

SIAPS Ukraine End of Project Report

July 2017



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SIAPS 
Systems for Improved Access
to Pharmaceuticals and Services

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About SIAPS

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to ensure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

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ACRONYMS

ADR	adverse drug reaction
CSO	civil society organization
DTC	Drug and Therapeutics Committee
DUR	drug utilization review
EML	essential medicines list
EU	European Union
GVP	Good Pharmacovigilance Practices
LOE	loss of efficacy
MOH	Ministry of Health
NSCA	National Supply Chain Assessment
NGO	nongovernmental organization
PV	pharmacovigilance
PAIS	Pharmacovigilance Automated Information System
STG	standard treatment guideline
SEC	State Expert Center
SPS	Strengthening Pharmaceutical Systems
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
USAID	US Agency for International Development
UCDC	Ukrainian Center for Disease Control

BACKGROUND

Following the collapse of the Soviet Union, Ukraine inherited a highly centralized, nationally controlled health care system, many aspects of which remain unreformed. The system has traditionally been input rather than output based and has had little chance to operate effectively, given that the resources required have been significantly greater than the economic capacity of the state.

As of 2014, approximately half (50.7%) of the total health expenditure was from public-sector sources.¹ This has significant implications for equity in health system financing because private spending, almost entirely in the form of out-of-pocket payments (93.9%), makes up the balance.² Out-of-pocket payments accounted for 46.2% of the total health expenditure in 2014.³ The existing health care financing system puts the burden of financial expenses for medicines mainly on patients and their families. In 2011, 30% of the total health expenditure was in the form of out-of-pocket payments for medicines. Given the high cost of medicine, this meant that disadvantaged patients had little if any access to treatment.⁴

Therefore, one of the key challenges of the health care system in Ukraine is access to affordable quality medicines. In addition, health care administrations at all levels have little experience with a results-oriented approach to management. Obsolete legislation and an underperforming supply chain have resulted in poor patient service and high medicine prices. Paper-based record keeping and recording systems hinder evidence-based interventions and are vulnerable to inefficiencies, irrational medicine use, and corruption.

The US Agency for International Development (USAID)-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program in Ukraine began in 2013, during the second year of the global program. The SIAPS mandate in Ukraine was to reduce opportunities for corruption and address mismanagement in pharmaceutical systems, thereby targeting both poor governance and weak management practices. SIAPS applied a systems strengthening approach to organize interventions that support adherence to principles of good governance.

¹ World Bank. Health expenditure, public (% of total health expenditure). Available at: http://data.worldbank.org/indicator/SH.XPD.PUBL?locations=UA&name_desc=true+%E2%80%94OK

² World Bank. Out-of-pocket health expenditure (% of private expenditure on health). Available at: http://data.worldbank.org/indicator/SH.XPD.OOPC.ZS?locations=UA&name_desc=true&view=chart

³ World Bank. Out-of-pocket health expenditure (% of total expenditure on health). Available at: http://data.worldbank.org/indicator/SH.XPD.OOPC.TO.ZS?locations=UA&name_desc=true

⁴ Lekhan VN, Rudyi VM, Shevchenko MV, Nitzan Kaluski D, Richardson E. Ukraine: Health system review. Health Systems in Transition, 2015; 17(2): 1–153, 58. Available at: http://www.euro.who.int/__data/assets/pdf_file/0018/280701/UkraineHiT.pdf

KEY INTERVENTIONS AND ACHIEVEMENTS

National TB Registry (e-TB Manager) Transferred to Ukrainian Center for Disease Control

In 2008, during the Strengthening Pharmaceutical Systems (SPS) Program, a predecessor to SIAPS, the Ministry of Health (MOH) requested technical support from USAID for the adaptation and implementation of an electronic TB management information system for the Ukrainian context. SPS and national partners, including the Ukrainian Center for Disease Control (UCDC), the State Penitentiary System, the National TB Institute, and the nonprofit Development of Ukraine, collaborated to customize e-TB Manager to the country's needs. e-TB Manager is a web-based system that operates as the Ukrainian national TB register and supports transparency and accountability while providing timely and accurate information for program monitoring and management.

For e-TB Manager to replace the inefficient paper-based registry and reporting system, all TB cases had to be entered into the new system. Piloting began in April 2011, and approximately 5,000 cases were entered. SIAPS was a leader in operating e-TB Manager and worked closely with the MOH and the UCDC to ensure a prompt feedback loop and provide necessary improvements to the system based on stakeholder requests. In 2012, e-TB Manager was approved as the official TB patient registry and its use became compulsory for TB facilities. As a result, the number of cases in the system continued to grow, and a data quality assurance protocol was developed to reduce errors in the registry and reporting. As of August 2015, 185,760 cases were in the system, and the consistency between paper-based and electronically generated reports was approximately 99%.

The unification of the operational procedures, which is a key feature of the system, has reduced the amount of time that staff spend on paperwork, thereby increasing efficiency, and the deployment of the medicines management module has allowed for more effective procurement planning. For example, data from e-TB manager were used to forecast consumption of medicines, which helped improve budgetary requests. The integration of these two achievements has improved the supply chain management of TB medicines, thereby increasing access to both the medicines themselves and pharmaceutical services.

In 2015, SIAPS/Ukraine officially transferred administration of e-TB Manager to the UCDC. The transfer is evidence of the strong relationships and foundation that have been formed to ensure the sustainability of the national TB registry and management system.

Promoting Rational Medicine Use in HIV and TB Treatment Centers

Implementing a drug utilization review (DUR) as a continuous quality improvement mechanism allows for the analysis of prescription practices and medicine use to improve service delivery and patient treatment outcomes. The DUR was successfully piloted in the Kyiv oblast TB dispensary in 2015. With support from the MOH, State Expert Center (SEC), UCDC, and other stakeholders, SIAPS trained members of the dispensary's Drug and Therapeutics Committee (DTC) and

provided technical assistance during data collection and review. The DUR pilot results shed light on the challenges in building adherence to standards of treatment for both doctors and patients and revealed that more regimens were in use than are stipulated in the standard treatment guidelines (STGs), unjustified substitutions and cancellation of medicines were detected within different regimens, necessary laboratory tests were not completed, and approximately 45% of intensive-phase patients were found to have been discharged for the ambulatory phase with regimen violations. These findings highlighted far-reaching organizational and technological changes that would be needed to significantly increase adherence to STGs and improve health outcomes. To address some of these issues, SIAPS helped organize DTCs in five TB facilities to monitor adherence to STGs using the DUR tool. In 2016, implementation of the DUR continued in two AIDS centers (Kyiv City and Chernihiv oblast). Based on these DURs, an action plan for nationwide implementation was developed and approved.

Ensuring Patient Safety through Strengthened Pharmacovigilance

SIAPS worked with government partners to develop the Pharmacovigilance Automated Information System (PAIS), a comprehensive electronic system used by the SEC, the national pharmacovigilance (PV) authority, and the MOH to collect and analyze data on adverse drug reactions (ADRs) and loss of efficacy (LOE). PAIS was successfully piloted in 2015 in four oblast AIDS centers and the National Institute of Infectious Diseases and continues to attract new users. The introduction of PAIS equips the SEC and MOH with a state-of-the-art instrument for data analysis and allows them make better informed decisions to ensure medicine safety and efficacy.

Challenges to a functional pharmaceutical system in Ukraine were historically related to difficulties in monitoring and reporting ADRs and LOE. The paper-based PV system has been unreliable for capturing and submitting quality data in a timely manner for analysis, identifying potential risks, and designing mitigation strategies. SIAPS worked with government partners to develop PAIS to ensure effective ADR/LOE monitoring and improve reporting practices.

PAIS captures ADR reports, supports data analysis, and automatically notifies users of potential threats. The system is open to users from the public, private, and civil sectors, including medical staff, data analysts, marketing authorization holders, individual patients, and patient organizations.

PAIS was piloted in 11 regional AIDS centers beginning in 2015. Trainings included 25 SEC staff, 69 physicians, and 20 regional representatives of patient organizations. The pilot resulted in 386 case submissions, which was much higher than anticipated. In 2016, the MOH made PAIS the official government system, and a link between PAIS and e-TB Manager was established so that e-TB Manager users can send TB-related ADR and LOE reports directly to PAIS.

The automated electronic process reduced staff workload by decreasing the amount of paperwork required for PV tasks and increased compliance to reporting standards by making it more difficult to circumvent reporting requirements. Through analysis and alerts, the regulatory authority can confidently make changes to STGs based on aggregated information on adverse effects or LOE.

Harmonizing Ukraine's Pharmacovigilance Policies to Align with International Standards

SIAPS was tasked with developing national PV guidelines and aligning them with European Union (EU) regulations, particularly in terms of approaches to data collection, reporting, and analysis and decision making regarding safety of medicines. The national guidelines comprise 16 modules and represent the adapted version of the Guidelines on Good Pharmacovigilance Practices (GVP) developed between 2012 and 2015 by the European Medicines Agency, which is the EU agency that evaluates pharmaceutical products. PV activities are organized by distinct but connected processes, and each GVP module presents a major component of PV.

SIAPS began supporting this activity in 2013, and all modules have been adapted to the Ukrainian context. Four modules have been approved by the MOH as of June 2017, with the remaining modules under review. Once finalized, the national PV guidelines will apply to all medicines authorized in Ukraine and will facilitate the performance of PV activities nationwide. Similar to institutionalizing PAIS, updating and harmonizing the national PV guidelines will contribute to promoting rational medicine use and patient safety by decreasing adverse events.

Combatting Corruption by Enhancing Transparency in the Procurement Process

A 2013 legislative analysis determined that the Government of Ukraine allowed multiple, non-harmonized medicines lists that enabled drug suppliers to manipulate the drug procurement process in favor of higher-priced products. As a result, it was decided to revise the national essential medicines list (EML). This builds on the Parliament Coalition Agreement, which requires the new national EML to be the sole basis for public procurement as an element of health care reform.

SIAPS was tasked with assisting to institutionalize and update the EML through a transparent, inclusive process. Despite this being a very high-profile issue, national stakeholders expressed contradictory ideas about the EML, and it took considerable effort to bring all parties to consensus. The SIAPS/Ukraine team provided extensive technical assistance to the MOH in facilitating the initial discussions, followed by targeted advocacy, which resulted in a remarkable change in public perception of the EML concept.

SIAPS/Ukraine worked with key stakeholders to establish the legal basis for a sustainable, transparent process to develop and revise the EML. The new national EML was approved in March 2017. This legal framework includes the adoption of amendments to current legal documents and the development of new ones. To date, several core documents have been developed and approved by the MOH, including regulations on the national EML and on the EML Expert Committee. SIAPS/Ukraine provided technical assistance and expertise to ensure bias-free selection of EML Expert Committee members and further development of the new national EML.

Improving Procurement Practices at the Regional Level

SIAPS assisted in piloting a framework agreement mechanism in selected regions to build the capacity of local staff and give them the opportunity to experience the process and the ability to replicate it. The country has had legislation to support the framework agreement since 2012 and it is seen as an international best practice, but it has never been utilized to procure pharmaceuticals. The introduction of framework agreements for 2015 public health care procurements in the Poltava and Dnipropetrovsk oblasts reduced the risk of stock-outs and helped employees use their time more efficiently by creating more flexible, shorter procurement procedures and decreasing opportunities for corruption.

Despite the short funding period, the piloting of framework agreements as a mechanism for better procurement practices has been well received. This approach gained more interest from the public sector and nongovernmental organizations (NGOs). To respond to the rising need for capacity building, SIAPS developed a training curriculum on framework agreements to be used at both the regional and national levels. The results and the stakeholder commitment have the potential for more efficient use of public funds through the development of a more transparent and accountable procurement system.

Assessing the National Supply Chain

The USAID Mission in Ukraine and the MOH requested that SIAPS provide assistance in the assessment of Ukraine's supply chain management system to produce evidence for making decisions on interventions for reform. SIAPS implemented the National Supply Chain Assessment (NSCA) in 2015 to assess the capability and performance of the supply chain system, identify gaps, and prioritize efforts to address those gaps according to the impact they might have on the supply chain system. The Government of Ukraine used this evidence during the decision making process for its health care reform initiative. SIAPS/Ukraine finalized the report in October 2016, and an action plan was developed based on the recommendations from the report, including the creation of a central procurement working group.

Developing and Implementing Legislation to Improve Cost Containment of Pharmaceuticals

SIAPS supported the development of legislation to amend the price regulations framework and introduce reimbursement of medicines for ambulatory care. Price referencing was introduced as a cost-containment policy measure in January 2017. The maximum wholesaler price is determined from the lowest prices for the same medicine by international nonproprietary name in five neighboring EU countries. This pricing mechanism is applied to those pharmaceuticals included in the national reimbursement list, which is a subset of the national EML.

SIAPS worked closely with key stakeholders, including the MOH, SEC, the nonprofit Patients of Ukraine, distributors (wholesalers), and pharmacies (retailers) to implement "Affordable Medicines," the state reimbursement program. SIAPS' role was to assist in developing a

comprehensive set of procedures and rules that have been officially adopted to facilitate the selection of products, price registration, and prescription rules to support the implementation of the program.

The reimbursement program began in April 2017 and covers 21 essential medicines for cardiovascular diseases, type 2 diabetes, and asthma. There are 157 pharmaceutical products available in the program, with 23 of them free and others having a small co-pay. According to the MOH, 4,715 pharmacies are currently participating in the program, and this number is growing as new contracts between pharmacies and regional budget holders are signed. According to the Kyiv City Administration, during the first week of the program, approximately 11,000 packages of reimbursable medicines were dispensed to patients in Kyiv.

CONTRIBUTIONS TO US GOVERNMENT GOALS

According to USAID’s Vision for Health Systems Strengthening, 2015–2019, health system strengthening is a foundational and integral part of ending preventable child and maternal diseases and achieving an AIDS-free generation, as well as protecting communities against infection diseases. Meeting these goals requires high-performing health systems that provide financial protection, ensure coverage of quality essential services, reach all people, and are responsive to their needs and preferences.

All SIAPS/Ukraine interventions contribute to reaching priority objectives envisioned for three of the six health system functions.

Health System Function	Priority Objective	Relevant Key HSS Intervention
Health Governance	Developed sustainable country capacity in transparent and accountable law, policy, planning, leadership, and management	<ul style="list-style-type: none"> • Reimbursement and price regulation
Health Information	Supported strategic, incremental, expansive improvement in integrated health information systems, including routine systems and evaluations vital for achieving USAID and partner countries’ shared goals	<ul style="list-style-type: none"> • Established e-TB Manager
Medical Products, Vaccines, and Technologies	Strengthened supply chain components to ensure the uninterrupted supply of quality-assured health commodities, including creating a supportive environment for commodity security and sustainable supply chains	<ul style="list-style-type: none"> • Piloted a framework agreement mechanism • Implemented the NSCA
	Strengthened medicine regulatory capacity to protect the public from counterfeit products and improved pharmaceutical-sector governance to promote transparency and accountability through appropriate laws, regulations, and policies	<ul style="list-style-type: none"> • Established the national EML
	Increased and enhanced human and institutional capacity to manage pharmaceutical systems and services, including promoting evidence-based use of medications, ensuring therapeutic efficacy, protecting patient safety, and slowing the emergence and spread of antimicrobial resistance	<ul style="list-style-type: none"> • Implemented DURs • Developed PAIS • Developed national PV guidelines

SIAPS interventions in Ukraine were aligned with the development objectives and intermediate results of the Results Framework of USG/Ukraine Country Development Cooperation Strategy, 2012–2016.

LESSONS LEARNED

Stay focused on goals and be flexible and ready to redesign the policy agenda to achieve results. In countries with an unstable political situation, rigid donor-driven action plans are often an obstacle to moving forward. The consequences of not being able to adapt to the changing political environment, although fully preventable, may include considerable loss of time and, more importantly, political support. The SIAPS/Ukraine team recognized these threats and benefited from changing its approaches to advocate for and assist stakeholders in the development of the new national EML.

Engage subnational regulatory bodies as stakeholders and sensitize them on planned interventions to avoid misunderstandings. In a highly regulated setting, regulatory offices were likely to block initiatives if they were uninformed, unfamiliar, or believed the initiatives did not align with current regulations. Local partners notified the SIAPS/Ukraine team about potential obstacles if subnational regulatory authorities were not engaged prior to piloting the framework agreement mechanism for procurement. A special meeting was held with local stakeholders, including representatives from regulatory bodies, to ensure that all possible regulatory issues were addressed.

Engage and educate patient organizations and other civil society organizations (CSOs) while moving forward with developing and implementing new approaches, mechanisms, and tools. In highly corrupt (i.e., distrustful) settings, such innovations may appear to be another form of corruption to CSOs and lead to massive resistance. To avoid such resistance in the case of the new EML, SIAPS extended its educational efforts to these organizations to ensure their awareness of the benefits of the updated EML and dispel any myths surrounding it.

SUSTAINABILITY AND COUNTRY OWNERSHIP

e-TB Manager

The midterm results of the e-TB Manager implementation were impressive, and positive feedback from system users and administrators provided confidence to the Government of Ukraine, resulting in the official adoption of e-TB Manager as the national TB registry in 2012. The same year, e-TB Manager was verified for data security issues and certified by the State Security Service of Ukraine.

In 2015, SIAPS/Ukraine implemented a year-long transition plan that resulted in the smooth transfer of e-TB Manager from SIAPS to the UCDC and ensured that the UCDC is able to provide sustainable operation of the system. Since September 2015, the national TB registry has been owned and sustained by the UCDC.

Drug Utilization Review

The implementing facilities have the capacity to sustain and replicate DURs. Because a DUR is a cyclic process by nature, its continuous application is essential for its success. It is envisioned that DURs will be an effective tool for rationalizing medicine use in Ukraine and will expand to include other health facilities. SIAPS trained DTC members to help sustain DURs as the best practice approach to ensuring rational medicine use.

Pharmacovigilance Automated Information System

PAIS was handed over to the SEC after the security protocol for data protection was finalized and approved in November 2016. The SEC, as a state enterprise, has the capacity to fully maintain the system and cover related costs. The link established between PAIS and e-TB Manager allows for sustainable integration between the systems, which benefits patients.

Essential Medicines List

There was resistance to the process of establishing an EML as the sole basis of public-sector procurement because of vested commercial interests. However, a number of key stakeholders, including the MOH, SEC, National Medical University, and major NGOs, have been very supportive in the development and implementation of the new EML. The new national EML was approved in March 2017 and will become effective on January 1, 2018.

National Supply Chain Assessment

Country ownership was embedded in the assessment from its inception in 2015. Key stakeholders have been included in all communications and planning of the assessment. The working group on reforming the national supply chain of medicines had a subdivision responsible for shaping the assessment and recognizing its results. SIAPS was open and transparent with the process and the findings of the NSCA, which facilitated further implementation of the recommendations derived from the assessment's results.

Reimbursement Program

The reimbursement program is regulated by several decrees of the Cabinet of Ministers and orders of the MOH. The program is centrally financed from the state budget through the mechanism of special targeted subvention. Financial support for the program is included in the budgetary resolution for 2018–2020, from which the state budget will be drafted. As a result, reimbursement of medicines is now a part of government health policy, and the program has good opportunities for expansion.