



# Systems for Improved Access to Pharmaceuticals and Services Program, Mozambique: Program Description

October 2012



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## **Systems for Improved Access to Pharmaceuticals and Services Program, Mozambique: Program Description**

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**SIAPS** 

The SIAPS logo features the word "SIAPS" in a bold, green, sans-serif font. To the right of the text is a stylized blue graphic of a person with arms raised, similar to the USAID logo.

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## **About SIAPS**

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to assure 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. SIAPS began September 23, 2011, and will end September 22, 2016. SIAPS is implemented by Management Sciences for Health.

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## ACRONYMS AND ABBREVIATIONS

CMAM	Centro de Medicamentos e Artigos Medicos (Central Medical Store)
DF	Departamento Farmaceutico (Pharmacy Department)
DFH	Departamento de Farmacia Hospitalar (Department of Hospital Pharmacy)
DNAM	Direccao Nacional de Assistencia Medica (National Directorate of Medical Assistance)
DTC	Drug and Therapeutic Committee
M&E	monitoring and evaluation
MISAU	Ministerio da Saude de Mozambique (Ministry of Health)
MSH	Management Sciences for Health
PEPFAR	President's Emergency Plan for AIDS Relief
PHP	priority health program
PMIS	Pharmaceutical Management Information System
PV	pharmacovigilance
SIAPS	Systems for Improved Access to Pharmaceuticals and Services Program
SOP	standard operating procedure
USAID	United States Agency for International Development

## BACKGROUND AND JUSTIFICATION

The expansion of diagnosis and treatment for priority health programs (PHPs) has resulted in an increase in pharmaceutical products in the health system. This increase has highlighted the need to address gaps in pharmaceutical policies and delivery of pharmaceutical services so that access to safe, efficacious, and quality pharmaceutical commodities can be ensured.

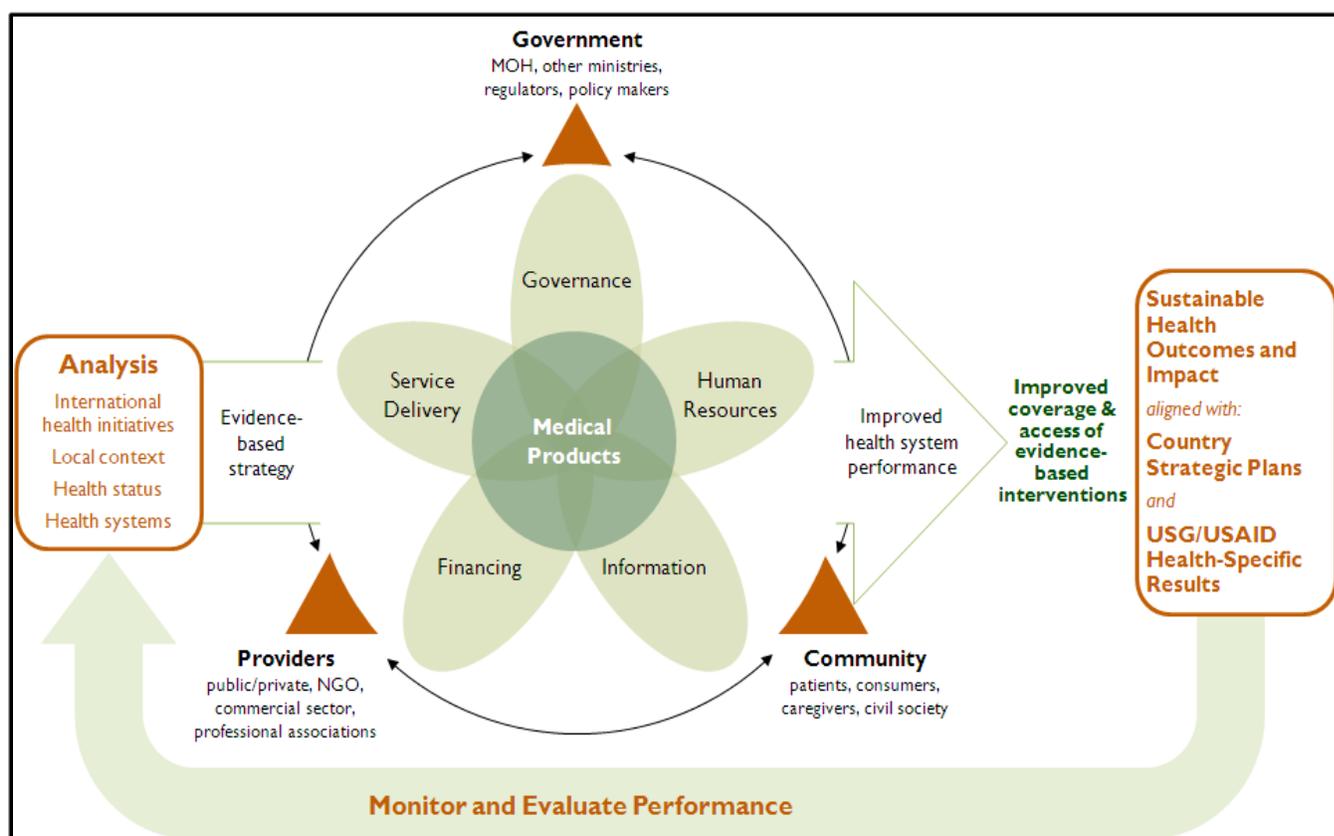
These aspects of Mozambique's pharmaceutical system have received limited technical support and need to be addressed by strengthening the pharmaceutical sector of the Ministry of Health, *Ministerio da Saude de Mozambique* (MISAU).

Establishing an effective and sustainable regulatory system under the leadership of the Pharmacy Department, *Departamento Farmaceutico* (DF) is a high priority. Stronger governance that is based on technically sound policies, legislation, regulations, and standards and is supported by transparent and accountable systems is needed. In addition, turnover in the DF staff has exposed the need to build technical capacity and improve the effectiveness of inexperienced staff. Gaps in the availability of training materials, technical guidelines, and standard operating procedures (SOPs) have been identified and must be addressed. An improved information management system is also required to help the Department generate strategic information that can be used for planning, monitoring, and evaluating its activities.

Another gap in the pharmaceutical sector is the delivery of pharmaceutical services. To this end, in 2010, MISAU created the Department of Hospital Pharmacy at the National Directorate of Medical Assistance, *Departamento de Farmacia Hospitalar/Direccao Nacional de Assistencia Medica* (DFH/DNAM) to manage and strengthen pharmaceutical services at the facility level. In addition to needing assistance with the development of its strategic vision and corresponding work plans, this newly established unit needs technical support to promote medicine safety and rational use through the introduction of Drug and Therapeutic Committees (DTCs) at hospitals; to build the capacity of facility-level pharmacy staff in good pharmaceutical practices; and, to effectively supervise their overall functioning.

## PROGRAM DESCRIPTION

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, implemented by the non-profit organization Management Sciences for Health (MSH) and funded by the United States Agency for International Development (USAID), is to strengthen pharmaceutical systems to ensure access to safe, effective, and quality pharmaceutical products and services. SIAPS uses a system-strengthening approach illustrated in the framework in figure 1.



**Figure 1. SIAPS Pharmaceutical System Strengthening Framework**

Because of existing gaps in the pharmaceutical system in Mozambique and the technical assistance needs of MISAU, USAID/Mozambique has allocated funding to SIAPS under the President’s Emergency Plan for AIDS Relief (PEPFAR) to address the following objectives—

- Strengthen governance in the pharmaceutical sector
- Increase and enhance capacity in pharmaceutical management
- Increase utilization of strategic information for decision making
- Improve pharmaceutical services to achieve desired health outcomes

SIAPS will work directly with MISAU's pharmaceutical sector partners, primarily the DF and the DFH in DNAM, to implement planned activities. The focus of SIAPS' support to DF will be improving the effectiveness, efficiency, transparency, and overall functioning of the regulatory system—including product registration, pharmacovigilance (PV), and inspection—to ensure the safety, efficacy, and quality of pharmaceutical products in circulation in the country. SIAPS will focus on improving pharmaceutical services at public hospitals, including the management of commodities, rational use of medicines, and patient safety. SIAPS' work is intended to complement the on-going efforts of the Central Medical Store, *Centro de Medicamentos e Artigos Medicos* (CMAM) and its partners to improve the supply chain management of essential commodities in the public health system.

The sections below outline SIAPS' proposed activities to strengthen governance, capacity building, use of strategic information, and delivery of services in the pharmaceutical sector. Strategic and annual work plans will be developed in collaboration with MISAU and then harmonized and coordinated with other partners. The work plan and any subsequent changes, if applicable, will be submitted to USAID for approval before implementation begins.

USAID has allocated \$1.2 million in PEPFAR funds in the first year, and is expected to provide \$500,000 the second year, to finance all of SIAPS' technical assistance activities and to support the establishment of a field office for SIAPS under the management MSH. Year 1 of the project began October 2011, with Year 2 activities starting October 2012. To this end, the work plan and objectives submitted under this program description document focus primarily on Year 2 activities.

## **Governance in the Pharmaceutical Sector**

SIAPS will work with MISAU to update the legal framework that governs the availability and use of pharmaceuticals products in Mozambique, including policies, legislation, and regulations. Norms and standards will also be defined, documented, shared, and adopted to promote transparency and accountability, particularly in the country's regulatory system. In addition, support will be provided to DF and DFH/DNAM to develop strategic, evidence-based plans that reflect the needs and priorities of the country's health system and guide MISAU's work in the regulation of medicines and delivery of pharmaceutical services. SIAPS' activities will emphasize using and institutionalizing management processes that are transparent, participatory, and consensus-oriented and that improve the efficiency, effectiveness, and responsiveness of the pharmaceutical sector.

Year 1 and Year 2 activities to improve governance—

- Assist with the initial revision of the National Medicines Policy
- Provide technical support for the development and institutionalization of processes, procedures, and criteria for the registration of medicines

- Conduct a stakeholders' meeting to build consensus on the framework for the national PV system and agree on roles and responsibilities
- Provide technical support to the DF to develop a five-year strategic plan and corresponding annual work plan for the regulatory system
- Provide technical support to DHP/DNAM for the development of a five-year strategic plan and corresponding annual work plan for pharmaceutical services at hospitals
- Assist with the finalization of the National Medicines Policy and consensus building among pharmaceutical sector stakeholders
- Conduct meetings to disseminate and discuss the procedures, guidelines, and criteria for evaluating medicines for registration with stakeholders
- Provide technical assistance to the registration team to ensure effective and efficient implementation of the guidelines and tools
- Assist pharmaceutical sector partners with the annual revision of strategic plans and development of work plans

### **Capacity Building in Pharmaceutical Management**

SIAPS will increase and enhance in-country capacity in pharmaceutical management at the institutional and individual levels to improve access to quality pharmaceutical products and services. SIAPS' approach is based on the concept that "capacity" includes structures, systems, and roles; staff and infrastructure; skills; and tools. All of these must be institutionalized to strengthen the ability of Mozambique's pharmaceutical sector to implement and maintain effective systems and provide appropriate pharmaceutical services. SIAPS will work toward institutionalizing stronger capacity-building strategies, activities, and tools, which can eventually be sustained by MISAU and the pharmaceutical sector partners with minimal external technical support.

Year 1 and Year 2 activities to build pharmaceutical management capacity—

- Assist the DF with PV training for provincial-level staff
- Assist DFH/DNAM with the implementation of training in pharmaceutical management for hospital pharmacy staff, including training of trainers (TOT)

### **Utilization of Strategic Information for Decision Making**

SIAPS will collaborate with MISAU to strengthen the availability and utilization of strategic information for improved decision making in the pharmaceutical sector. Comprehensive

pharmaceutical management information systems (PMIS) that support both products and patients and link with other health management information systems will be promoted to integrate, analyze, and use all types of information for better decision making. SIAPS will systematically analyze strategic information-system options in close collaboration with stakeholders to select systems and tools that are compatible with local technology and capacity, including existing information systems. Once systems are in place and/or strengthened, SIAPS will work to ensure that the strategic information is institutionalized in decision-making processes and procedures.

Year 2 activities to improve the utilization of strategic information for decision making—

- Assist DF with the development of a monitoring and evaluation (M&E) plan
- Conduct a baseline assessment of the regulatory system with the Regulatory System Assessment Tool (RSAT)
- Conduct an options analysis to identify an appropriate information system that supports the regulatory system for pharmaceuticals
- Initiate an options analysis to identify an appropriate PMIS for hospitals
- Assist DF with the implementation of their M&E plan
- Assist DFH/DNAM with the development of an M&E plan
- Provide technical assistance and other requirements for the implementation of an electronic information system for the regulatory system
- Identify an appropriate PMIS for hospitals in collaboration with stakeholders and pilot the system at select sites

### **Delivery of Pharmaceutical Services to Achieve Desired Health Outcomes**

SIAPS will work with partners, including PHPs, to improve pharmaceutical services, so that pharmaceutical products are not only available at service delivery points but also are prescribed and dispensed appropriately, used correctly by patients, and monitored for safety and efficacy with the aim of achieving desired health outcomes. SIAPS will provide technical support for the implementation of the national PV system to improve medicine safety; the creation of DTCs at hospitals to improve medicine use; the collection and analysis of medicine-use information for decision making; and the implementation of integrated, supportive supervision and materials (e.g., guidelines, SOPs, training materials, job aids). Opportunities to improve patient adherence will also be identified and implemented in collaboration with partners. These interventions will be integrated and coordinated to reinforce each other and improve the overall efficiency, cost-effectiveness, and quality of pharmaceutical services.

Year 2 activities to build capacity in pharmaceutical management—

- Collaborate with DHP/DNAM and other stakeholders to plan piloting DTC at one hospital
- Provide technical assistance to DNAM and the DTC pilot hospitals to plan rational use studies
- Assist DNAM in strengthening supportive supervision for pharmaceutical management at the hospital level
- Provide technical support to the DF and select PHPs to pilot surveillance activities and share information
- Assist DFH/DNAM with the roll out of DTCs at pilot hospitals, including trainings
- Provide technical support to implement rational use studies at DTC pilot hospitals and apply the results to planning
- Assist DFH/DNAM with implementing supportive supervision activities at hospitals

**Table 1. Implementation Plan Year 2**

The proposed implementation plan is tentative. Several activities that had originally been planned for Year 1 were moved to Year 2 due to some delays in the registration process for MSH. The details of each activity and the exact timelines for implementation will be defined and agreed upon with MISAU and other partners.

Activities (1)	Technical area 1 (2)	Technical area 2 (2)	Partners and collaborators	Timeline											
				October 1, 2012 – September 30, 2013											
				Q1			Q2			Q3			Q4		
				O	N	D	J	F	M	A	M	J	J	A	S
<sup>a</sup> Activity 1.1.1: Provide technical support for the development and institutionalization of processes, procedures and criteria for the registration of pharmaceutical products	Pharmaceutical sector governance	Regulatory issues	DF, CTTF	x	x	x	x	x	x	x	x	x	x	x	x
<sup>b</sup> Activity 1.1.2: Provide support to the DF to develop a licensing and inspection control system			DF, DNAM			x	x	x	x	x	x				
<sup>a</sup> Activity 1.1.3: Support the DF to revise the National Essential Medicines List (NEML)			DF, CTTF, DFH/DNAM, CMAM, WHO				x	x	x	x	x	x	x	x	x
<sup>b</sup> Activity 1.2.1: Support the DF in the implementation of the monitoring and evaluation (M&E) plan			DF		x	x	x								
<sup>a</sup> Activity 1.3.1: Provide technical support to the Pharmacy Department to develop a 5-year strategic plan and corresponding annual work plan for the regulatory system			DF, CMAM, MISAU, USP/PQM		x	x	x	x							
<sup>a</sup> Activity 2.1.1: Support the Ministry of Health to implement capacity building in PV	PV	Pharmaceutical sector governance	DF, DFH/ DNAM, health programs (immunization, HIV/AIDS, TB)			x		x		x		x	x	x	
<sup>a</sup> Activity 3.1.1: Provide technical assistance to support the implementation of the electronic information system for the regulatory system	Pharmaceutical management information systems	Regulatory issues	DF				x	x	x	x	x	x	x	x	x

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Activities (1)	Technical area 1 (2)	Technical area 2 (2)	Partners and collaborators	Timeline											
				October 1, 2012 – September 30, 2013											
				Q1			Q2			Q3			Q4		
				O	N	D	J	F	M	A	M	J	J	A	S
<sup>b</sup> Activity 4.1.1: Provide assistance to the DF to control the price of medicines	Pharmaceutical sector governance	Regulatory issues	DF, MISAU				x	x	x	x	x				
<sup>b</sup> Activity 5.1.1: Provide technical support to the Pharmacy Department Pharmacovigilance Unit and priority health programs to scale-up active surveillance activities	PV	Pharmaceutical sector governance	DF, health programs (immunization, HIV/AIDS, TB)		x	x	x	x	x	x	x	x	x	x	
<sup>b</sup> Activity 5.1.2: Assist DFH to establish a Drug and Therapeutic Committees at a hospital level	Pharmaceutical management capacity building; pharmaceutical services	Supply chain management	DFH/DNAM; select hospitals		x	x	x	x	x	x	x	x	x	x	
<sup>b</sup> Activity 5.2.1: Provide technical assistance to DHP/DNAM and the DTC pilot hospitals to plan rational use studies	Medication safety; rational use	Pharmaceutical services								x	x	x	x	x	

<sup>a</sup>Lead technical staff is Abdel Raouf Qawwas.

<sup>b</sup>Lead technical staff is STA (TBD).

**Table 2. Performance Monitoring Matrix**

Program goal: To assure access to safe, efficacious, and quality pharmaceutical products and to effective pharmaceutical services to help achieve desired health outcomes

<b>Program objectives and sub-objectives</b>	<b>SIAPS result or sub-result areas</b>	<b>Related USAID result areas<sup>a</sup></b>	<b>Performance indicators</b>	<b>Activities contributing to program objectives and sub-objectives</b>	<b>Activity products or deliverables</b>
Objective 1: Governance in the pharmaceutical sector strengthened	IR 1	IR 3.3.3 and 3.3.5			
Sub-objective 1.1: Medicines policies, legislations, regulations, norms, and standards improved	IR 1.2	IR 3.3.5	<ul style="list-style-type: none"> <li>• Percentage of pharmaceutical product dossiers appropriately evaluated according to criteria established in law</li> <li>• Percentage of medicines in EML, STG, and national procurement list that are registered</li> <li>• Average time to evaluate and register medicines in past year</li> </ul>	Activity 1.1.1: Provide technical support for development and institutionalization of processes, procedures, and criteria for registration of pharmaceutical products	Registration of pharmaceutical products tools implemented and shared with stakeholders; process is streamlined, efficient, and accountable
			Licensing and inspection control system developed	Activity 1.1.2: Provide support to DF to develop a licensing and inspection control system	Licensing and inspection system framework developed with the required guidelines, SOPs, JDs, and training program needed for implementation
			NEML draft developed and submitted for approval	Activity 1.1.3: Support DF to revise the National Essential Medicines List (NEML)	NEML drafted and disseminated among stakeholders for review
Sub-objective 1.2: Pharmaceutical management systems are transparent and accountable	IR 1.3	IR 3.3.4 and 3.3.5	Percentage of indicators in M&E plan generated	Activity 1.2.1: Support DF in the implementation of the monitoring and evaluation (M&E) plan	DF M&E system implemented; reports generated and disseminated effectively

*Systems for Improved Access to Pharmaceuticals and Services Program, Mozambique: Program Description*

<b>Program objectives and sub-objectives</b>	<b>SIAPS result or sub-result areas</b>	<b>Related USAID result areas<sup>a</sup></b>	<b>Performance indicators</b>	<b>Activities contributing to program objectives and sub-objectives</b>	<b>Activity products or deliverables</b>
Sub-objective 1.3: National pharmaceutical sector development plans are strategic and evidence based	IR 1.4	IR 3.3.4 and 3.3.5	Annual work plan for DF developed in accordance with strategic plan	Activity 1.3.1: Provide technical support to DF to develop a 5-year strategic plan and corresponding annual work plan for the regulatory system	DF 5-year strategic work plan developed and implemented
Objective 2: Capacity in pharmaceutical management increased	IR 2	IR 3.3.3, 3.3.4, and 3.3.5			
Sub-objective 2.1: Pharmaceutical management capacity of individuals, institutions, organizations, and networks strengthened	IR 2.1	IR 3.3.5	<ul style="list-style-type: none"> <li>• Number of persons trained in PV (disaggregated by gender)</li> <li>• Number of ADRs reported in the last quarter</li> </ul>	Activity 2.1.1: Support the MISAU to implement capacity building in PV	Health care providers are capacitated in PV and reporting of ADRs; materials for in-service training on PV/ADR reporting produced and available for future trainings
Objective 3: Utilization of strategic information for decision making increased	IR 3	IR 3.3.3, 3.3.4, and 3.3.5			
Sub-objective 3.1: Innovative and proven tools broadly available and used	IR 3.2	IR 3.3.5	Number of registration dossiers entered in electronic registration system	Activity 3.2.1: Provide technical assistance to support implementation of electronic information system	Institutionalization and sustainability of electronic information system and its use in the DF are insured
Objective 4: Financing strategies and mechanisms strengthened to improve access to medicines	IR 4				

*Program Description*

<b>Program objectives and sub-objectives</b>	<b>SIAPS result or sub-result areas</b>	<b>Related USAID result areas<sup>a</sup></b>	<b>Performance indicators</b>	<b>Activities contributing to program objectives and sub-objectives</b>	<b>Activity products or deliverables</b>
Sub-objective 4.1: Financial barriers reduced	IR 4.1		Price control system revised and endorsed by DF	Activity 4.1.1: Provide assistance to DF to control price of medicines	Revised medicine pricing system implemented and used
Objective 5: Pharmaceutical services to achieve desired health outcomes improved	IR 5	IR 3.3.3			
Sub-objective 5.1: Patient safety and therapeutic effectiveness assured	IR 5.2	IR 3.3.3 and 3.3.5	Number of active surveillance reports submitted	Activity 5.1.1: Provide technical support to the DF PV unit and priority health programs to scale-up active surveillance activities	Increased number of medicine safety reports generated, which will result in more informed clinical decisions in PHPs
		IR 3.3.3	Number of DTC meetings held and documented	Activity 5.1.2: Assist DFH to establish DTCs at hospital level	DTC at one pilot hospital created; terms of reference defined/developed in addition to training and guiding hospital through planning and implementation process
Sub-objective 5.2: Medication use improved	IR5.3	IR 3.3.3	Number of rational use study protocols developed	Activity 5.2.1: Provide technical assistance to DHP/DNAM and DTC pilot hospitals to plan rational use studies	Improved and rationalized medicine logistics systems in hospitals and country

<sup>a</sup>USAID result areas correspond to the intermediate results (IR) defined in *Strategic Plan and Results Framework for USG/Mozambique Support to the Pharmaceutical Sector* (July 2011):

IR 3.3.3: Improved use of medicines and more effective pharmaceutical services

IR 3.3.4: Strengthened MISAU/DF strategic planning and management capacity

IR 3.3.5: Strengthened regulatory capacity

## MANAGEMENT AND STAFFING

The SIAPS program in Mozambique will be supported by a combination of US-based and in-country staff. Sarah Craciunoiu, the Portfolio Manager, based out of the SIAPS office in the United States, will be responsible for the overall management of the portfolio, assuring the quality of the technical work; compliance with all USAID rules, regulations, and contract agreements; and achievement of the program objectives. Abdel Raouf Qawwas, the Country Project Director (CPD), will be based in the Maputo field office and will manage technical activities and staff, represent the SIAPS programs at meetings, liaise with MISAU and other partners, submit reports to stakeholders (USAID, MISAU, etc.), develop work plans in collaboration with partners, and manage field office operations. He will be the primary point of contact for SIAPS/Mozambique. The CPD will also act as a technical advisor in regulatory affairs. In addition, a Maputo-based technical advisor for pharmaceutical services will be embedded at the DF and DNAM and will lead the technical activities in this area with additional support from technical associates (to be hired as the program is scaled up). A finance and operations staff will also be hired.

Additional technical support in specialty areas will be provided, as needed, through short-term technical assistance from international SIAPS staff and consultants, who will travel to Mozambique to work alongside in-country technical staff and partners. Short-term technical assistance is expected in the areas of product registration, PV, electronic information systems/tools, and pharmacy curriculum development.

## SUSTAINABILITY

USAID/Mozambique funds will sustain SIAPS operations for a minimum of two years and, provided annual funding continues, up until September 2016 (the length of the global SIAPS cooperative agreement between MSH and USAID/Washington, DC). Throughout project implementation and once project funding ends, responsibility for implementing, maintaining, and building on pharmaceutical system strengthening activities undertaken with SIAPS funding and technical support will be assumed by the relevant partners within MISAU.

SIAPS' approach to the provision of technical assistance and system strengthening is designed to promote country ownership, enhance and strengthen existing systems, and build the full scope of a country's capacity, thereby minimizing reliance on external financial and technical support for long-term sustainability. Prior to implementation of any new activity, SIAPS builds support among stakeholders and works with in-country partners to analyze all the available options for addressing gaps and weaknesses in the various technical areas, and then collaboratively selects context-appropriate interventions, tools, and technologies that can be sustained over the long term. SIAPS also seeks out opportunities for system integration, based on the notion that integration is more cost-effective and less vulnerable to changes in funding priorities. All activities are oriented towards building the technical, management, and leadership capacity of institutions through improved systems, structures, roles, staff, and infrastructure and the capacity of individuals through improved skills and tools.