement; three bilingual monthly newsletters; an infographic on the e-catalogue in response to COVID-19; press releases; and visual materials that provide the MOH, CPA, and NHSU with high-caliber communication products in the project’s work stream.

B. Activity Administration
During this reporting period, SAFEMed quickly began working on the activities in its newly approved annual implementation plan. The project has made additional changes in the project organogram and identified and hired additional staff to align staffing with project deliverables and fill vacant positions.
C. Subsequent Reporting Period

SAFEMed will continue to progress in its project activities despite the disruption being caused by the threat of COVID-19 across the globe. The project will focus on being flexible in supporting government counterparts so that the most impact is made against the spread of COVID-19 while attempting to move forward with the majority of the project’s planned activities.

IV. KEY NARRATIVE ACHIEVEMENT

SAFEMed applies health system strengthening best practices to create evidence-based interventions and strengthen Ukraine’s pharmaceutical system in line with the MOH’s health care reform objectives. It aims to improve access to appropriate, quality medicines to maximize availability within the MOH’s budgetary constraints. In pursuit of its goal, SAFEMed has three project objectives: Strengthening governance within the pharmaceutical sector of Ukraine, optimizing the financing of the pharmaceutical sector, and increasing the availability and appropriate use of medicines in Ukraine.

All project activities are implemented via technical, financial, and legal assistance (Section XIII) in the work streams of health priority setting, public procurement, reimbursement program, and supply chain as well as quality assurance with a focus on bioequivalence and verification. When combined, work streams and activities collectively strengthen the system from all angles, from medicines selection to forecasting to actual procurement to ensuring quality.

In addition, SAFEMed is contributing directly to two President’s Emergency Plan for AIDS Relief (PEPFAR) goals that aim to maintain life-saving treatment for individuals and to accelerate progress toward controlling the pandemic through optimization of antiretroviral drug (ARV) regimens for adults and pediatrics, including transition to dolutegravir (DTG)-based regimens, and phasing out legacy regimens, and adoption and implementation of differentiated service models, including multi-month dispensing and decentralized drug distribution. In utilizing a thorough, consultative process and through close collaboration with the MOH, CPA, NHSU, CPH, SEC, patient groups, other USAID implementing partners, and the private sector, SAFEMed interventions work to institutionalize evidence-based medicine selection, strengthen and systematize public procurement of pharmaceuticals and commodities, support sustainable public-sector pharmaceutical financing, and strengthen the pharmaceutical supply chain. SAFEMed’s approach relies on direction from its government counterparts and aligns with Ukraine’s National Health Care System Reform and the partnership agreement between Ukraine and the European Union (EU) that requires pharmaceutical reforms to align with EU standards. The project is guided by the robust, transformative vision of Ukraine’s pharmaceutical system as more transparent and cost efficient with more medicines of better quality available to the Ukrainian public, contributing to the Government of Ukraine’s goal of a health care system that produces better health outcomes and sustained epidemic control.

Policy Priority Setting: HTA and EML

Establishment of an HTA function in Ukraine has been a top priority to ensure evidence-based health care policymaking and aid decision makers in selecting health technologies that provide the best value for the Ukrainian health care system. Frequent changes in the MOH’s administration have brought uncertainties as to whether the interest in and dedication to developing an HTA function will continue or more and closer interaction will be necessary to increase awareness and support implementation of HTA in Ukraine. During this reporting period, SAFEMed continued to
communicate the need for HTA and despite COVID-19 limitations completed successful steps toward a well-established HTA function in Ukraine as the political will was successfully sustained.

The major success this quarter has been the Cabinet of Ministers’ (CMU) approval of the HTA decree, which will be the main milestone for future independent HTA function. In addition, SAFEMed took part in several MOH and NHSU working groups to engage the HTA vision for decision making in different areas of focus; supported the development of a decree introducing MEA; spoke at several meetings to promote using HTA in different processes of the market access of pharmaceuticals; started discussions with stakeholders on the update of the HTA Roadmap based on the decree changes; and initiated Electronic Common Technical Document snap shot analysis to support a modernized market authorization procedure in Ukraine.

**Approval of the Decree about the State HTA Procedure**

The HTA department under the SEC was established as an interim solution until an independent agency could be developed to promote evidence-informed decision making in Ukraine. SAFEMed has been supporting the MOH to set the legislative framework for this transition, and the department has proven its success since its establishment. With support from SAFEMed and its legal partners, the MOH drafted the decree and asked for public consultation. During Q1, SAFEMed supported the MOH in answering numerous questions and comments received during public consultation and from governmental authorities who was reviewing the draft HTA decree. In the second half of Q1, SAFEMed and its legal partners reacted to the questions and recommendations from the CMU of Ukraine during preparation for the approval of the decree.

On December 23, 2020, the CMU of Ukraine approved Decree №1300 “About the approval of the State Health Technology Assessment Procedure”. The decree is the main legislative document in the Ukrainian HTA ecosystem. It provides new opportunities in health care system development in accordance with best global HTA practices.

Key strategic actions that were approved by the HTA decree include:

- Until January 1, 2022, take measures to establish a state unitary commercial enterprise that is authorized to conduct state HTA. Independence is one of the key criteria in the development of a transparent HTA ecosystem. Creation of an independent HTA agency in the form of a state unitary commercial enterprise will bring more transparency to HTA users and will allow them to provide high-quality, evidence-based recommendations to decision makers.
- Create and approve HTA guideline for medicines within six months.
- State HTA of health technologies other than medicines will start January 1, 2022. A guideline for HTA of non-drug technologies should be developed by January 1, 2022. HTA of other health technologies will make it possible to have evidence-based recommendations during the decision-making process for state procurement of medical devices, vaccines, and health interventions, taking into account clinical aspects and budget impact analysis that are parts of state HTA.
- Until January 1, 2023, conduct state HTA for the products included in the lists used for public procurement. This will give an opportunity to review the items in the lists that had not gone through HTA before the function was in place in Ukraine. Eventually, all publicly covered medicines will be reviewed and updated in accordance with HTA recommendations and will be used for a single positive list creation.
Annexes approved by the HTA decree (e.g., application forms for HTA, HTA dossier requirements for submissions, HTA report requirements) provide clear, structured, and well-described process for all HTA stakeholders who will submit the applications and perform assessment with further recommendations.

**HTA Methodology for First Practical Application in Medicines Public Procurement**

Last year, SAFEMed facilitated collaboration between the HTA Department of the SEC and the MOH on inclusion of medicines into nomenclature lists for central public procurement. A review of the evidence for two medicines used in the treatment of kidney cancer—sunitinib and pazopanib—found that their safety and effectiveness are equivalent. After HTA and further discussions, it was decided to announce the procurement combining two International Nonproprietary Names (INNs) into one procurement item. Two manufacturers competed, which led to significant savings of 156 million UAH. Moreover, having this work done by the HTA Department in collaboration with the MOH and CPA allowed the government to cover 100% of patients with kidney cancer eligible for the treatment. This experience shows in practice that using HTA for decision making in medicines procurement can bring additional value for Ukraine and its patients.

**HTA Collaboration with the CPH**

As a part of the HTA Roadmap strategic objective to create an HTA informed decision-making ecosystem in the Ukrainian health care system, SAFEMed created list of points of collaboration with the CPH that included support of systematic reviews and evidence-based guidance on the introduction of new vaccines in national immunization schedules; sharing best practices in cost-effectiveness analysis before the introduction of a new vaccine in national immunization schedules; sharing evidence-based criteria for prioritization of vaccines to be introduced in the national schedules; and supporting HIV and TB activities led by the CPH and MOH. A meeting with the CPH is planned to discuss these in detail in January 2021.

**Advancing Public Procurement Instruments and Operations, Regionally, and Centrally**

**CPA Staff Recruiting**

SAFEMed continued to support in the recruitment, evaluation, selection, and funding of key personnel seconded at the CPA for business continuity, with 11 of the 15 agreed positions currently in place. Specifically, the seconded positions are focused on supporting the CPA’s regional outreach and cooperation efforts and strengthening its internal information technology (IT) capacity. The majority of these individuals are supporting a variety of MedData developments that further enable the CPA to use technology to enhance business operations and further build its capacity as a national central procurement agency.

**Regional Outreach Efforts**

SAFEMed organized two regional events to help facilitate dialogue and increase communication between the CPA and regional health care departments. The events were successful in creating a platform for communication, helping regions understand new requirements of the procurement reforms, specifically as they relate to distribution services provided by the CPA, and providing feedback and comments for continuous improvement of CPA services. Two online training sessions were held as a part of the course in which the CPA provided training on:
- CPA's procurement cycle
- Supply chain and legal regulations
- Documentation requirements and management

To garner feedback from regions, SAFEMed created and issued an initial survey that achieved a 30% response rate from attendees, with 93% of respondents indicating that the information presented was helpful for their daily operations.

**Introducing Managed Entry Agreements**

SAFEMed coordinated two high-level roundtable events to support a coherent and common vision among key stakeholders, including the committee on health care of the Verkhovna Rada, the MOH, patient groups, industry associations, and the CPA. The events helped attendees to agree on two key legislative amendments:

- The exclusion of MEA from the law on public procurement, which would enable confidentiality of contractual terms, including pricing, to maximize effective use of the tool in accordance with global best practices and
- The law on “Basic principles of healthcare of Ukraine”, which will be amended with provisions that mandate the use of HTA before MEA and will publish general contractual information on MEA to the public, excluding pricing, for public awareness.

SAFEMed also provided technical support in drafting a package of legal amendments to be submitted to the committee for registration and further processing. In addition, SAFEMed supported the MOH in the development of the MEA decree and supporting legislative documents, which provide detailed instructions on how to implement the tool in the country and create additional legal grounds for doing so. The MOH published the documents for public consultations, and SAFEMed supported reviewing, aggregating, and conducting the preliminary analysis of the results with reference to related literature reviews and global best practices. Once public comments were considered, the documents were sent to other key government counterparts such as the ministries of finance, justice, and economic development and trade for additional review. SAFEMed supported the MOH in finalizing the documents, which have been approved and signed by the Minister of Health and sent to the CMU for voting in Q2.

**Setting Up an Internal Audit Department**

SAFEMed supported the CPA to set up an internal audit department and helped design the department structure, defined the controls to be audited, and assessed personal requirements in a manner that aligns with the CPA’s overall business strategy. The audit department has a direct reporting line to the General Manager and the soon to be established Supervisory Board to ensure an adequate level of authority and independent oversight across the entire organization. With support from SAFEMed, the CPA defined the competencies, professional skills, ethics, and values required by the audit team to undertake public-sector audits in line with global standards and best practices. The audit department was designed to reflect the standards set out by the International Organization of Supreme Audit Institutions to increase transparency in the process in accordance with applicable Ukrainian legislation, and it has three main areas of control:

1. Financial: to ensure that the CPA’s financial information is in accordance with the applicable financial reporting and regulatory framework
2. Compliance: to ensure that properly identified authorities within the CPA and across the government are involved in the applicable subject matter, such as financial transactions, in accordance with the authorities that govern it
3. Performance: to ensure that all CPA initiatives and departments are performing in an efficient and effective manner and identify areas for continuous improvements

SAFEMed trained CPA staff on a list of controls the project created related to good distribution practices (GDP) to ensure the efficient flow of health products through the supply chain in a manner that safeguards the integrity of the products in accordance with international standards. The CPA is well equipped to assess the distribution policies and procedures at any of its outsourced logistics partners.

**Using Technology in the Procurement Cycle**

*E-Catalogues*

In project year (PY) 4 Q1, the e-catalogues team successfully added more than 600 products to the e-catalog platform, with sales of about 7 million UAH. In 2020, 3,253 products were added to the system, more than 800 health care facilities are currently active on the tool, and total annual sales amounted to 20 million UAH. SAFEMed supported the CPA in creating a number of campaigns to increase awareness of the tool and provided training sessions for regional health care facilities.

The e-catalogue is on the rise as a foundational procurement tool to be used across regional health care facilities in Ukraine, and on November 11, 2020, legislation was passed that granted the CPA the ability to continue administering the tool beyond its pilot phase into 2021 and beyond.

*Supporting the COVID-19 Response in Ukraine*

MedData, which is a demand planning tool developed by SAFEMed, continued to collect real-time stock information from 631 hospitals, 29 laboratories, and 25 emergency departments across the 24 regions of Ukraine for all COVID-19-related commodities. The CPA successfully procured and delivered more than 2 million units of personal protective equipment (PPE) with an estimated value of 73.9 million UAH in PY4 Q1.

**Strengthening NHSU Pharmaceutical Policy**

The Ukrainian reimbursement program was launched on April 1, 2017 and covers 21 INNs to provide continuous treatment and decrease capital health care-related expenses for patients diagnosed with the three most common noncommunicable diseases: cardiovascular disease, asthma, and type II diabetes. During the program life cycle, the medicines reimbursement list was expanded twice. On December 21, 2020, the CMU expanded the reimbursement medicines list for the third time and added three medicines for the treatment of cardiovascular disease: warfarin, nifedipine, and acetylsalicylic acid. This is the most tangible reimbursement expansion since the
program’s launch. It should be mentioned that the MOH and NHSU were considering unlinking the Ukrainian reimbursement program and the national EML to have more potential INNs for the reimbursement expansion. SAFEMed addressed visible risks of such action to government authorities who are managing reimbursement in Ukraine. After rounds of negotiations, the decision was made to keep the NHSU reimbursement program based on the national EML and to keep developing a positive list for further reimbursement expansion.

Facing limitations of the national EML from one side but understanding the importance of having a clear and transparent medicines selection process for the guaranteed benefits package from another, the NHSU originally stated in Law #2168, “About the state financial guarantees of medical service of the population”, that the Ukrainian guaranteed benefit package should be based on the national EML. To provide more flexibility for health care facilities during the pandemic and give an opportunity for the NHSU to develop effective health packages, SAFEMed and its legal partners were asked to support changes to Law #2168. One change was developed to postpone getting clause 10 of article 10 in force until 2022: “Medicines included in the National List of Essential Medicines, approved by a resolution of the Cabinet of Ministers of Ukraine, and medical guarantee programs are subject to payment at the expense of the State Budget of Ukraine.” Such technical changes to the law will give the NHSU an opportunity to develop an appropriate benefits package and cover health care facility expenses with state budget funds in 2021 but will keep a needed norm in Law #2168 to leave space for a positive list to replace the national EML in the future. The SAFEMed team, supported by its partner, Legal Alliance, developed and negotiated changes to the law in just two days, but it took an additional two days for the Verkhovna Rada health care committee to support such changes and another five days for Verkhovna Rada to vote and accept changes to Law #2168, which were proposed with support from SAFEMed. On December 29, 2020, the President of Ukraine signed the new law reduction making this change the fastest Law changing process that was supported by the SAFEMed. Just 13 calendar days from the internal team brainstorm to the President’s signature.

**Working Group on Expanding the List of Medicines to be Reimbursed for Treatment of Insulin-Dependent Diabetes**

In PY3, SAFEMed supported NHSU with development of the insulin reimbursement by defining the referral criteria for the primary care level to the level of the endocrinologists, as well as revision of the categories for reimbursement rules, supporting NHSU with the development of insulin ePrescription TOR and insulin pricing models, based on external reference price.

According to the new MOH and NHSU plan, the inclusion of insulin medicines in the reimbursement program will take place in June 2021. Understanding the complexity of the biologics and biosimilars reimbursement, the NHSU has initiated a working group that includes endocrinologists, key opinion leaders, clinicians, and SAFEMed project representatives. During the first two meetings of the working group, NHSU reimbursement department representatives shared with participants the updated insulin-dependent patient pathways and the new categorization of insulins. All documents were developed with support from SAFEMed in PY3. Endocrinologists had a chance to review and discuss potential changes during the meeting, and they were asked to submit their feedback on proposed insulin reimbursement changes by filling in a questionnaire created by the NHSU. Their feedback will be utilized by the NHSU to update the insulin reimbursement program model and submit to the MOH for review and approval.
**Anti-fraud Activities within ePrescription**

As reimbursement in Ukraine is managed by the NHSU using ePrescription, further development and expansion for the reimbursement program requires improvement of ePrescription’s anti-fraud functions. To assist the NHSU in further enhancing ePrescription’s protection functions, SAFEMed continue to support the NHSU with two consultants in web design and business analytics. During the reported period, consultants managed work on the developed version of the front-end system for reimbursement, including:

1. Developed a form for adding users who will have access to certain functionalities (e.g., mailing letters with reports assigned to a specific person). The restriction on rights will help to avoid mistakes that appeared while using Google tables. There were cases when unauthorized NHSU employees accidentally processed reports by mistake. The problem of accidentally deleting data from reports has been resolved.
2. Parsing report status by period was developed. In the old approach, the status was set in the Google table and reporting period. For now, the NHSU will use its front-end system and store data in PostgreSQL.
3. The concept module for automating the process for sending excel files and parsing answers from letters is ready. Consultants carried out synthetic tests during the creation of the concept module and recognized problem areas. Running preproduction tests and correcting errors helped avoid problems during real work.
4. Bug tracking for the parsing mail module will improve report processing by reducing the number of manual checks.
5. The NHSU IT department and consultants prepared a prerelease version in Gitlab to test existing functionality with the NHSU reimbursement department. This approach will help the NHSU transfer from the existing telegram bot’s functionality to Django technology, progressively improving the existing functionality of ePrescription.

**Optimizing PEPFAR Supply Chain Contributions**

**Public-Private Partnership (PPP) Logistics Pilot**

During the reporting period, SAFEMed produced a final report of the logistic pilot in Odesa region that contains an overview of 11 months of the PPP pilot in Odesa region with results of two surveys provided by sub-regional health care facilities, follow up recommendations, and further actions for stakeholders. The goal of the pilot was to attract the private sector to provide high-quality logistics services for the transportation of HIV and TB commodities from the regional level to service delivery points (“last mile” delivery), utilizing specialized transport and in accordance with GDP standards. Since the PPP pilot in Odesa region has demonstrated good results and a high level of satisfaction among end users, the CPH suggested expanding the pilot to all 24 regions and Kyiv with inclusion of medicines for the treatment of viral hepatitis.

On November 10, 2020, a tender for participation in the pilot of logistic companies was announced. It was decided to use two models of service providing:

- National - 15 regions to be covered by one national logistics operator
- Regional - in the other 10 regions, local carriers to be involved

Based on tender results, the national logistics operator selected was FM Logistic—a well-known international logistics provider with activities in 14 countries, including Ukraine since 1996. For the regional model, two winners were announced—FM Logistic and PharmWay Trading, a company
that has experience in the storage and delivery of pharmaceutical products in more than 450 pharmacies throughout Ukraine.

SAFEMed held a conference call with the MOH, heads of structural subdivisions on health care in the regions, and Kyiv city administration on November 16, 2020. The experience of the pilot in Odesa was presented, including the details, next steps, and benefits identified during 11 months of implementation. Following the meeting, an official letter from the MOH to the heads of structural units for health care in regional state administrations was sent to identify regional coordinators who will cooperate with SAFEMed and promote the implementation of the pilot. SAFEMed created a list of regional coordinators and held preliminary negotiations with them. A memorandum of understanding is an essential document that should be signed by each regional state administration and SAFEMed, and this is the first step in collaborating with coordinators.

With the necessary political will and preparing the legislation basis for the extension of the successful pilot in Odesa to all regions in Ukraine, it is expected that monthly deliveries to service delivery points will start in Q2.

**Assessment of Regional Distribution Centers**

In connection to the “last mile” logistics, SAFEMed will conduct an assessment of the existing distribution centers that store ARV, TB, and viral hepatitis therapies at the regional level to create a more comprehensive logistics model for Ukraine. The assessment is expected to include the analysis of the regional distribution centers’ compliance with national legislation and GDP requirements and will be done by on-site monitoring visits to the health facilities in Q2. SAFEMed and the CPH have developed terms of reference for this activity for the potential vendor, determined the list of health facilities to be inspected, and developed a comprehensive checklist for the assessment. Analysis of the distribution centers’ capacity will help identify existing gaps; come up with recommendations for the MOH, CPH, and regional health administrations; look for opportunities for private-sector engagement in the warehousing field, including via PPPs; and be included in the final assessment reports.

**Quantification Support to the CPH**

To enhance the CPH’s quantification and forecasting efforts, SAFEMed has provided technical assistance in the development of a modern e-tool for ARV demand quantification with further inclusion of TB, Hep C, and medication-assisted therapy (MAT) commodities. In PY4 Q1, SAFEMed facilitated a discussion within a small working group (SWG) comprising representatives from the CPH; CPA; and E-life, which developed a management information system (MIS) for HIV. This SWG was created to streamline the development of the new tool, set up a platform for communication among key stakeholders, and come up with a common vision and approach for quantification and forecasting of HIV medicines.

Since its creation, the SWG has:

- Developed a standard operating procedure for ARV quantification and forecasting
- Defined a data set required for effective quantification and forecasting
- Assessed the preparedness of both CPH’s HIV MIS and CPA’s MedData system for potential data exchange and integration with a new e-tool and conducted a comparative analysis of both systems to define which is more feasible to serve as a master system

The outputs of the SWG’s work were presented to CPH and CPA management to provide information for further decision making and agree on next steps for the development of the
quantification tool and general collaboration between the CPH and CPA. Once the decision is made, the SWG should work on the specifications for the data exchange, programming algorithm for calculation, and creating visuals for the analysis of the quantification reports produced by the e-tool.

SAFEMed also continued supporting the CPH in creating visuals and charts on ARV stock level status for CPH’s communication with donors and other stakeholders and preparing the analytical notes on ARV availability in the country, namely TLD, and possible risks in treatment continuity related to delays in the supply of some drugs. SAFEMed also developed a user-friendly tool for monitoring the antiretroviral therapy optimization plan and forecasting ARV stock at the national and regional levels. The data from this tool are used for CPH touch base weekly meetings with the regions for decision making and mitigating the risks of stock-outs and treatment disruption.

**Supporting the COVID-19 Response in Ukraine**

During Q1, SAFEMed was involved in the work of Ukrainian National Headquarters on the COVID-19 response. The organization serves as an analytical center for COVID-19 and is responsible for a number of issues, including:

- Analyzing key epidemic indicators and treatment technologies for COVID-19
- Working with 540 first-wave hospitals to collect information about current stock levels and needs
- Supporting Ukrainian COVID-19 HQ with daily monitoring, analysis, and preparing information for the centralized CMU COVID-19 dashboards
- Providing legislative support for all COVID-19-related activities and contributing to the development of key COVID-19-related documents (e.g., CMU decrees, decrees of chief sanitary doctor, orders of National COVID-19 HQ, MOH orders)
- Working with national and international counterparts and coordinating humanitarian and supply chain activities
- Supporting the MOH in collaboration with the CMU, President’s Office, Minister of Foreign Affairs, Ministry of Social Politics, customs authorities, and international donor platform headed by Vice Prime Minister to ensure timely deliveries of humanitarian aid to all 24 regions and Kyiv

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Strengthening Collaboration with CPH

As an important step in fruitful collaboration, on December 22, 2020, the CPH and SAFEMed signed an official memorandum of understanding and cooperation to strengthen efforts in the fight against HIV/AIDS, TB, and viral hepatitis and provide a basis for further coordination toward the achievement of common goals.

The memorandum of cooperation builds on accomplishments and work done since the Activity’s start in 2017, expanding on priority areas to improve access to safe and affordable medicines for the Ukrainian population:

- National scale up of the logistics pilot for the delivery of medicines and related products for the treatment and/or diagnosis of TB, HIV, and viral hepatitis with engagement of the private sector to ensure timely and effective distribution of such medicines and products to patients
- Joint analysis to determine cost-efficient distribution models for essential medicines at the regional level and preparing interim reports to present results and findings to inform the selection of the most efficient distribution models
- Introduction of legislative changes to improve access to HIV testing and pre-exposure prophylaxis (PrEP), including at primary health care facilities and through family physicians
- Supporting Ukraine's COVID-19 response to ensure an effective supply of medicines, PPE, medical devices, and tests
- Distribution of ARVs and drugs for PrEP through private and public pharmacies as a part of the decentralized drug distribution model
- Providing technical assistance to the CPH in the development of an effective and up-to-date tool to forecast supply and demand of ARVs, viral hepatitis, and TB medicines
- Providing technical assistance to the CPH in the preparation of dashboards and data visualization related to the provision of patients with essential drugs based on a monthly analysis of information on available stock

Collaboration between SAFEMed and the CPH will help improve the availability of medicines for the treatment of HIV, TB, and viral hepatitis; introduce innovations to improve the efficiency of Ukraine's drug delivery system; and strengthen the institutional capacity of the Public Health Center as a key institution in combating life-threatening diseases in Ukraine.

Quality of Medicines: Bioequivalence and Serialization

Bioequivalence

During this reporting period, SAFEMed continued moving forward with the roll-out of the bioequivalence strategy in Ukraine. In several meetings with the MOH, SAFEMed advocated for the importance of development and regulation in this field as bioequivalence is one of the key instruments in ensuring the quality of generic medicines that are included in the governmental programs or central procurements programs.

With support from Legal Alliance, SAFEMed developed draft changes to CMU Decree #152 “On ensuring the availability of medicines” to settle bioequivalence as a criterion for inclusion of the medicines in the reimbursement registry. According to the proposed changes, manufacturers have to provide official information from the MOH SEC about successful bioequivalence studies, starting on January 1, 2023.
In preparation for the formal assessment of the Ukrainian institutions that conduct bioequivalence studies scheduled for PY4 Q2, during this reporting period SAFEMed and international consultant Dr. Werner Gielsdorf considered and created a goal and methodology for the assessment. Selection criteria for laboratories were created and reviewed, and the preliminary list of laboratories for the assessment was updated. In addition, Dr. Gielsdorf summarized the existing requirements in the EU and Ukraine.

During the official meeting with the new acting head of the SEC, SAFEMed and other groups raised the importance of the bioequivalence strategy implementation. The acting head of the SEC indicated his support in the conduct of the SAFEMed/SEC assessment of Ukrainian institutions that perform or possibly can perform bioequivalence studies aimed to understand the capacity and readiness of the local laboratory network as the next step of the bioequivalence roll-out.

**Verification**

There have been three attempts to introduce a verification system in Ukraine—in 2013–2014, 2017, and 2019. The last pilot project on marking medicines with control identification signs and monitoring the circulation of medicines was planned for September 1, 2019–December 31, 2020. However, as of December 2020, the requirements of the legislation had not been met in a timely manner, and the pilot was suspended.

In 2020, Ukrainian media posted information about several cases of counterfeit medicinal products. At the same time, according to an analysis of statistics conducted by lawyers from the Legal Alliance, over six years only six falsification-related crimes were actually investigated, and no criminal was imprisoned. Taking into consideration the EU-Ukraine association agreement that gives Ukrainian manufacturers the opportunity to expand into the EU market, it is vital to Ukraine to better prevent and detect substandard and falsified medicines.

Accordingly, the necessity of having a fully operating verification system that is in line with EU requirements was supported by the MOH and industry. To move forward, the MOH established a working group on 2D codes of medicines to prevent the circulation of counterfeit/falsified medicines in Ukraine. SAFEMed joined the MOH working group as a well-known counterpart and expert in the field since advocating for these changes in 2018–2019 and provided the report and roundtable. As an MOH working group member, SAFEMed was asked to translate EU legislation to create a mutual understanding on the European Medicines Verification Organization (EMVO) verification process and basic principles of the European approach to fighting counterfeit and substandard medicines using 2D coding.

Based on previous developments, SAFEMed prepared a concept document on the implementation of a 2D verification system in Ukraine. This document consists of a review of previous attempts to implement verification systems in Ukraine, their legal components, and results. A comparison of 2D coding models and technical requirements for implementation are key points in the document. Based on this, SAFEMed proposed a description of the model, implementation stages, and funding mechanisms and regulatory changes that need to be made to current legislation.

SAFEMed shared the concept policy paper document on the introduction of a 2D coding system with the MOH and working group representatives. Once feedback is received, we plan to arrange a verification and serialization forum to engage all counterparts for the concept policy discussion.
Strategic Communication

During this reporting period, SAFEMed communications activities included a variety of soundbites; one finalized success story; 12 media monitoring releases related to public procurement; three bilingual monthly newsletters; an infographic on the e-catalogue in response to COVID-19; press releases; and visual materials that provide the MOH, CPA, and NHSU with high-caliber communication products in the project’s work stream.

Communications Support to the CPA

During this report period, SAFEMed supported the CPA to streamline its communication efforts. SAFEMed worked with the CPA to develop three “videobites” that showcased the CPA’s results in public procurement while procuring medicines for oncology patients. Other videobites demonstrate the procurement and installation of computer tomographs in one of the hospitals in Vyshgorod, accompanied by a video instruction storyline on how doctors are being instructed to use them. Two success stories have been created to demonstrate the overall money savings via a patient’s personal story and the effective use of a modern procurement tool—the e-catalogue—and its use in purchasing COVID-19 goods in regional hospitals. This e-catalogue success story demonstrated the easy-to-use Prozorro purchasing platform, which is aimed at its end users—central and regional procurement representatives in the hospitals. All success stories have been promoted internationally and to the USAID communications team.

SAFEMed Supports NHSU’s Successful Participation in the Global Digital Forum 2020

The NHSU joined the virtual 7th Annual Global Digital Health Forum December 7–9, 2020. Focusing on making digital health work for everyone, the NHSU led a presentation titled When Digital World Meets the People, featuring Oksana Movchan, Deputy Head of the NHSU. Movchan spoke about the implementation of medical reform in Ukraine and the electronic health care platform.

“Ukraine’s healthcare transformation has included a successful transition from paper prescriptions, recommendations and records that have led to falsification of reporting and incorrect figures, to innovative digital tools that ensure transparency and accountability. The electronic health care system in Ukraine has been developed according to the advanced international standards of medical information management and with the support of international partners.” – stressed Oksana Movchan.

Thanks to electronic tools, information on the processes and the results of concluding contracts and payments are available to all end users through analytical panels on the NHSU website. The first dashboard appeared in December 2018, and since then public dashboards have become open and transparent tools for patients and doctors who can track how many health care facilities have been contracted and what services they provide to patients. The government can now rely on numbers and make evidence-based decisions.
## V. Monitoring, Evaluation, and Learning

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Disaggregated by:</th>
<th>Unit</th>
<th>Baseline</th>
<th>YR1</th>
<th>YR2</th>
<th>YR3</th>
<th>YR4</th>
<th>YR5 (EOP)</th>
<th>Means of Verification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Proportion of out of pocket (OOP) spending on medicines (out of total spending on medicines)</td>
<td>Type (EML vs. non-EML)</td>
<td>Ratio</td>
<td>2016</td>
<td>86%</td>
<td>85%</td>
<td>85.4%</td>
<td>78%</td>
<td>81.5%</td>
<td>74%</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>YR1</td>
<td>YR2</td>
<td>YR3</td>
<td>YR4</td>
<td>YR5 (EOP)</td>
<td>Data Source</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Target</td>
<td>Actual</td>
<td>Target</td>
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<tr>
<td>2 Number of prescriptions filled (out of total number of medicines prescribed under the “Affordable Medicines” Program)</td>
<td>n/a</td>
<td>Thousand receipts</td>
<td>2017</td>
<td>11,897.2</td>
<td>26,154</td>
<td>26,155</td>
<td>40,249</td>
<td>43,396</td>
<td>53,343</td>
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<tr>
<td>3 Number of people trained in anti-corruption measures in the pharmaceutical sector as a result of U.S. Government (USG) support</td>
<td>Gender (male, female)</td>
<td>Individual, who attend 80% of training</td>
<td>2017</td>
<td>0</td>
<td>1,200</td>
<td>1,200</td>
<td>300</td>
<td>884</td>
<td>81 M: 157 F: 727</td>
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<tr>
<td>4 Number of pharmaceutical-sector legislations adopted by the Government of Ukraine as a result of USG support</td>
<td>n/a</td>
<td>Nakaz Strategy Policy</td>
<td>2018</td>
<td>No data collected</td>
<td>No data collected</td>
<td>No data collected</td>
<td>10</td>
<td>11</td>
<td>15</td>
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</tr>
</tbody>
</table>

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2 As of January 18, 2020, SMD data are only available through October 2020

3 Number of prescriptions is from April 2017 (beginning of Affordable Medicine program) to January 2021

4 See more details on the legislation adopted in Annex XIII

SAFEMed Quarterly Progress Report: October 1, 2020–December 31, 2020 ||16
<table>
<thead>
<tr>
<th>Indicator</th>
<th>Disaggregated by:</th>
<th>Unit</th>
<th>Baseline Date</th>
<th>Baseline Value</th>
<th>YR1 Date</th>
<th>YR1 Value</th>
<th>YR1 Target</th>
<th>YR2 Date</th>
<th>YR2 Value</th>
<th>YR2 Target</th>
<th>YR3 Date</th>
<th>YR3 Value</th>
<th>YR3 Target</th>
<th>YR4 Date</th>
<th>YR4 Value</th>
<th>YR4 Target</th>
<th>YR5 (EOP) Date</th>
<th>YR5 (EOP) Value</th>
<th>YR5 (EOP) Target</th>
<th>Means of Verification</th>
<th>Data Source</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 Amount of money saved by the health care system through central procurements as a result of USG support</td>
<td>n/a</td>
<td>Ukrainian hryvnia (millions)</td>
<td>Oct 2018</td>
<td>0</td>
<td></td>
<td></td>
<td>6M UAH</td>
<td></td>
<td>6M UAH</td>
<td></td>
<td>10M UAH</td>
<td></td>
<td>1.026B UAH</td>
<td>10M UAH</td>
<td></td>
<td>997M UAH</td>
<td>10M UAH</td>
<td>CPA</td>
<td>Quarterly</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 Amount of money saved by the health care system through regional procurements via external price referencing as a result of USG support</td>
<td>n/a</td>
<td>Ukrainian hryvnia (millions)</td>
<td>2018</td>
<td>Savings on 600M UAH spent on 20 top INNs</td>
<td></td>
<td></td>
<td>60M UAH</td>
<td></td>
<td>60M UAH</td>
<td></td>
<td>80M UAH</td>
<td></td>
<td>102M UAH</td>
<td>80M UAH</td>
<td></td>
<td>244M UAH</td>
<td>80M UAH</td>
<td>SMD Database</td>
<td>Quarterly</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 Number of individuals who have been newly enrolled on antiretroviral pre-exposure prophylaxis (PrEP) to prevent HIV infection in the reporting period (PrEP_NEW)</td>
<td>Gender Key populations</td>
<td>Individual</td>
<td>2019</td>
<td>0</td>
<td></td>
<td></td>
<td>200</td>
<td></td>
<td>0</td>
<td></td>
<td>400</td>
<td></td>
<td>0</td>
<td></td>
<td>1,000</td>
<td>CPH data</td>
<td>Semi Annually</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5 Savings for central programs managed by the CPA with 2020 budget funds (October 2020-December 2020)

6 As of January 18, 2021 SMD, data are only available through November 2020. Figure reflects total savings from January-November 2020
VI. LESSONS LEARNED

The COVID-19 pandemic remains the highest priority for the Ukrainian health care system, but it appears that the MOH understands the level of urgency for the implementation of the CMU Government action plan. To address emergency health care reform development components and mobilize key stakeholders, MOH selected a tactic of establishing working groups. During this reporting period, several MOH and NHSU working groups were established to reprioritize numerous reform components, including ePrescription, eStock, electronic registry of market authorized medicines, eCTD, NHSU insulin reimbursement, medicines verification, and serialization system development. We expect the new MOH working group on positive list will be established soon.

VII. ENVIRONMENTAL MONITORING

SAFEMed does not have any activities that have an environmental impact and/or require mitigation measures.

VIII. PROGRESS ON LINKS TO OTHER ACTIVITIES

SAFEMed continued to collaborate with the various USAID-funded projects and activities in Ukraine working across health and anticorruption technical areas by continuing to maintain open communication in working groups and meetings.

IX. PROGRESS ON LINKS TO HOST GOVERNMENT

SAFEMed continued to collaborate—both proactively and effectively—with key host government counterparts despite numerous changes at the MOH administration and its agencies, including the NHSU, and CPH, and COVID-19 related restrictions. SAFEMed successfully built a rapport, exercised flexibility, and demonstrated continuous willingness to support the Government of Ukraine’s changing priorities and supply chain challenges related to the global COVID-19 pandemic.

X. FINANCIAL INFORMATION

<table>
<thead>
<tr>
<th>Total Budget</th>
<th>$19,434,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Obligations:</td>
<td>$14,044,121</td>
</tr>
<tr>
<td>Estimated expenditure as of December 31, 2020:</td>
<td>$10,463,755</td>
</tr>
<tr>
<td>75% of the obligations</td>
<td>$7,850,366</td>
</tr>
<tr>
<td>54% of the total budget</td>
<td>$10,463,755</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pipeline Projections:</th>
<th>Actual Expenditure as of Nov 30, 2020</th>
<th>Accruals</th>
<th>Estimated Expenditures in Dec 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>PY4 Q2</td>
<td>$10,116,599</td>
<td>$14,094</td>
<td>$342,656</td>
</tr>
<tr>
<td>PY4 Q3</td>
<td>$1,264,884</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PY4 Q4</td>
<td>$1,265,154</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
XI. SUB-AWARD DETAILS

<table>
<thead>
<tr>
<th>Name</th>
<th>Effective Dates</th>
<th>Total Amount (USD)</th>
<th>Total Expenses (USD)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>OVERSEAS STRATEGIC CONSULTING, LTD.</td>
<td>01-Sep-17 to 30-Aug-22</td>
<td>$439,558</td>
<td>$264,279</td>
<td>Subcontractor (Small US business) is responsible to support project communications efforts with a full-time project staff.</td>
</tr>
<tr>
<td>LEGAL ALLIANCE LAW FIRM</td>
<td>11-May-18 to 31-May-22</td>
<td>$832,659</td>
<td>$391,941</td>
<td>Objective of the subcontract is to provide relevant legal support to promote the sustainability of the medicine’s selection process for procurement and reimbursement as a part of the reform process.</td>
</tr>
</tbody>
</table>

XII. ACTIVITY ADMINISTRATION

A. Constraints and Critical Issues

On December 31, 2020, the MOH did not approve next year’s operational budget for the CPA, jeopardizing further efficient procurement of health care products, including COVID-19 commodities. In addition, no mechanism and state funds for the regional distribution of COVID-19 commodities were set in 2020, and this could be an issue for scaling regional distribution during the roll-out of the vaccination roadmap.

B. Personnel

During this reporting period, MSH identified a suitable candidate for the COP position, and all necessary documents were submitted to USAID for approval. In addition, SAFEMed finalized the mobilization of SAFEMed Senior Technical Advisor Ahmed Zayan and his family by obtaining a Ukrainian temporary residence permit.

In October 2020, SAFEMed’s communications associate went on maternity leave, resulting in recruitment of a short-term consultant to cover her duties. The consultant was hired in December 2020 with a contract until May 2021.

Lastly, starting October 1, 2020, three of SAFEMed’s junior consultants were approved as project staff: Dmytro Nestor, Technical Officer, Quantification; Anna Dobrova, Technical Officer, Pricing; and Valentyna Pryz, Communications Associate. These specialists make a valuable addition to the team in several priority areas of the project.

C. Contract, Award, or Cooperative Agreement Modifications and Amendments

SAFEMed did not have any modifications and amendments during this reporting period.

D. Status of Deliverables/Milestones

<table>
<thead>
<tr>
<th>Deliverables</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 Summary report on HTA capacity building results at the end of the year</td>
<td>Ongoing</td>
</tr>
<tr>
<td>1.2 Summary report on stakeholder meeting results</td>
<td>Ongoing</td>
</tr>
<tr>
<td>1.3 Summary report of 3rd National Forum</td>
<td>Planned</td>
</tr>
<tr>
<td><strong>Deliverables</strong></td>
<td><strong>Status</strong></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>1.4 HTA Roadmap updated in Q1; implementation through Q2–4</td>
<td>Ongoing</td>
</tr>
<tr>
<td>1.5 Three PEPFAR-related evidence summaries completed jointly with the HTA department and CPHI to support evidence-based decision making</td>
<td>Planned</td>
</tr>
<tr>
<td>1.6 PEPFAR-related clinical protocols developed based on the evidence summaries</td>
<td>Planned</td>
</tr>
<tr>
<td>1.7 Positive list concept and action plan approved and implementation initiated</td>
<td>Planned</td>
</tr>
<tr>
<td>1.8 Normative acts developed and submitted for approval by respective government bodies</td>
<td>Ongoing</td>
</tr>
<tr>
<td>1.9 Report on options analysis for pharmaceutical pricing strategies</td>
<td>Planned</td>
</tr>
<tr>
<td>1.10 Four EML/positive list market analysis reports</td>
<td>1/4 Completed</td>
</tr>
<tr>
<td>2.1 15 consultants recruited for secondment to the CPA</td>
<td>11/15 Completed</td>
</tr>
<tr>
<td>2.2 Brief summary training report prepared with findings and recommendations. Office equipment and supplies procured and transferred to the CPA. International learning trips conducted.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>2.3 Dashboard for each category and calculations of the savings methodology developed</td>
<td>Ongoing</td>
</tr>
<tr>
<td>2.4 Key internal CPA business processes and policies developed</td>
<td>Ongoing</td>
</tr>
<tr>
<td>2.5 Recruit, supervise, retain, and assess members of the Supervisory Board</td>
<td>Ongoing</td>
</tr>
<tr>
<td>2.6 Normative acts approved by respective government bodies. WHO prequalification criteria applied for ARVs and TB therapies.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>2.7 Normative acts approved by respective government bodies</td>
<td>Ongoing</td>
</tr>
<tr>
<td>2.8 HIV commodities procured by the CPA in the most cost-effective, transparent, and timely manner</td>
<td>Ongoing</td>
</tr>
<tr>
<td>2.9 Business case for private-sector engagement in warehousing prepared</td>
<td>Planned</td>
</tr>
<tr>
<td>2.10 S&amp;OP processes developed</td>
<td>Ongoing</td>
</tr>
<tr>
<td>2.11 MedData upgraded to include Material Management System</td>
<td>Ongoing</td>
</tr>
<tr>
<td>2.12 GPS tracking system introduced with web-based and mobile status monitoring, tracking, digital proof of each delivery, and visualization</td>
<td>Ongoing</td>
</tr>
<tr>
<td>2.13 Brief training report with feedback from participants prepared</td>
<td>Ongoing</td>
</tr>
<tr>
<td>2.14 Seven training courses conducted with up to 400 trained in 12 PEPFAR priority regions</td>
<td>2/7 Completed</td>
</tr>
<tr>
<td>3.1 New medicines are successfully integrated into state reimbursement program</td>
<td>Ongoing</td>
</tr>
<tr>
<td>3.2 Normative acts for state reimbursement program</td>
<td>Ongoing</td>
</tr>
<tr>
<td>3.3 Summary report from Reimbursement Forum</td>
<td>Planned</td>
</tr>
<tr>
<td>3.4 Promotion and communication materials developed and disseminated</td>
<td>Ongoing</td>
</tr>
<tr>
<td>3.5 Fraud prevention and detection functions incorporated into ePrescriptions</td>
<td>Ongoing</td>
</tr>
<tr>
<td>3.6 Additional NHSU staff trained to expand, manage, and evaluate state reimbursement programs</td>
<td>Ongoing</td>
</tr>
<tr>
<td>3.7 Scope of work for IT module for ARVs</td>
<td>Planned</td>
</tr>
<tr>
<td>4.1 Logistics pilot report with follow up recommendations and actions</td>
<td>Q1 Completed</td>
</tr>
<tr>
<td>4.2 TB, HIV, and viral hepatitis therapies distributed to service delivery points as scheduled</td>
<td>Ongoing</td>
</tr>
<tr>
<td>4.3 Assessment report with description of proposed models for decision makers</td>
<td>Ongoing</td>
</tr>
<tr>
<td>4.4 Assessment report with description of existing gaps and recommendations</td>
<td>Ongoing</td>
</tr>
<tr>
<td>4.5 Interim reports submitted to stakeholders</td>
<td>Planned</td>
</tr>
<tr>
<td>4.6 Final pilot report on the distribution of ARVs and PrEP in the pilot region(s)</td>
<td>Ongoing</td>
</tr>
<tr>
<td>4.7 Necessary normative acts are endorsed. Primary health care providers are better engaged in providing HIV-related services to patients.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>4.8 Roadmap for implementation of the tool is developed. Tool is successfully piloted and compatible with other electronic systems (e.g., HIV MIS, MedData, E-Health)</td>
<td>Ongoing</td>
</tr>
</tbody>
</table>
### Deliverables

<table>
<thead>
<tr>
<th>Deliverables</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.9 Trainings carried out for regional and national representatives responsible for the forecasting and quantification for TB and HIV medicines/commodities</td>
<td>Planned</td>
</tr>
<tr>
<td>4.10 Normative acts endorsed and approved by respective government bodies</td>
<td>Planned</td>
</tr>
<tr>
<td>4.11 Expert(s) seconded to CPH</td>
<td>Completed</td>
</tr>
<tr>
<td>4.12 Procured health products/PPE delivered in accordance with GDP requirements (including cold chain) to end recipients</td>
<td>Ongoing</td>
</tr>
<tr>
<td>5.1 Normative acts for bioequivalence strategy</td>
<td>Ongoing</td>
</tr>
<tr>
<td>5.2 List of priority medicines with rationale</td>
<td>Ongoing</td>
</tr>
<tr>
<td>5.3 Qualitative criteria for the state reimbursement program</td>
<td>Ongoing</td>
</tr>
<tr>
<td>5.4 Market modeling report with emphasis on the centralized nomenclature for the treatment of HIV/AIDS, TB, hepatitis C, and adult oncology</td>
<td>Planned</td>
</tr>
<tr>
<td>5.5 Assessment report with findings and recommendations</td>
<td>Ongoing</td>
</tr>
<tr>
<td>5.6 EU model sensitized for Ukraine accepted by key stakeholders with clear roles defined</td>
<td>Ongoing</td>
</tr>
<tr>
<td>5.7 Normative acts aligned with EU standards and legislation</td>
<td>Planned</td>
</tr>
<tr>
<td>5.8 Brief forum report with findings and recommendations</td>
<td>Ongoing</td>
</tr>
<tr>
<td>5.9 Technical requirements for the national medicines serialization system</td>
<td>Planned</td>
</tr>
<tr>
<td>6.1 Three success stories developed</td>
<td>1/3 Completed</td>
</tr>
<tr>
<td>6.2 52 media monitoring reports produced</td>
<td>12/52 Completed</td>
</tr>
<tr>
<td>6.3 12 news digests produced and disseminated</td>
<td>3/12 Completed</td>
</tr>
<tr>
<td>6.4 Up to five communications materials or products developed</td>
<td>Planned</td>
</tr>
<tr>
<td>6.5 Up to four communication products for pharmacies and health care facilities developed</td>
<td>Planned</td>
</tr>
<tr>
<td>6.6 Up to three communication products for SEC, MOH, and health care facilities developed</td>
<td>Planned</td>
</tr>
<tr>
<td>6.7 Oral or poster presentations at three national or local conferences</td>
<td>1/3 Completed</td>
</tr>
<tr>
<td>6.8 Up to five communication products developed and disseminated</td>
<td>Planned</td>
</tr>
<tr>
<td>6.9 Up to five communication products developed</td>
<td>3/5 Completed</td>
</tr>
</tbody>
</table>

### E. Coordination and Partnerships

SAFEMed continued to maintain the positive relationships it developed during the previous year with key government counterparts that are still in place and continues to build relationships with newly appointed staff. In addition, SAFEMed maintain strong relationships with other donor-funded projects, patient organizations, and the private sector.

### F. Geographic Information

No geographic information was uploaded during this reporting period. All project activities took place in Kyiv, Ukraine.
### XIII. LIST OF LEGISLATION DEVELOPED WITH SAFEMED SUPPORT

<table>
<thead>
<tr>
<th>No.</th>
<th>Legislative Document</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Policy Priority Setting: Health Technology Assessment and Essential Medicines List</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>CMU Decree No. 1300 - On the approval of the State Health Technology Assessment Procedure</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Approved December 23, 2020</td>
<td></td>
</tr>
<tr>
<td><strong>Strengthening NHSU Pharmaceutical Policy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>CMU Decree No. 1299 - About the state financial guarantees of medical service of the population in 2021. Decree expanded the reimbursement medicines list by adding three medicines for the treatment of cardiovascular disease: warfarin, nifedipine, and acetylsalicylic acid.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Approved December 21, 2020</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Law No. 2168 - About the state financial guarantees of medical service of the population in 2021</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Approved December 29, 2020</td>
<td></td>
</tr>
</tbody>
</table>
XIV. SUCCESS STORIES

USAID helps Ukraine revolutionize access to medical treatment for all

Anton Kulagin was a professional volleyball player and avid sportsman when, at the age of 22, he was diagnosed with multiple sclerosis (MS). This diagnosis was devastating personally and for his career, but even more so, was the news that the treatment needed was often unavailable and inaccessible through Ukraine’s national health system. Across the country, there are hundreds of thousands of patients just like Anton – combating diseases including cancer, HIV, TB, and cardiovascular who lack uninterrupted access to safe, effective and affordable medicines due to suboptimal procurement processes and severe delays in incoming shipments, lack of available funding and widespread corruption. Medicines were constantly unavailable with out-of-stock issues becoming the norm rather than the exception and, in some cases, certain groups of medicines were supplied with 2-year delay periods.

Since 2015, the Ministry of Health has led ambitious and fast-paced procurement reforms aimed at improving efficiency, cost-effectiveness, and transparency and with support from USAID and other donors, Ukraine’s Medical Central Procurement Agency (CPA) was established in October 2018. USAID’s SAFEMed project led by Management Sciences for Health, supported CPA in building its own purchasing power and implementing best international practices into its daily operations. The adoption of a set of rules and regulations based on transparency, equal access, and efficiency has enabled the Agency to revolutionize access to treatment while also saving billions in Ukrainian hryvnia (UAH) on public spending.

"...everyone will be able to see the systematic effect and improvement with time, but so far what is visible is quite successful [the CPA activity] ... " shared Anton Kulagin.

In 2019, CPA’s very first tender announcement for the Global Fund Program resulted in cost savings of six million Ukrainian Hryvna on a 17 million auction purchase of lifesaving medicines for HIV/AIDS. In March 2020, CPA received the official legal status required to start procuring for 14 centralized government funded programs accounting for 489 items with a total budget of 9.7 billion UAH.

By October 2020, the Central Procurement Agency of Ukraine crossed the UAH 1 billion ($330M USD) savings mark through 158 auctions (out of 430 planned) in Prozorro, with over 61 million UAH for ARV’s, based on the MOH’s estimated prices.

Thanks to the CPA and their fair and transparent procurement procedures the reliability of incoming deliveries of medicines and medical equipment has increased significantly compared to previous years. Despite receiving the required legal status to procure for public funds in March, the CPA received the first consignments of goods on October 20, which is only 5 months after the announcement of tenders, with the first ARV shipments arriving in December 20. As we move in 2021, all 489 items are expected to be received by CPA’s logistics partner, who won their 1st ever tender for distribution services earlier this year, at a central warehouse for further handling and distribution across all 24 regions of Ukraine.

Anton and other patients cherish the hope that Ukraine’s newly established centralized government body, the CPA, brings to their treatment options since its establishment as an independent organization in the country.

This year, Anton Kulagin, together with other patients is closely monitoring the results in the Prozorro system, the official electronic public procurement platform in Ukraine, because the
ministry has delegated bidding for programs to combat MS among adults to the CPA. Anton appreciates the savings achieved, although he believes that the situation in the country, remains at risk of corruption.

Arsen Zhumadilov, Director General of the Central Procurement Agency of Ukraine says, “All the public funds that we managed to save is, on the first place, the money of the Ukrainian taxpayers. We are extremely conscious about that. It is a vivid market competition during the auctions that ensure such significant savings. Our auctions showed that there is great interest from the participants, including international and Ukrainian pharmaceutical companies and suppliers in our tenders. This became possible due to the professional work of our team, high-quality preparation for tenders, strong internal anti-corruption procedures and reputation of the CPA of Ukraine as a reliable partner."

CPA’s 2020 major win - UAH 1 billion savings and early deliveries will provide a further opportunity to increase access of Safe Effective and Affordable Medicines to vulnerable groups of Ukrainian patients.