

Our specific approaches to each of the five result areas follows—

GOVERNANCE

Under SIAPS, our approach to improving governance and accountability focuses on establishing transparent management systems grounded in policies based on best practices, legislation supported by the rule of law, and regulation supported by appropriate technology and capacity.

BUILD CAPACITY FOR PHARMACEUTICAL MANAGEMENT AND SERVICES

To increase efficiency, SIAPS works with stakeholders to assess a country's capacity to manage pharmaceuticals at all levels. Then, using a stakeholder consensus approach, we identify areas for improvement and develop interventions to strengthen the system for the long term, such as building capacity among facility level staff to track medicine consumption.

INFORMATION FOR DECISION-MAKING

Our approach to improving information systems is to integrate pharmaceutical data collection, processing, and presentation of information to help staff at all levels of a country's health system make evidence-based decisions to manage health and laboratory commodities and pharmaceutical services, as well as harmonize our tools with tools developed by others.

STRENGTHEN FINANCING STRATEGIES

Through SIAPS, we also help countries conduct analyses to inform policy decisions regarding cost containment, greater efficiency, and options for mobilizing financing. Our health management expertise combined with SIAPS partners' knowledge and experience in innovative financing strategies allows countries to maximize their pharmaceutical resources.

IMPROVE PHARMACEUTICAL SERVICES

Our strategy for improving pharmaceutical services is not limited to assuring product availability; our holistic approach strives to ensure that patients receive medications optimized to their clinical needs, in doses that meet their individual requirements, for a sufficient time, and at the lowest cost to them and their community. To ensure services that result in optimal treatment outcomes, we build capacity within local systems to provide medicine information and counseling, train health professionals and providers, conduct drug utilization reviews, formulate policies and regulations for improved pharmaceutical care, and disseminate information and educational materials to promote public health.

To achieve results, SIAPS uses a flexible approach to designing a tailored intervention, implementing and managing that intervention, monitoring performance, and measuring outcomes. We fully engage local partners to ensure that they are contributing to and building skills at each stage of the intervention and that solutions are locally relevant and sustainable without ongoing support. The key to many of our project achievements has been the broad-based support from all stakeholders built through a participatory approach to project design and implementation.

SIAPS ASSISTANCE IS GROUPED INTO FOUR TECHNICAL AREAS

- Pharmaceutical Systems
- Supply Chain Management
- Pharmaceutical Services
- Tools, Software Solutions, and
Pharmaceutical Management Information
System Strengthening Activities

The **SIAPS GOAL** is to assure the *availability of quality pharmaceutical products and effective pharmaceutical services* to achieve desired health *outcomes*.

The **SIAPS OBJECTIVE** is to promote and use a *systems-strengthening methodology* that will result in a positive and sustainable *health impact*.

The USAID-funded Systems for Improved Access to Pharmaceuticals and Services' technical approach emphasizes Global Health Initiative principles, especially improving metrics, monitoring and evaluation, capacitating local governments and organizations, and increasing country ownership. Toward this end, the SIAPS framework and result areas reflect the dynamic relationships among five health systems building blocks: governance, human resources, information, financing, and service delivery, with a pharmaceutical product overlay that guides technical content.

The SIAPS Program is carried out by a team led by MSH that includes core partners and a select group of organizations that serve as specialized resources.

LEAD

Management Sciences for Health

Improving management systems, strengthening pharmaceutical management systems, promoting access to services, and influencing public policy and global project management

CORE PARTNERS

Accreditation Council for Pharmacy Education (ACPE)

Accreditation of pharmacy education and training; development and evaluation of quality standards for pharmacy degree programs and continuing education providers in the United States and abroad; training of evaluators to provide standardization and consistency in the accreditation review process

Harvard University

Pharmaceutical health insurance, treatment adherence, and pricing information/ mechanisms; applied and operations research and evaluation of programs and policies; cost-effective analysis of different interventions; and policy and program activities in logistics systems and pharmaceuticals

Logistics Management Institute (LMI)

Pharmaceutical supply chain and logistics management in support of global health initiatives; acquisition management, and financial management expertise to conduct policy option analyses on contracting for pharmaceutical-related services

University of Washington

Pharmacoepidemiology, pharmaceutical care services, pharmacovigilance, pharmacoconomics, and product quality control and assurance

SPECIALIZED RESOURCE PARTNERS

African Medical and Research Foundation

Strengthening laboratories as an integrated part of strengthening health systems: management and supervision, integrating laboratory diagnostics, establishing or strengthening external quality assurance schemes; and strengthening training of clinicians and laboratory workers

Ecumenical Pharmaceutical Network

Liaison to mission sector in developing countries, coordination and networking, development and provision of technical assistance on pharmaceutical policy and services, human capacity development, and consumer/patient education related to pharmaceutical management and medicines use

Research for Development (R4D)

Research and evaluation; leadership development to advance policy and strengthen health systems; health financing and demand-side models such as health insurance; strengthening the capacity of civil society organizations; and integration and collaboration of the public and private sectors to better achieve national health goals

RTT Group

South Africa-based warehousing and distribution service support

VillageReach

Management information systems in a developing country context, particularly mHealth and open-source solutions; reaching the last mile of the supply chain; offices in Malawi and Mozambique

William Davidson Institute

Operations research, supply chain management in developing countries, investigation of business-based approaches to improving health care delivery, and research to advance the transition from donor dependence to market-based health systems

Systems for Improved Access to Pharmaceuticals and Services

Improved Access. Improved Services.
Better Health Outcomes.



USAID
FROM THE AMERICAN PEOPLE

SIAPS
Systems for Improved Access
to Pharmaceuticals and Services

SIAPS PHARMACEUTICAL SYSTEMS

Through its pharmaceutical systems capabilities, SIAPS helps countries improve access to health products and services by adopting sound pharmaceutical policies and implementing effective regulatory, financing, and pharmaceutical quality and safety initiatives.

SIAPS activities build on Strengthening Pharmaceutical Systems Program experiences and focus on pharmaceutical policies, laws, and regulations. Others center on medicine registration, product quality assurance, pharmacovigilance and postmarketing surveillance, pharmaceutical financing, product selection, pharmacoeconomics, and the assessment and integration of new health technologies and diagnostics.

SIAPS strategies to address these areas include building capacity of local institutions to organize and manage pharmaceutical systems; harmonizing policies and regulations; applying proven, effective, and efficient policy and financing solutions, adopting evidence-based approaches to decision making and strategic planning; generating additional resources and using them more efficiently; and advocating for good governance practices within the pharmaceutical sector.

As a result of SIAPS activities, pharmaceutical management procedures throughout the health system will be more transparent, proven effective health technologies will be broadly available and used, and financial barriers for medicines will be reduced, which all lead to better access to health products and services.

PHARMACOVIGILANCE—A SYSTEMS APPROACH TO PROMOTE PATIENT SAFETY

Studies have reported the huge impact that poor product quality, adverse drug reactions (ADRs), and medication errors have on health care in general and on patients' health in particular. However, few developing countries have the structures, systems, or resources in place to develop a functional medicine safety system, and countries often lack unbiased, evidence-based information to help guide regulatory and patient safety decisions.

Using a systems perspective, SIAPS supports programs to adopt both active and passive approaches to identify medicines-related problems including ADRs, product problems, and product use errors. SIAPS applies diagnostic tools such as our indicator-based assessment tool to identify pharmacovigilance system gaps and develop system strengthening activities. We build capacity of local partners to incorporate pharmacovigilance activities at all levels of the health system, and we also help implement effective ways to communicate medicine safety information to policy makers, health care professionals, and the public.

These activities will produce readily available medicine safety information for stakeholders to use in making evidence-based decisions that reduce risks to patients and maximize health outcomes.

STRENGTHENING THE REGULATORY SYSTEM TO IMPROVE ACCESS TO MEDICINES

National medicine regulatory authorities in developing countries are often confronted with systematic challenges; for example, backlogs of drug registration applications wait for review, and regulatory activities are not conducted transparently or with accountability.

SIAPS provides support to national medicine regulatory authorities to improve pharmaceutical sector governance and strengthen regulatory systems to ensure timely access to medicines and other health supplies.

Determining the appropriate technical assistance involves a review of the existing regulatory system, legislation, and policies, and an assessment of a country's regulatory capacity and operations. Those results then form the basis of a strategic framework and plan to strengthen the regulatory system. SIAPS uses assessment tools developed by the World Health Organization and the Strengthening Pharmaceutical Systems Program, including its regulatory systems assessment tool, and adapts guidelines from acknowledged sources such as the World Health Organization and the International Conference on Harmonisation.

To bolster the policy and regulatory environment, SIAPS helps countries apply appropriate technological and capacity-building initiatives to create efficient and sustainable drug registration systems, monitor medicine quality, control medicine promotion and advertising, and fulfill other regulatory mandates. The result is better access to quality, safe, and effective health products.

SIAPS SUPPLY CHAIN MANAGEMENT

Through its supply chain management capabilities, SIAPS helps national country systems ensure the continuous availability of quality pharmaceutical products by conducting options analyses and designing and implementing supply chain interventions including those related to logistics information management.

SIAPS activities build on Strengthening Pharmaceutical Systems Program experiences and focus on pharmaceutical forecasting, quantification, and supply planning. Others center on procurement planning and management, transportation, warehousing and inventory management, distribution planning, and logistics management information systems.

SIAPS strategies to address these areas include working with in-country partners to conduct supply chain options analyses, exploring and implementing innovative solutions including establishing viable private sector partnerships, applying emerging technologies such as web-based and mobile solutions to manage supply chain information, improving local competencies and task-shifting, promoting system integration, seeking supply chain standards certification, and monitoring supply chain system performance.

A stronger national supply chain system makes logistics information readily available to facilitate evidence-based decision making, maximizes system efficiencies, helps integrate new medicine and diagnostic technologies, and increases health product availability.

STRENGTHENING CAPACITY TO MANAGE PHARMACEUTICAL PROCUREMENT

The procurement component of the supply chain is often challenged by limited funding, complex and often conflicting regulations, policies, and procedures, a lack of skilled personnel to manage procurement activities, and difficulty ensuring tendering competition and transparency. Such issues may lead to a lack of public trust in the process, delays in procurement, compromised product quality, and higher costs.

SIAPS works with local stakeholders, including government ministries, donors, and supply chain partners, to evaluate existing practices and improve procurement methods and procedures while emphasizing transparency and competition. We also help streamline the selection process for pharmaceuticals to be procured and build staff and system capacity to adhere to rules and regulations and select and negotiate with the most qualified suppliers. Where appropriate, SIAPS supports countries' evaluation, selection, and application of appropriate technologies and solutions, such as e-procurement systems and framework contracts, and also helps develop and implement web-based procurement tracking to promote transparency and process monitoring.

These efforts help ensure that the right amount of appropriate quality pharmaceuticals is consistently available at the best price. The results promote both public and donor trust in the pharmaceutical system.

STRENGTHENING CAPACITY FOR QUANTIFICATION TO ENSURE MEDICINE AVAILABILITY

Accurate quantification of pharmaceutical requirements is critical to ensure adequate procurement planning. Multiyear forecasts make it easier to advocate for resources to ensure commodity security. Challenges to accurate quantification include lack of reliable consumption or morbidity data, little coordination among stakeholders and clarity of their roles, a lack of information on system capacities, and limited ability to monitor quantification and supply plans.

SIAPS helps build the capacity of national-level staff members to execute efficient quantification and supply planning. Support includes setting up coordination mechanisms for in-country stakeholders, including the ministry of health, donors, and development partners, to estimate medium- to long-term needs; determining funding gaps and aligning resources to meet estimated medicine procurement costs; and helping strengthen data and information management systems. We help staff members use effective tools such as Quantimed and PipeLine® for forecasting and supply planning and provide formal and on-the-job training, mentoring, and supportive supervision.

SIAPS technical assistance improves the quality of information needed for quantification, streamlines workflow processes, and maximizes financial resources, which all help ensure commodity security.

SIAPS PHARMACEUTICAL SERVICES

Through its pharmaceutical services capabilities, SIAPS helps countries improve pharmaceutical services provided to patients, thus increasing treatment effectiveness and achieving desired health outcomes.

SIAPS activities build on Strengthening Pharmaceutical Systems Program experiences and focus on improving rational medicines use and containing antimicrobial resistance (AMR). Related technical areas include medication adherence, standard treatment guidelines, formularies and clinical algorithms, essential medicine lists, facility and community-based case management, medicine and therapeutics information, and infection control.

SIAPS strategies to address these areas include working with stakeholders to establish or revitalize Drug and Therapeutics Committees (DTCs) and infection control programs and incorporating rational use and AMR into pre-service and in-service training for health care providers. Other targeted objectives include building local capacity to regularly update standard treatment guidelines and essential medicine lists, supporting drug use evaluation studies that identify irrational practices and inform the design of effective corrective interventions, establishing pharmaceutical care programs, advocating for the containment of AMR, and using information, education, and behavior change approaches for consumer education.

Results will include pharmaceutical service standards being defined, adopted, and implemented, and consequently, local systems that are empowered to provide quality pharmaceutical services. Better pharmaceutical services improve medication use and thereby slow the emergence of AMR and improve health outcomes.

DRUG AND THERAPEUTICS COMMITTEES—AN IMPORTANT STRATEGY TO IMPROVE PHARMACEUTICAL SERVICES

Supporting Drug and Therapeutics Committees (DTCs) is a proven strategy that supports effective, safe, and cost-effective use of medicines in a health facility. However, many developing country institutions lack functioning DTCs or face challenges in managing them effectively.

SIAPS focuses on DTCs as a core strategy to improve medicine use and contain AMR—primarily by collaborating with in-country partners, including ministries of health and hospitals, to establish, revitalize, or improve the efficiency of DTCs. This strategy includes training DTC members, providing technical assistance to members to plan and implement improvement activities, and conducting plan reviews. SIAPS establishes local cadres of DTC master trainers to build local capacity and sustain DTC scale-up. SIAPS also helps DTCs conduct studies to identify medicine use problems and use the results to find appropriate and cost-saving solutions. Committees receive support to develop and maintain standard treatment guidelines and formularies, provide medicine information to health care providers and patients, and carry out pharmacovigilance activities.

Effective DTCs help improve medicine availability, promote rational use and medicine safety, and contain AMR within their institutions.

A CAPACITY-BUILDING APPROACH FOR THE CONTAINMENT OF ANTIMICROBIAL RESISTANCE

Just a few countries are implementing the World Health Organization's global strategy for the containment of antimicrobial resistance (AMR). Only when AMR is identified as an urgent priority will AMR policies, medicine regulations, and research be implemented adequately; therefore, national and regional stakeholders must support the creation of local coalitions and advocacy efforts to combat AMR.

SIAPS continues to support country and regional coalition-building efforts around AMR as described in our publication, *Building Local Coalitions for Containing Drug Resistance*. Our approach involves rapid information gathering to identify AMR-related issues and important stakeholders. We then follow-up by establishing a local champion group with the mandate to mobilize and catalyze partners and develop locally feasible action plans to contain AMR. Plans should consider strategies that strengthen health systems overall, such as infection prevention and control programs, pre-service and in-service curricula reforms that address AMR and rational antimicrobial use, establishment of effective Drug and Therapeutics Committees, public awareness and education campaigns, formulation and enforcement of AMR-related policies and regulations, and institution of antimicrobial use and resistance surveillance activities.

Enhanced antimicrobial stewardship at the regional and country levels will help preserve antimicrobial effectiveness and contribute to AMR containment.

TOOLS, SOFTWARE SOLUTIONS AND PHARMACEUTICAL MANAGEMENT INFORMATION SYSTEM STRENGTHENING ACTIVITIES

Through our tools, software solutions, and pharmaceutical management information system activities, SIAPS helps ensure that quality pharmaceutical information is available to formulate pharmaceutical policy and plans and monitor supply chain systems and pharmaceutical services.

Tools that SIAPS uses include—

- **Pharmadex**—medicines registration
- **Quantimed**—forecasting and quantification
- **Electronic Dispensing Tool**—medicine dispensing and treatment adherence tracking
- **RxSolution**—patient management, dispensing, and inventory management
- **e-TB Manager**—management information needs for tuberculosis patients

SIAPS activities build on Strengthening Pharmaceutical Systems Program experiences and focus on aggregation, analysis, presentation, and dissemination of the information generated by these tools to support evidence-based decision making.

To address these areas, SIAPS strategies include assessing and evaluating local information needs; leveraging mobile phone and other technology in designing tools; harmonizing tools to help integrate pharmaceutical management information systems; and strengthening local organizations to customize, maintain, and take ownership of the tools and also to analyze, manage, and use the resulting data.

As a result, SIAPS country partners use innovative and proven tools to generate accurate and timely information on pharmaceutical systems to improve access to products and services.

E-TB MANAGER—A WEB-BASED TOOL TO MANAGE TUBERCULOSIS PROGRAMS

The emergence of drug-resistant TB, including multidrug-resistant TB and extensively drug-resistant TB, is a significant health challenge in many countries, and one which increases the need for information to manage TB-related cases and medicines effectively.

A web-based tool, e-TB Manager was developed to address all TB programs' information needs related to both case and inventory management. SIAPS works with recipient programs to adapt the tool to local country settings, including making it available in the local language. Training for national TB control staff uses well-established training methodologies and materials to build capacity to plan, implement, and sustain the tool.

The SIAPS strategy is to establish local cadres of master trainers and programmers to scale-up implementation of the tool and provide troubleshooting and maintenance after it is in place. As part of its holistic approach, our technical assistance capacitates TB program managers to analyze and interpret information related to diagnosis, treatment, drug resistance, co-infection, and inventory management of first- and second-line TB medicines.

SIAPS technical assistance helps national TB control programs gain better access to strategic information to support program planning and implementation, which ultimately improves health outcomes through better access to medicines and improved TB case management.

PHARMADEX—AN ELECTRONIC TOOL TO SUPPORT REGISTRATION OF PHARMACEUTICAL PRODUCTS

A drug regulatory authority should know what pharmaceutical products it has approved for sale in the country along with specifics about the products and suppliers. Being able to track a product's application in the registration process also promotes accountability.

However, processing and tracking medicine registration can be complicated and time-consuming tasks. Significant backlogs of applications are common and can delay the availability of critical products on the market.

The Pharmadex tool is an easy-to-use platform for national drug authorities to streamline the registration process and track applications; it also easily generates an updated list of a country's approved medicines.

SIAPS works with national drug authorities to implement the Pharmadex tool after reviewing and optimizing their workflow process and adapting the tool for their specific needs. Staff members receive training to use the tool to create an efficient and sustainable medicine registration system. The tool also provides managers and decision makers with information to compare and analyze products and suppliers.

The result is a transparent registration process that assures that priority products are made available to the country's people without delay.