

## **SIAPS Activity and Product Status Report**

A report on quarterly progress achieved towards activities, products, and results

---

Project Year 1 Quarter 4

July - September 2012



**USAID**  
FROM THE AMERICAN PEOPLE

**SIAPS** 

The SIAPS logo consists of the word "SIAPS" in a bold, green, sans-serif font. To the right of the text is a blue icon of a stylized human figure with arms raised in a 'V' shape, suggesting movement or achievement.

This report is made possible by the generous support of the American people through the US Agency for International Development (USAID), under the terms of cooperative agreement number AID-OAA-A-11-00021. The contents are the responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government.

## **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.

## **Recommended Citation**

This report may be reproduced if credit is given to SIAPS. Please use the following citation.

Systems for Improved Access to Pharmaceuticals and Services. 2012. *Strengthening Pharmaceutical Systems Program: Activity and Product Status Report, July-September 2012*. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health.

Systems for Improved Access to Pharmaceuticals and Services  
Center for Pharmaceutical Management  
Management Sciences for Health  
4301 North Fairfax Drive, Suite 400  
Arlington, VA 22203 USA  
Telephone: 703.524.6575  
Fax: 703.524.7898  
E-mail: [siaps@msh.org](mailto:siaps@msh.org)  
Website: [www.siapsprogram.org](http://www.siapsprogram.org)

## CONTENTS

Acronyms and Abbreviations .....	iv
Highlights From Siaps Headquarters .....	vi
Common Agenda .....	1
Malaria Core .....	1
MCH Core.....	5
TB Core.....	12
USFDA Core.....	22
Angola.....	29
Bangladesh.....	36
Brazil.....	50
Burundi .....	59
Cameroon.....	68
Dominican Republic .....	77
Democratic Republic of the Congo.....	82
Ethiopia.....	96
Guinea.....	114
Haiti.....	124
LAC AMI.....	125
LAC SAIDI.....	130
Lesotho.....	133
Liberia.....	142
Mali.....	150
Mozambique .....	160
Namibia.....	165
Rwanda .....	180
South Africa.....	186
South Sudan MAL/PHARM.....	205
South Sudan EPI .....	217
Swaziland.....	223
Vietnam.....	233

## ACRONYMS AND ABBREVIATIONS

ACT	artemisinin-based combination therapy
ADDO	accredited drug dispensing outlet
ADR	adverse drug reaction
ADT	ARV Dispensing Tool [MSH]
AHSEP	Afghanistan Health Services Enhancement Project
AIDS	acquired immunodeficiency syndrome
ALCO	Abidjan to Lagos Corridor Organizations
APR	annual progress report
AQ	amodiaquine
APR	annual progress report
ART	antiretroviral therapy
AS	artesunate
CAMERWA	Centrale d’Achat des Médicaments Essentiels du Rwanda (CMS of Rwanda)
CBO	community-based organization
CMS	Central Medical Store
COP	chief of party
CPDS	Coordinated Procurement and Distribution System
DTC	Drug and Therapeutics Committee
EML	essential medicines list
EU	European Union
FDC	fixed-dose combination
FEFO	first expiry, first out
FHI	Family Health International
FY	fiscal year
GDF	Global Drug Facility
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
GoB	Government of Bangladesh
GoK	Government of Kenya
HBC	home-based care
HIV	human immunodeficiency virus
HMM	home management of malaria
HSSP	Health Systems and Services Strengthening system
IC	infection control
ICAT	Infection Control Assessment Tool
IEC	information, education, and communication
INRUD	International Network for Rational Use of Drugs
IPT	intermittent prevention treatment
IRS	indoor residual spraying
JSI	John Snow, Inc.
M&E	monitoring and evaluation
MDR	multidrug resistant
MIS	management information system
MoH	Ministry of Health
MoHSW	Ministry of Health and Social Welfare (Swaziland)
MoPH	Ministry of Public Health
MOU	Memorandum of Understanding
MSH	Management Sciences for Health
MTP	Monitoring, training, planning (methodology)
NASCOP	National AIDS and STD Control Program
NDTC	National Drug and Therapeutics Committee

---

*Acronyms and Abbreviations*

---

NGO	nongovernmental organization
NMCP	National Malaria Control Program (Senegal)
NSP	National Strategic Plan (South Africa)
PCI	Pharmaceutical Control and Inspection [Namibia]
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PLWHA	People Living With HIV/AIDS
PM	pharmaceutical management
PMI	President's Malaria Initiative
PMIS	pharmaceutical management information system
PMTCT	prevention of mother-to-child transmission
PSI	Population Services, International
PV	pharmacovigilance
QA	quality assurance
RBM	Roll Back Malaria
RDT	rapid diagnostic test
REACH	Rural Expansion of Afghanistan's Community-based Healthcare
RH	reproductive health
RMU	rational medicine use
RPM Plus	Rational Pharmaceutical Management Plus
SCMS	Supply Chain Management System
SOW	statement of work
SPS	Strengthening Pharmaceutical Systems (Program)
STG	standard treatment guideline
STI	sexually transmitted infections
TA	technical assistance
TB	tuberculosis
TBCAP	TB Control Assistance Program
TOR	terms of reference
TOT	training of trainers
TWG	technical working group
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
UNFPA	United Nations Population Fund
UNION	International Union Against Tuberculosis and Lung Disease
URC	University Research Co.
USAID	U.S. Agency for International Development
USG	United States Government
WHO	World Health Organization
XDR-TB	extensively drug-resistant tuberculosis

## HIGHLIGHTS FROM SIAPS HEADQUARTERS

### Technical Area Progress during the Quarter

During the quarter, the technical team received 18 technical assistance requests from 13 different SIAPS portfolios. Of these, 10 represent country requests and the other 3 pertain to core portfolios. Requests have been reviewed by cluster leads and members to assure quality of the requested scopes. The requests cut across several functional areas including supply chain management, pharmaceutical management information systems, medicine safety, and pharmaceutical services.

During this same reporting period, 35 technical assistance trips were conducted by members of the technical team in support to 15 core and country portfolios. Key highlight activity of the quarter was the focus on the portfolio work planning process. Members of the technical assistance team provided initial support to the design of these plans followed by a detailed review of each of them. In support to the effort to finalize the monitoring and evaluation plan, the team collaborated with the M&E Specialist to conduct a review of the proposed plan along with the different core (Global level) indicators prior to its submission to USAID.

As a next step, the team will be working with the M&E Specialist towards the development of a set of country level indicators to complement the core indicators. During this quarter, SIAPS updated and finalized the manual entitled *How to Investigate Antimicrobial Use in Hospitals: Selected Indicators*. SIAPS also translated and finalized the French and Spanish versions of this manual. All three versions are now published.

A Senior Technical Advisor (STA) joined the technical assistance team in support to the Pharmaceutical Systems Cluster. The new STA is expected to also contribute to Common Agenda activities. To help facilitate the allocation of technical human resources, several discussions took place. There was consensus to acquire a resource allocation tool that will enable us to track technical assistance members' availability. Currently, the team is looking at options to have a system deployed soonest.

To facilitate continuous communication between the technical team, core and country portfolios, a Technical Working Group was established. Roles and modus operandi were discussed. The first actual meeting is expected to take place next quarter.

### Country Program/Portfolio Progress in the Quarter

During this quarter, The Portfolio management team coordinated the development and review and submission of work plans for SIAPS Core and Country Portfolios. The process was participatory and iterative with all SIAPS headquarters and country teams working together to ensure that work plans were both of high technical quality and appropriately aligned to expressed Country and USAID priorities. The teamwork and joint ownership generated during the planning process is expected to continue into implementation during the next quarter.

We conducted our Quarterly review meeting with USAID to assure ongoing engagement with USAID in reviewing SIAPS performance, discussing program implementation issues and sharing feedback and ideas for program improvement. Additionally, SIAPS Portfolio Managers conducted portfolio management visits to provide hands-on support to their country teams to enhance program implementation. In-country portfolio reviews were conducted in South Sudan, Democratic Republic of Congo and Liberia.

In order to strengthen our new Country Project Directors capacity to effectively manage the projects, deliver on the project's vision, technical strategy and results, improve project documentation and communication, and strengthen their client relations, the team initiated the development of a comprehensive on-boarding plan for CPDs for implementation during the next quarter. It also re-

organized and streamlined the headquarters portfolio management team to better maximize team member skills in the support of country portfolios. Following this review, recruitment of an additional portfolio manager was initiated.

### **M&E and Reporting Activities**

During this quarter, monitoring, evaluation, and reporting resources were focused on (a) refining and finalizing SIAPS-level indicators, (b) SIAPS year 2 work planning, and (c) continued configuration and implementation planning for the new M&E tool: Newdea. M&E staff continued to work with management, technical cluster leads, and health elements to refine the list of SIAPS-level indicators. This included finalizing country-level indicators that would be rolled-up at the SAIPS-level to show the overall impact of SIAPS portfolio work.

In addition, because quarter 4 coincided with work planning, the M&E team spent considerable time reviewing each work plan, including the results framework, performance monitoring matrix, and M&E-related activities. Detailed comments and suggestions were given to each portfolio and in some cases, M&E staff worked directly with country teams to make improvements to indicators and M&E plans. Lastly, the M&E team continued to work with Newdea to configure the site to meet SIAPS needs and to plan and coordinate the implementation of the tool and its use for quarter 4 reports. This required development of training materials, guidance documents, and a detailed implementation plan to ensure timely and smooth reporting for quarter 4.

### **Capacity Building and Performance Improvements**

The CB&PI Unit brought onboard a new Capacity Building and Training Advisor to assist the SIAPS project with internal and external capacity building efforts. At the corporate level, the Unit participated in the RFP process for a MSH-wide eLearning platform. This involved reviewing proposals, participating in discussion meetings, and attending vendor meetings and culminated into the RFP team choosing a final eLearning vendor.

The Unit participated in the extensive review process of the SIAPS PY2 Work plans and reviewed 20 country and health element portfolio work plans for capacity building and training interventions, providing input into design and inviting requests for assistance from the Unit where applicable.

The CB&PI Unit drafted and disseminated the strategy for on-boarding newly hired Country Project Directors and building the capacity of seasoned Country Project Directors. The strategy consists of three major parts: a two-week participatory onboarding program, an anticipated day-long session at the SIAPS 2013 Global Meeting, and an online platform for ongoing training and performance improvement opportunities.

The Unit coordinated the adaptation and revitalization of a quantification training. The Unit coordinated the process of making the two-week training more participatory and based on learner's needs and worked with facilitators and technical staff to ensure program success. The CB&PI Unit hosted a CPM Frameworks Orientation in August, where ten newly hired technical staff, as well as some tenured staff, participated in a two day workshop to either familiarize or refresh themselves on CPM's technical frameworks and approaches.

The Unit drafted the strategy for the design and development of an innovative online learning solution requested by the SIAPS TB Core portfolio. The online solution will consist of a flexible Learning Management System, including discussion forums, quizzes, and tests, and will offer 30-minute participatory course modules on global TB topics.

A team member from the Unit brought new skills to the SIAPS project by participating in two online training programs to capacitate herself in the open-source online Learning Management System, Moodle.

The programs included how to design online courses using the system, as well as how to administer users and courses on the system. This system will be the basis for the global online platform.

The CB&PI Unit hosted two internal SIAPS Technical Discussion Series during the quarter: in August, staff participated in a lively discussion of the SIAPS maternal and child health portfolio and in September, staff discussed the updates to the SPS indicators study. The Unit managed the coordination and recruitment of six interns during Q4. The interns consisted of two PharmD students and four graduate level students, who assisted in a range of project topics from analyzing baseline survey data on knowledge, practices, and availability of TB medicines in Pakistan to identifying health and pharmaceutical financing tools used to assess and evaluate pharmaceutical systems in low and middle-income countries. The pilot launch of the Literature Search Skills eLearning course continued during this quarter. Preliminary improvements were made to course implementation and the strategy for course expansion was developed.

### **Knowledge Management (KM)**

This quarter the KM team contributed to all SIAPS annual work plan reviews to better reflect KM requirements across the program to help document results, lessons learned and best practices. The CPM Director for Knowledge Exchange participated in SIAPS management meetings to integrate KM and strategic communications into the program and support improved results through learning and knowledge sharing.

The KM Team continued editing content for the SIAPS web site, created new material and events and refined use of software plugins to improve information management on the site. The KE Director planned and carried out an STTA visit to Rwanda to conduct key informant interviews, gather material and manage technical writing consultants to create a final document on the program retrospective as part of transition to country ownership. The final document is anticipated for December 2012.

Specifically, the SIAPS core KM staff:

- Continued regular story and news updates about SIAPS on the SIAPS web site in preparation for its going public
- Supported the TB team for the Africa TB meeting by setting up and maintaining the event web site, materials design and branding, sending out updates about the conference on listservs, posting about the event on twitter and Facebook and assisting with branding of materials
- Supported two additional conferences with materials design and branding as well as content editing: Mozambique Workshop: Training on Pharmacovigilance/Sept 2012; Working Meeting to Evaluate Antimalarial Medicine Supply Management, Ecuador/Sept 2012
- Designed and edited eight posters (5 posters/FIPS Conference/Oct 2012; 1 poster/ASTMH/Nov 2012; 2 posters/AIDS Conference/July 2012)
- Ongoing social media support on Twitter and Facebook to help build those audiences in preparation for the launch of the SIAPS web page
- Coordinate technical writing and editing of content on for the SIAPS site
- Additionally, during the quarter, the team edited either in-house or contracted for services to produce: 22 technical reports, 2 AMR manuals (French & Spanish, 7 short documents (1-3 pages; press releases, flyers, abstracts, etc., 1 handbook, 2 newsletters, 1 business card template and 1 journal article.

### **Systems Analysis and Software Products**

Actively recruiting for STA MIS; Java Developer. SOW for Re-design of Quantimed finalized, actively recruiting consultants. Management of core SIAPS Software Upgrade EDT to run on new Windows 7 OS and MS Office 10; Upgrade EDT to run on SQL server back end; refined data exchange capabilities Upgraded Quantimed to run on Windows 7 OS and MS office 10 Defined roadmap of upgrade of Pharmadex and e-TB manager. Initiated review of existing support structures for all software tools.

Developing MIS intervention design and evaluations framework to help countries plan and refine MIS interventions in work-plans. Finalizing success stories – EDT in DRC; RxSolution wins award in SA.

**Management Travel during the Quarter**

The SIAPS Project Director undertook a trip to Ukraine during the quarter, with Archil Salakaia and Dmitriy Semenov. The purpose of the trip of the was to meet with the USAID country mission to discuss a proposed strategy of the SIAPS Ukraine program, to meet with the Government counterparts and key stakeholders to introduce the SIAPS program, and to meet with the current SPS staff to discuss transition from the SPS to SIAPS program. A key agreement at the meeting was that the “Scope of Work for The Strengthening Pharmaceutical and Supply Chain Management Systems (SPSCMS) Project”, will be the guiding document for the development of the strategy and work plan for SIAPS Ukraine.

An outline of the proposed SIAPS Ukraine strategy, implementation approach and timeline for next steps was presented and discussed. USAID/Ukraine mission endorsed the strategic approach and requested that we develop a detailed work plan for the first year of the project. It was agreed that the work plan will be developed within 4-6 weeks and will be submitted to the mission for approval. A program performance monitoring plan was also being developed as part of the overall strategic plan.



## **COMMON AGENDA**

Annual activities under the Common Agenda portfolio

### **Pathway 1: Pharmaceutical Management**

Common Agenda Pathway 1

#### **Sub-Pathway 1.1**

Improved capacity for pharmaceutical systems strengthening

##### **Activity 1.1.1**

Develop an accreditation credentials framework for pre-service education, in-service training and continuing education programs in support pharmaceutical systems strengthening.

##### **Activity 1.1.2**

Strengthening local institutions: Collaboration with EPN

##### **Activity 1.1.3**

Develop an HTA Guidance document and strategic approach.

#### **Sub-Pathway 1.2**

Improved data for decision-making

##### **Activity 1.2.1**

Develop a consensus framework and harmonized metrics for measurement of pharmaceutical systems strengthening interventions and performance

#### **Sub-Pathway 1.3**

Financial mechanisms strengthened to improve access to medicines

##### **Activity 1.3.1**

Develop and test tools for analyzing and improving pharmaceutical financing

#### **Sub-Pathway 1.4**

Improved Pharmaceutical Services

##### **Activity 1.4.1**

Develop a review document for options for improving supply chain operation

#### **Sub-Pathway 1.5**

Contribute to dissemination of evidenced-based approaches and best practices

##### **Activity 1.5.1**

Collaborate with WHO/EDM for the development and maintenance of a SIAPS knowledge management portal for the documentation and dissemination of results and lessons learned.

### **Activity 1.5.2**

Donor Coordination and participation in Conferences/Seminars/Networks.

#### **Quarterly Report Fields (Sub-Objective)**

Fields for reporting quarterly progress at the sub-objective level.

Quarterly progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - Develop an accreditation credentials framework for pre-service education, in-service training and continuing education programs to support pharmaceutical systems strengthening: Representatives from the Accreditation Council for Pharmaceutical Education held a brown bag to present the preliminary findings from the survey conducted in 10 countries with support from SPS. The survey ascertained the capacity of 10 developing countries to establish an accreditation program for pharmaceutical education. The draft report was shared for review. Following finalization of the report, SIAPS and ACPE will discuss the approach for the development of an accreditation framework that builds on the findings from the survey.

Collaboration with Regional Networks and Institutions to promote local capacity building in pharmaceutical management: Discussions were held with the management of the Ecumenical Pharmaceutical Network around the key priority activities that will be implemented building on the previous EPN work and that contribute towards the SIAPS results. As a follow-up action, SIAPS developed a draft illustrative scope of work that delineates such priority activities. EPN is in the process of developing a detailed plan and budget for two key activities this year that will focus on: a) developing the capacity of one or two member countries to train local staff in the area of containing antimicrobial resistance; and b) build own network capacity to evaluate the outcome resulting from the implementation of their own interventions.

Also during this quarter, the work continued for mapping regional institutions that SIAPS could partner with for promoting their local capacity to deliver training, technical assistance or services in the area of pharmaceutical management. A preliminary list of over 30 organizations has been compiled. This work will continue into next quarter to refine the result from the mapping.

Quarterly progress toward sub-objective 1.2

Current Value: **(Sep 2012)** - During the quarter, the team discussed the approach for the development of the framework and metrics for measuring pharmaceutical systems strengthening interventions and a draft concept note was developed. Accordingly, the framework will be developed through a process of consultation with key stakeholders on an agreed set of metrics for the evaluation of a pharmaceutical system, and the effectiveness of related systems strengthening interventions. The concept note calls that, in addition to the framework and metrics, a how-to manual on pharmaceutical systems evaluation and a data collection tool will also be developed. As a next step, a literature review will be conducted to review other initiatives in this area while analyzing the different strengths and weaknesses of each of these. Ultimately, the framework is expected to build upon some of the elements that have shown to work. In addition to WHO, several of SIAPS partners are expected to be consulted in the consultation process especially Harvard University. The framework, once developed and consulted, will be tested in selected countries to test its

validity and feasibility.

Quarterly progress toward sub-objective 1.3

**Current Value: (Sep 2012)** - Develop guidance for conducting options analysis for improving supply chain operations: A draft concept note was developed to articulate the process for developing the guidance for options analysis for supply chain. The approach is to review and document experiences and lessons learned in supply chain options analysis as well as review the effectiveness of these approaches. Viable options and variables will be identified through a consensus approach based on set criteria. A how-to-manual will be developed; this will provide guidance on how to go about the implementation of the agreed upon approach. Update and adapt key guidance tools and training materials in support to pharmaceutical services: During this quarter, SIAPS updated and finalized the Manual entitled “How to Investigate Antimicrobial Use in Hospitals: Selected Indicators. SIAPS also translated and finalized the French and Spanish versions of this manual. All three versions are now published. This document will help DTCs, physicians, pharmacists, managers, and researchers monitor and assess antimicrobial use in their facilities. The Manual defines 17 indicators (hospital, prescribing, patient care, and supplemental indicators) to objectively measure antimicrobial management and use. This practical manual also provides detailed step-by-step instructions to help design and carry out an assessment in hospitals. For each indicator, the manual gives the rationale, definition, data collection, calculation, instrument, and example. Necessary templates and forms are also included as annexes.

Quarterly progress toward sub-objective 1.4:

**Current Value: (Sep 2012)** - Following on a June planning session to establish the scope of work for collaboration with WHO on refreshing the essential medicines KM portal and expanding its use, Peter Hobby, SIAPS Director of KM and Communications, travelled to Geneva for technical consultations August 5 through 9 2012. During the consultation the specific approach to updating the web site’s design and features were discussed with WHO/EMPP staff Richard Laing and Claude Da Re and Human Info IT firm staff Dr. Michel Loots. In brief, the approach included the two following objectives: a) review, develop, test and deploy new features and systems upgrades to strengthen the analytical and knowledge sharing support offered by the WHO Medicines Publications and Documentation portal (year 1 and 2); and b) enable continued access and use of the portal through web-portal maintenance and content management (year 1 and 2). The systems modifications outlined in the trip report from the consultations were agreed on during the August consultation.

During this time discussions also began on alternate approaches to fund the common agenda effort overall given challenges in SIAPS providing resources directly to WHO. Having ascertained the most viable option to move ahead on the IT systems side was direct support to the IT consultant, in September 2012 the process began for putting a purchase order in place with Human Info for required modifications to the portal. During the quarter SIAPS staff also set in place a process to provide documents to the system to expand the collection with the latest USAID reporting and analysis. Discussions continue on how to support WHO staff directly and options to offer in kind support through funding travel, per diem and accommodations for the expected travel needed to re-launch and apply the system. It is anticipated the systems updates and content updates will be completed on time to meet the deadline for presentation at the May WHA meetings.



## **MALARIA CORE**

Malaria Core work plan details for Year 1 of the SIAPS Program

### **Quarterly Report Background**

Every year, malaria causes 300 to 500 million cases of acute illness resulting in more than a million deaths worldwide of which 90% occur in Sub Saharan Africa. Most affected populations are children under five, pregnant women and people living with HIV/AIDS. The economic burden of the disease is significant with a GDP reduction estimated at 1.3% per person per year in high transmission areas. Funds for the procurement of malaria medicines and commodities are increasingly becoming available through the Global Fund, the World Bank Booster Program, the President's Malaria Initiative, UNITAID, and other interventions such as the Affordable Medicines Facility for Malaria Mechanism. With this comes the growing challenge to ensure coordination among partners, dissemination and application of best practices for appropriate use, medication safety, adequate procurement, distribution and supply chain management. Improving health outcomes through reduced malaria mortality and morbidity can only be achieved through improving access to and appropriate and safe use of quality malaria medicines.

SIAPS will build on the successes of its predecessor programs, and will redouble emphasis on GHI principles, especially in improving metrics, monitoring, and evaluation, capacitating local governments and organizations, and increasing country ownership. SIAPS will collaborate with national malaria control programs and central medical stores to develop and implement strategies to strengthen pharmaceutical management for malaria prevention and case management. SIAPS will also support the Roll Back Malaria (RBM) Partnership Secretariat and the regional RBM networks. In addition, SIAPS will support to the Global Fund in proposal design, the development of Procurement and Supply Management Plans and in addressing grant implementation bottlenecks.

### **Goal: Malaria Core Year 1 Work Plan Goal**

Assure the availability of quality pharmaceutical products and effective services to achieve desired health outcomes

#### **Objective 1**

Pharmaceutical sector governance strengthened

##### **Sub-Objective 1.1**

Put into effect good governance principles.

##### **Activity 1.1a**

Global malaria leadership including support to RBM Secretariat and participation in RBM working group

#### **Objective 2**

Increase capacity for pharmaceutical supply management and services

##### **Sub-Objective 2.1**

Capacity of networks, organizations, and institutions in pharmaceutical management strengthened

##### **Activity 2.1a**

Develop, publish, and disseminate guide on increasing access to ACTs through private sector

**Objective 3**

Increase utilization for information for decision-making

**Sub-Objective 3.1**

Strengthen the use PMI tools

**Activity 3.1a**

Provide technical support to the Implementation of President Malaria Initiative tools in PMI countries

**Sub-Objective 3.2**

Strengthen Logistics Management System for malaria commodities

**Activity 3.2a**

Apply the Monitoring-Training-Planning (MTP) approach to Implementation of Logistic Management System for Malaria Commodities

**Objective 4**

Strengthen financing strategies and mechanism to improve access to medicines

**Sub-Objective 4.1**

More efficient use of existing resources

**Activity 4.1a**

Carry out a retrospective costing exercise to estimate the cost of distribution of malaria commodities

**Goal: Quarterly Report Fields**

These are the fields that will be used to collect information for quarterly reports.

Overall Quarter Progress

Current Value: **(Sep 2012)** - During this quarter, SIAPS continued to enforce good governance principles through technical leadership and support to the Roll Back Malaria Secretariat and working groups as well as disseminating lessons learned to the global community. PMI was able to make key procurement decisions based on stock status reports and supply plans for malaria commodities information provided by SIAPS. Similarly, two countries (Burundi and Mali) were able to address different challenges that were identified through EUV surveys. In an effort to strengthen financing mechanisms and improve access to medicines, SIAPS is working towards identifying distribution costs for ACTs, RDTs, and nets from CMS to facilities.

Key challenges faced during the quarter

Current Value: **(Sep 2012)** - None

### **Quarterly Report Fields (Objective)**

Objective-level fields for collecting information for quarterly reports.

Quarterly Progress for Objective 1

Current Value: **(Sep 2012)** - To strengthen pharmaceutical sector governance SIAPS presented approaches on pharmaceutical management to the West Africa Malaria regional partners. SIAPS also submitted a paper for publications in the malaria journal and abstracts for presenting at the ASTMH annual meeting.

Quarterly Progress for Objective 2

Current Value: **(Sep 2012)** - No significant progress during this reporting period

Quarterly Progress for Objective 3

Current Value: **(Sep 2012)** - SIAPS contributed to this objective by providing information on the stock status of malaria medicines, supply plan of malaria commodities and availability and use of malaria medicines at the end user level to PMI. PMI uses the information to make procurement decisions.

Quarterly Progress for Objective 4

Current Value: **(Sep 2012)** - During this reporting period, SIAPS received approvals to continue with activities under this objectives.

### **Quarterly Report Fields (Sub-Objective)**

Fields for reporting quarterly progress at the sub-objective level.

Quarterly progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - Under this sub objective, SIAPS participated in the WARN meeting in Praia, Cape Verde during which SIAPS approaches on pharmaceutical management were shared with West Africa regional partners. Two abstracts were accepted for the ASTMH annual meeting in Atlanta in November 2012 for presentations; one on global options for avoiding stock outs and the second on the causes of stock outs in Burundi. A paper was submitted to the Malaria Journal on global options for avoiding stock outs. Also, SIAPS participated in the ACTWatch Advisory Committee meeting in Geneva in September 2012. The role of the Advisory Committee for ACTWatch 2 was discussed.

Challenges in progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - None

Deliverables: Sub-Objective 1.1

Current Value: **(Sep 2012)** - Presentation "SIAPS approaches on pharmaceutical management"  
Abstracts: "On global options for avoiding stockouts" and "Causes of stockouts in Burundi"

Quarterly progress toward sub-objective 2.1

Current Value: **(Sep 2012)** - As per PMI request activities under this objective were suspended

Quarterly progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - To facilitate procurement decision at PMI, SIAPS aggregated data and reported on stock status and supply plan of malaria commodities from Angola, Benin, Burundi, Ethiopia, Kenya, Mali, Malawi, Senegal, and Uganda. Also under this objective, SIAPS provided valuable information on EUV implementation and findings from countries to PMI senior staff at USAID office on July 26, 2012. Support was provided to countries teams to ensure that results and lessons learned from SIAPS year I are taken into consideration for the design of next year work plan activities.

Deliverables: Sub-Objective 3.1

Current Value: **(Sep 2012)** - EUV presentation

Quarterly progress toward sub-objective 3.2

Current Value: **(Sep 2012)** - A guide for strengthening Logistics Management System for malaria commodities using the MTP approach is under editing.

Challenges in progress toward sub-objective 3.2

Current Value: **(Sep 2012)** - None

Deliverables: Sub-Objective 3.2

Current Value: **(Sep 2012)** - LMIS guide

Quarterly progress toward sub-objective 4.1

Current Value: **(Sep 2012)** - A concept paper that was developed as a contribution to this objective was approved by USAID/PMI on July, 2012. The concept paper was sent to USAID/Kenya and USAID/Benin to seek for country USAID mission approval. We received approval for both USAID mission on September 2012. We presently are waiting for USAID/Washington contract office approval for signature of the sub contract with WDI to start field work.

Challenges in progress toward sub-objective 4.1

Current Value: **(Sep 2012)** - None

Deliverables: Sub-Objective 4.1

Current Value: **(Sep 2012)** - Concept paper

## **MCH CORE**

MCH Core work plan details for Year 1 of the SIAPS Program

### **Quarterly Report Background**

Despite progress made in reducing both maternal and child mortality rates over the past few decades, the rates still remain high and very few countries are on track to meet the Millennium Development Goal targets of reducing the maternal mortality ratio by three-quarters and the under-five child mortality by two-thirds, by 2015. What is most alarming about the situation is that most of these deaths could have been avoided if women and children had access to adequate health services, where the necessary medicines and supplies were available and skilled health providers were present. The preventative and curative measures for the major causes of maternal and child deaths are well-known, but access to them remains elusive for many.

As part of the global effort to improve maternal and child health (MCH), the United States Global Health Initiative (GHI) has included targets for maternal and child health in its strategic plan, specifically to reduce maternal mortality by 30 percent and to reduce under-five mortality rates by 35 percent across USG assisted countries. Under the GHI, USAID is focusing on effective interventions addressing key high-mortality complications along the continuum of care from pregnancy to childhood, such as postpartum hemorrhage, hypertension (pre-eclampsia/eclampsia), and infections (diarrheal disease, pneumonia and malaria).

Beginning under the Rational Pharmaceutical Management Plus program, and continuing under the Strengthening Pharmaceutical Systems program, MSH has supported USG efforts to improve maternal and child health through activities designed to improve access to and appropriate use of the medicines and supplies necessary to prevent and treat the leading causes of morbidity and mortality. In terms of maternal health, MSH worked with other USG-funded initiatives, such as the Prevention of Postpartum Hemorrhage Initiative (POPHI) to document the pharmaceutical management issues related to active management of the third stage of labor (AMTSL). MSH also worked with national stakeholders in several countries to identify and address weaknesses in their pharmaceutical systems and thereby improve access to the medicines and supplies necessary for AMTSL.

With respect to child health, MSH focused on pharmaceutical management for integrated management of childhood illness, both within health facilities and at the community level. MSH developed assessment tools and training materials to help ensure availability of medicines and supplies. MSH also worked with national stakeholders to adopt new recommendations of treatment for common childhood illnesses, such as zinc and low osmolarity ORS for diarrhea. Lastly, MSH developed innovative strategies to incorporate the private sector in community case management. Building on this wealth of experience, SIAPS will contribute to GHI objectives and achievement of the MDGs by working with international organizations to increase global awareness of the barriers to access to essential maternal and child health medicines and supplies, and assisting national stakeholders in developing innovative approaches to addressing these barriers in their countries.

### **Goal: MCH Core Year 1 Work Plan Goal**

Assure the availability of quality medicines and supplies and effective pharmaceutical services to reduce maternal and child mortality

#### **Objective 1**

Capacity for maternal and child health pharmaceutical supply management increased and enhanced

#### **Sub-Objective 1.1**

Capacity of individuals, institutions, organizations to manage maternal health medicines and supplies strengthened

**Activity 1.1.1**

Prepare an action plan for improving access to maternal health medicines and supplies in Rwanda

**Activity 1.1.2**

Provide global technical leadership on pharmaceutical systems issues related to maternal health

**Sub-Objective 1.2**

Capacity of individuals, institutions, organizations, and to manage child health medicines and supplies strengthened

**Activity 1.2.1**

Provide global technical leadership on pharmaceutical systems issues related to child health

**Objective 2**

Utilization of information for decision-making increased

**Sub-Objective 2.1**

Innovative and proven tools broadly available and used

**Activity 2.1.1**

Develop a methodology for estimating potential “unmet” need for maternal health commodities

**Activity 2.1.2**

Update an intervention guide for use of medicines for the management of child illness

**Objective 3**

Pharmaceutical services for maternal and child health improved

**Sub-Objective 3.1**

Availability of pharmaceuticals for maternal health improved

**Activity 3.1.1**

Develop a roadmap for national program managers to increase access to maternal health commodities

**Sub-Objective 3.2**

Availability of pharmaceuticals for child health improved

**Activity 3.2.1**

Provide technical support to improve the availability of medicines for CCM in Mali

**Activity 3.2.2**

Provide technical support to improve the availability of medicines for CCM in Guinea

**Quarterly Report Fields (Objective)**

Objective-level fields for collecting information for quarterly reports.

Quarterly Progress for Objective 1

Current Value: **(Sep 2012)** - There has been significant progress towards objective 1, increasing and enhancing capacity for maternal and child health pharmaceutical supply management. The action plan for improving access to maternal health medicines and supplies in Rwanda was developed and finalized as well as the Rwanda maternal health assessment. SIAPS/MCH continues to provide global technical leadership on pharmaceutical management issues for maternal and child health. SIAPS/MCH continues to be active in the Maternal Health Supplies Working Group and the Pneumonia and Diarrhea Working Group as well as remains engaged in the CCM Task Force and with external partners such as MCHIP.

Quarterly Progress for Objective 2

Current Value: **(Sep 2012)** - Progress was made in developing tools for decision-making. A draft version of the methodology for estimating “unmet need” for maternal health commodities was developed. The first three chapters of the intervention guide for the management of child illness were revised by Harvard. The remaining two chapters are expected next quarter. The entire document will then be reviewed by external partners and other SIAPS staff next quarter.

Quarterly Progress for Objective 3

Current Value: **(Sep 2012)** - SIAPS/MCH made considerable progress in Mali however progress in Guinea for CCM and developing a roadmap for national program managers has been slow. In Mali, USAID implementing partners were allowed to begin activities following the unrest. In collaboration with SIAPS/ Mali and Mali’s Directorate of Pharmacy and Medicines (DPM), an assessment was initiated this past quarter on the existing logistics management information system (LMIS) for health commodities. SIAPS/MCH has been providing technical assistance to ensure that CCM was also included in the assessment.

**Quarterly Report Fields (Sub-Objective)**

Fields for reporting quarterly progress at the sub-objective level.

Quarterly progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - The SIAPS MCH Core portfolio made significant progress towards strengthening the capacity of individuals, institutions, and organizations to manage maternal health medicines and supplies in Rwanda. This quarter an options analysis workshop was held in Kigali on September 5th, 2012 to share the draft of the final report. Thirty-five people attended the workshop; this included 25 people from the Ministry of Health (MoH) at all levels of the supply chain, 4 development partners active

in MCH and SIAPS staff. During the workshop, the findings of the survey were presented and discussed, analyzed and prioritized. The participants were then split into groups to develop action plans. The recommendations from the group work were validated as the recommendations of the survey. A meeting was held with the director of MCH to plan the next steps in implementing the recommendations and the notes of the meeting were circulated. The survey report was finalized, incorporating comments from the workshop participants and the recommendations. This final report and the workshop report were shared with the director of MCH and currently the survey report is awaiting the signature of the Minister of Health.

In addition, a rapid analysis of the unmet need for oxytocin was conducted, studying theoretical need and amounts procured and distributed. This study highlights the gap in achieving coverage of every woman delivering in the public sector with oxytocin immediately following delivery. This study was also shared with the director of MCH who was very interested in the findings to be able to further improve their interventions to prevent post-partum hemorrhage.

Additionally, SIAPS MCH portfolio continued to provide technical leadership on pharmaceutical systems related to maternal health. SIAPS MCH participated in Maternal Health Supplies Working Group quarterly meeting held on September 18, 2012 as well as the subsequent meeting to develop the maternal health commodities work plan which was held in New York on September 28, 2012.

#### Challenges in progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - There were no challenges this quarter.

#### Deliverables: Sub-Objective 1.1

Current Value: **(Sep 2012)** - • Rwanda Trip report for Jane Briggs, 2-6th September 2012 • Rapid Assessment of Pharmaceutical Management of Medicines and Supplies for Preventing and Managing Emergency Obstetric and Newborn Conditions in Rwanda: September 2012; Final report • Options Analysis for Improving the Pharmaceutical Management of Medicines and Supplies for Preventing and Managing Emergency Obstetric and Newborn Conditions in Rwanda: Workshop Report, September 2012 • Unmet Need for Oxytocin in Rwanda; case-study flyer

#### Quarterly progress toward sub-objective 1.2

Current Value: **(Sep 2012)** - SIAPS has continued provide global technical leadership on pharmaceutical systems issues related to child health. This quarter SIAPS/ MCH participated in the Pneumonia and Diarrhea working group meeting in August 2012. Also, Beth Yeager and Jane Briggs from SIAPS met with the MCHIP team in August 2012 prior to Dyness Kasungami starting maternity leave. The priorities identified for collaboration were CCM in Guinea and Mali as well as on the CCM taskforce, specifically opportunities for re-engaging and reviving the logistics working group.

#### Deliverables: Sub-Objective 1.2

Current Value: **(Sep 2012)** - Not applicable.

#### Quarterly progress toward sub-objective 2.1

Current Value: **(Sep 2012)** - In an effort to address the unmet need for essential maternal health

commodities SIAPS MCH started to develop a tool to assess this unmet need and help countries to improve forecasting and planning of these medicines. Both qualitative and quantitative data was collected and global and country specific reports were reviewed including: international journals, research studies, DHS survey report, standard treatment guidelines, WHO and other international recommendations for prevention and treatment of PPH, PE/E, MCHIP reports, available forecasting tools for other health related medicines, and HMIS reports. Countries that have done some level of forecasting of these medicines were requested to share their procurement planning data which will be analyzed to assess the gap between need based assumption and actual forecasting by country programs.

This quarter, a draft of the tool was developed and it is planned to be shared with external partners and experts to get feedback and finalize the tool. Additionally, this quarter SIAPS MCH provided feedback to Harvard on the first few chapters of the intervention guide for use of medicines for the management of child illness. Next quarter Harvard will send the final chapters of the guide to SIAPS MCH team for review. Once reviewed and comments are integrated, the guide will be further reviewed by other SIAPS staff and then finalized. The field validation exercise in country will also be determined.

#### Challenges in progress toward sub-objective 2.1

Current Value: **(Sep 2012)** - Due to competing priorities and traveling schedules, there was delay by SIAPS in sending comments and feedback to Harvard on the first few chapters of the intervention guide as well as by Harvard in sending the final chapters of the guide.

#### Deliverables: Sub-Objective 2.1

Current Value: **(Sep 2012)** - Both the unmet need tool and intervention guide are expected to be finalized next quarter.

#### Quarterly progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - The development of the roadmap for national program managers to increase access to maternal health medicines has not progressed much this quarter due to competing priorities. However, the review of existing tools and materials that can serve as references materials for the roadmap was completed. A draft roadmap is expected to be completed in the next quarter and is expected to be reviewed by relevant SIAPS staff.

#### Challenges in progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - A major challenge has been competing priorities in regards to developing the roadmap. Next quarter this will be a priority activity and a draft of the roadmap should be completed by the end of next quarter.

#### Deliverables: Sub-Objective 3.1

Current Value: **(Sep 2012)** - A draft of the roadmap for national program managers for maternal health medicines will be completed by the end of next quarter.

#### Quarterly progress toward sub-objective 3.2

Current Value: **(Sep 2012)** - From the end of March to mid-July 2012, SIAPS was unable to implement programmatic activities due to the ban on implementation placed on all USAID

implementing partners in Mali following the March 21, 2012 coup d'état. However, SIAPS was among the first USAID implementing partners to be allowed to resume implementation of technical activities. The resumption of activities has come with some specific guidance, including ensuring that SIAPS activities focused more on the community level of the health system.

This quarter, SIAPS/Mali in collaboration with Mali's Directorate of Pharmacy and Medicines (DPM) within the MPOH planned to conduct an assessment of the existing logistics management information system (LMIS) for health commodities, in order to determine how to "knit together" the various information systems and tools already existing in the health system. The MCH Core portfolio is providing technical assistance to the country team to conduct the LMIS assessment and to make sure that CCM is integrated in the assessment and in the subsequent redesign of the LMIS system, based on the results and recommendations of the assessment.

The assessment is being done in two steps: the first phase will assess logistics indicators at all levels of the system and the second phase will use the data from the indicator assessment and group discussions involving all the key stakeholders to assess the logistics management system's performance, identify improvement areas and propose recommendations and an action plan to address identified priority areas for improvement. This assessment will also provide a baseline against which interventions to improve the functioning of the system and the availability of health commodities at the different levels of the system will be measured.

This quarter, the assessment tools were adapted and data collection began during Q4. We had meetings with the following key stakeholders to provide an overview of the assessment and discuss their expectations in preparation to the group discussions' workshop of the assessment: Direction de la Pharmacie et du Médicament (DPM); Programme National de lutte contre le Paludisme (PNLP); Pharmacie Populaire du Mali (PPM); MCHIP; and ATN Plus. Next quarter the assessment will be finalized and the results, recommendations and action plan will be disseminated to key stakeholders. We also hope to begin the implementation of the action plan.

In Guinea, another meeting was held this quarter between SIAPS and MCHIP (Serge Raharison). It was agreed that greater communication and collaboration is needed between SIAPS and MCHIP in order to support the field to support the MoH. As a result, SIAPS and MCHIP at HQ level shared ideas and guidance to transmit to the team in country. The first meeting of the technical steering committee was held in Conakry on September 27th, 2012, which was attended by the SIAPS country project director. As the meeting started late, not much was achieved, despite a list of discussion points provided by SIAPS via MCHIP. The next meeting is planned for October 4th, 2012.

Next quarter, SIAPS MCH has planned to provide short term technical assistance to the MoH and the local MCHIP team on management of medicines for CCM. Jane Briggs will be travel to Guinea for one week to start off initial discussions and Mbombo Wathum, from SIAPS Rwanda, will stay on in Guinea for two months to work closely with the MoH in improving aspects of medicines management. Additionally, a local consultant will be recruited to take over from Mbombo and guide the MoH in all supply chain aspects for CCM.

### Challenges in progress toward sub-objective 3.2

Current Value: (**Sep 2012**) - In Guinea, a major challenge has been the slow advancement of the MoH. SIAPS and MCHIP are coordinating to ensure that activities move forward. The in-

country presence of a SIAPS CCM expert is expected to facilitate further progress next quarter.

Deliverables: Sub-Objective 3.2

Current Value: (**Sep 2012**) - The Mali assessment is expected to be finalized next quarter.

## **TB CORE**

TB Core work plan details for Year 1 of the SIAPS Program

### **Quarterly Report Background**

According to the WHO 2011 Global TB Report, tuberculosis remains a major public health challenge. Despite the availability of highly efficacious treatment for decades, TB remains a major global health problem. In 2010, there were 8.8 million (range, 8.5–9.2 million) incident cases of TB, 1.1 million (range, 0.9–1.2 million) deaths from TB among HIV-negative people and an additional 0.35 million (range, 0.32–0.39 million) deaths from HIV-associated TB. Although the absolute numbers of cases, incidence and mortality rates have been slowly dropping in the past years, the rapid emergence of drug-resistant forms of tuberculosis and their weak management becomes a major challenge.

The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is a follow on to the Strengthening Pharmaceutical Systems (SPS) program. SPS has been a major USAID mechanism for providing technical leadership in pharmaceutical management for tuberculosis to Global TB initiatives, donors, Stop TB partners, and national TB programs. In the past years the focus of the response to the Global Plan to Stop TB 2006 – 2015 had been mainly on addressing its strategic components related to increasing the availability of, and ensuring access to quality assured first- and second-line TB medicines; this was done through the ongoing technical leadership to the Global Drug Facility, the Green Light Committee and STOP TB partners, capacity building exercises, and development and promotion of frameworks and approaches for strengthening pharmaceutical systems in the anticipation of new TB tools and technologies. SPS also responded to the threat of MDR/XDR TB and TB/HIV co-infection.

SIAPS will build upon successes and results of its predecessor projects, adapting them to rapidly changing dynamics and challenges of global TB control.

### **Goal: TB Core Year 1 Work Plan Goal**

Assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve Global TB goals.

#### **Objective 1**

Pharmaceutical Governance for TB strengthened at Global Level and country level

#### **Sub-Objective 1.1**

Improved global TB medicines policies and strategies in response to National TB control needs

#### **Activity 1.1.1**

Strengthen PM capacity of Global TB Initiatives

#### **Sub-Objective 1.2**

Best pharmaceutical management standards and practices available for the adoption by global and national partners

#### **Activity 3.2.1**

Conduct a regional conference on novel approaches to pharmaceutical management for TB

**Sub-Objective 1.3**

Frameworks and Guidelines for TB pharmaceutical management readily available

**Activity 4.1.1**

Revise and consolidate SIAPS guidelines for pharmaceutical management for tuberculosis

**Objective 2**

Capacity for TB pharmaceutical supply management and services increased and enhanced

**Sub-Objective 2.1**

Pharmaceutical management capacity of Stop TB partners and NTPs strengthened

**Activity 1.1.2**

Strengthen capacity of StopTB Partners and WHO to provide TA

**Sub-Objective 2.2**

Innovative approaches for TB pharmaceutical management capacity building developed and implemented

**Activity 4.4.1**

Adopt and implement innovative and proven approaches for building capacity in pharmaceutical management for TB

**Sub-Objective 2.3**

Capacity for operational research to inform health system interventions

**Activity 4.3.1**

Develop an operational pharmaceutical research strategy for NTPs

**Objective 3**

Improved utilization of information for TB control decision making

**Sub-Objective 3.1**

Innovative and proven MIS for TB tools available and updated

**Activity 4.2.2**

Continue to improve e-TB Manager as a system strengthening tool

**Objective 4**

Improved financing strategies for expedited access to new TB tools and pharmaceutical services.

**Sub-Objective 4.1**

Reduced financial barriers to expedite access to new TB tools for diagnosis and treatment

**Activity 3.1.1**

Investigate options and pilot guidelines for reducing financial barriers to increasing efficiencies of TB programs and rapid uptake of new TB tools

**Objective 5**

Improved pharmaceutical services and access to TB products to achieve TB Goals.

**Sub-Objective 5.1**

Improved access to TB and ancillary medicines in public sector

**Activity 1.1.3**

Provide emergency STTA to GDF recipient countries in resolving PSM bottlenecks

**Activity 2.1.1**

Provide technical leadership to global and regional GLC groups and StopTB MDR TB activities

**Sub-Objective 5.2**

Innovative approaches for engagement of private sector in pharmaceutical services for TB developed

**Activity 2.3.1**

Build model sustainable public-private partnerships to contain MDR TB

**Sub-Objective 5.3**

TB patient safety and treatment effectiveness assured

**Activity 1.4.1**

Develop risk management algorithms for TB/HIV co-medication

**Activity 1.4.2**

Pilot active surveillance for monitoring the safety of TB/HIV co-medication

**Sub-Objective 5.4**

Use of medicines in TB programs improved

**Activity 2.2.1**

Promote active surveillance for safety of MDR TB medicines and ancillary medicines

**Sub-Objective 5.5**

Improved management of childhood TB

**Activity 1.3.1**

Improve the availability and rational use of pediatric TB medicines

**Goal: Quarterly Report Fields**

These are the fields that will be used to collect information for quarterly reports.

Overall Quarter Progress

Current Value: (**Sep 2012**) - In quarter 4, SIAPS TB Core made considerable strides towards its aims of improved TB pharmaceutical governance, services, and access to quality anti-TB medicines. As part of these efforts SIAPS conducted workshops on TB drug management, a GDF monitoring mission, and addressed a GI request for technical assistance. Additionally, finalization of materials and logistical considerations were a primary focus of Q4 work as SIAPS prepares for both the World Union on Lung Health Conference in November 2012 and the Africa Regional TB Conference in December 2012.

During Q4 SIAPS TB Core also focused on creating an innovative platform to streamline future trainings and capacity building activities. Utilizing the expertise of the Capacity Building and Performance Improvement team at MSH, TB Core organized several meetings to identify target audience levels and their corresponding training needs. The Capacity Building and Performance Improvement team is working to identify the optimal platform for delivering trainings before beginning the development of materials.

In its efforts to improve the utilization of information for TB control decision-making, activities supporting e-TB Manager included updates and modifications to both the generic tool as well as country-specific versions. Other progress in the development of tools to assist with TB pharmaceutical management included assessments of financing strategies for new TB tools and pharmaceutical services. Data collection and assessment provided valuable insights on differences in the decision-making processes, coordination among partners and key players, and availability and management of financial sources.

Lastly, activities involving Public Private Mix and safety and utilization of MDR TB medicines focused on streamlining access to high-quality pharmaceutical services and TB products by: (1) involving key stakeholders in the chain of TB diagnosis to increase the number and rate of TB diagnoses; and (2) helping providers in the TB care continuum more accurately treat adverse drug reactions and manage TB treatment by categorizing TB medicines according to their level of risk.

Key activities planned for next quarter

Current Value: (**Sep 2012**) - In the upcoming quarter a primary focus will be conducting a workshop at the World Union Conference on Lung Disease. In combination with MSH partners, the full-day workshop will be led in collaboration with Stop TB Partnership's Global Drug Facility on Transitioning to Sustainable Pharmaceutical Management Systems for TB. The workshop will allow for sharing of experiences and strategies to help improve TB pharmaceutical

systems and promote sustainability of quality TB medicines.

An additional focus will be on conducting the Africa TB Conference 2012 in Zanzibar, Tanzania. The conference will focus on identifying and prioritizing country specific challenges for the management of TB medicines. By the end of the conference, participants will have worked to develop concrete action plans that will be widely disseminated for solicitation of technical assistance and support from donors and Stop TB partners. Lastly, the GDF strengthening strategy will be presented to the StopTB Board for approval. All other activities will proceed as planned for the FY12 funds workplan.

#### Technical Activity Coordination

Current Value: **(Sep 2012)** - FY12 (SIAPS year 2) workplan was finalized and submitted to USAID for approval.

#### Office management

Current Value: **(Sep 2012)** - N/A

### **Quarterly Report Fields (Objective)**

Objective-level fields for collecting information for quarterly reports.

#### Quarterly Progress for Objective 1

Current Value: **(Sep 2012)** - SIAPS played an integral role in placing an interim manager at the GDF. In a short period of time the interim manager made substantial strides in streamlining the processes of the GDF. Finalization of plans for the Africa TB Conference moved forward as presenters were identified and logistics finalized.

#### Quarterly Progress for Objective 2

Current Value: **(Sep 2012)** - Q4 progress related to increasing capacity for TB pharmaceutical supply management and services focused on the development of an innovative platform for SIAPS TB Core trainings. Through discussions and a review of training materials, the TB Core and Capacity Building and Performance Improvement team at MSH identified all target audience levels and their corresponding training needs. The Capacity Building and Performance Improvement team is working to identify the optimal platform for delivering trainings before beginning the development of materials. Additionally, SIAPS facilitated two drug management sessions at the WHO Collaborative Training Center in Riga, Latvia, with a total of 25 participants trained.

#### Quarterly Progress for Objective 3

Current Value: **(Sep 2012)** - Progress on improved utilization of information for TB control decision making during Q4 has focused on modifications and additions to the e-TB Manager tool. Highlights include the finalization of an updated e-TB Manager User's Guide, which has been sent to editorial for formatting. Progress with country-specific versions is varied; some countries continue to move forward while others have experienced funding challenges that have slowed the implementation process.

#### Quarterly Progress for Objective 4

Current Value: **(Sep 2012)** - Q4 has seen substantial activity with regard to the development of tools to assist with TB pharmaceutical management. Data collection and assessment of TB programs in Rwanda and Uganda provided valuable insights on differences in the decision-making processes, coordination among partners and key players, and availability and management of financial sources.

#### Quarterly Progress for Objective 5

Current Value: **(Sep 2012)** - Activities involving Public Private Mix and TB treatment effectiveness continued to progress and resulted in the development of a number of deliverables. By creating links between private entities and National TB Programs, Public Private Mix activities have documented past successes to inform efforts to reduce the cost of anti-TB medicines in the private sector; PPM activities are also working to minimize the time lag between when patients first seek care for TB-like symptoms and when they are diagnosed and receive appropriate medicines. Work in TB treatment effectiveness has also moved forward as Risk Management and Active Surveillance activities focused, respectively, on completing the analysis to categorize TB medicines according to their level of risk and mapping out the TB system flow for implementation of active surveillance. Consequently, a draft protocol (Risk Management) and draft implementation plan (Active Surveillance) have been crafted.

#### **Quarterly Report Fields (Sub-Objective)**

Fields for reporting quarterly progress at the sub-objective level.

##### Quarterly progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - At the request of the StopTB Secretariat and USAID, SIAPS identified and placed an interim manager at the GDF. In this position the interim manager developed draft strategies, conducted a tender, and streamlined TB medicines delivery.

##### Challenges in progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - Technical assistance to the GDF required substantial resources and leadership within a tight time frame.

##### Deliverables: Sub-Objective 1.1

Current Value: **(Sep 2012)** - GDF PA selection and draft strategy developed

##### Quarterly progress toward sub-objective 1.2

Current Value: **(Sep 2012)** - Preparations for the Africa TB conference are ongoing as the conference approaches in December. SIAPS has sent out invitation letters to target countries and their partners working in TB medicine management, while the arrangement of logistics is ongoing. SIAPS identified presenters for the 3 day conference and provided them with guidelines for presentation preparation, including timelines. The next steps include the following: review first draft of presentations

and send feedback to speakers; finalize and format presentations with editorial team; and finalize travel and lodging arrangements. The conference will be conducted in the next quarter.

Challenges in progress toward sub-objective 1.2

Current Value: **(Sep 2012)** - Communication challenges with country NTPs and WHO AFRO.

Deliverables: Sub-Objective 1.2

Current Value: **(Sep 2012)** - List of participants drafted, agenda developed, and agreement signed with facilities for the Africa TB Conference.

Quarterly progress toward sub-objective 1.3

Current Value: **(Sep 2012)** - This activity hasn't started yet.

Quarterly progress toward sub-objective 2.1

Current Value: **(Sep 2012)** - SIAPS facilitated a drug management session on the training of pediatricians at the WHO Collaborative Training Center in Riga, Latvia; 15 participants were trained. SIAPS facilitated a drug management session on training for TB Program Managers in WHO Collaborative Training Center in Riga, Latvia; 10 managers were trained in PM for TB basics.

Deliverables: Sub-Objective 2.1

Current Value: **(Sep 2012)** - Trip report written and training materials developed.

Quarterly progress toward sub-objective 2.2

Current Value: **(Sep 2012)** - SIAPS organized several meetings with the Capacity Building and Performance Improvement team to kick start this activity. Through discussions and a review of training materials, the TB Core and Capacity Building teams gained consensus on the approach and conceptualization of the activity; furthermore, the teams identified all target audience levels and their corresponding training needs. The Capacity Building and Performance Improvement team is working to identify the optimal platform for delivering trainings before beginning the development of materials.

Quarterly progress toward sub-objective 2.3

Current Value: **(Sep 2012)** - This activity hasn't started yet.

Quarterly progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - Progress continues both for the generic e-TB Manager, as well as country versions. The e-TB Manager User's Guide has been updated and sent to editorial for formatting. Next steps are to print and distribute it in hard or electronic copies, then update the Russian and Ukrainian versions, and update the training materials. Country updates are presented below: Namibia: the acting MSH e-TB Manager focal point in Namibia had regular meetings with the NTLP to discuss e-TB Manager implementation progress and agree on next steps. The ongoing pilot phase was extended until November and an evaluation/assessment meeting was scheduled

for December 2012.

The NTLTP is assessing the drug resistant-TB data managed by the system to produce specific reports in pilot sites. Kenya: the implementation process stopped due to withdrawal of funding (Kenya SPS); however, a new SIAPS/MSH mission to Kenya was undertaken. The NTP and SIAPS agreed to adapt the current version of the system to fit latest country needs and to provide new trainings on system operation to local staff. Planned to pull TB Core funds on the implementation process.

Uzbekistan: the lab module of e-TB Manager was finalized and tested. Bangladesh: Bangladesh to start with the Medicine module soon. Cambodia: The completion of training is expected in early October 2012, after which time Cambodia will be ready to start with pilot phase. Nigeria: Nigeria is soon approaching the end of pilot phase.

#### Challenges in progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - Namibia: The number of sites in Namibia has remained constant, resulting in a minimal increase in the number of users during the pilot phase (which lasts until December 2012). Future e-TB Manager support to the NTP after evaluating the pilot phase is unclear due to the lack of local SIAPS funds to date. The extension of the pilot phase final report to guide further customizations and set the rollout implementation plan has moved the expected date to January 2013. Lastly, all computers at one pilot site were stolen and they still need to be replaced by the NTP. Kenya: Lack of local funds and lack of available TA to revive e-TB Manager implementation countrywide. The following steps have been taken to address these challenges: Namibia: Continue the pilot phase with regular monitoring of activities and findings. Kenya: the NTP partially tested the system and provided feedback to MSH for further customizations and corrections.

#### Deliverables: Sub-Objective 3.1

Current Value: **(Sep 2012)** - Revised e-TB Manager User's Guide Kenya: Preliminary list of required adaptations and corrections for the system in Kenya sent to MSH by the NTP.

#### Quarterly progress toward sub-objective 4.1

Current Value: **(Sep 2012)** - Data collection and assessment were conducted in Rwanda and Uganda from July to September 2012. The assessment team met with TB program managers, USAID, CDC, key stakeholders and partners in TB programs in Rwanda and Uganda. The scope of the assessment was the rollout of GeneXpert in Rwanda, and the rollout of GeneXpert and MDR-TB treatment in Uganda. Both countries provide valuable insights on differences in the decision-making processes, coordination among partners and key players, and availability and management of financial sources.

The assessment underscored the need to assess the financing component of introducing new TB tools. The reports will be completed in October/November and findings will be presented at the Union TB Conference. Further development of the tool is pending on the assessment. The processes and availability of data during the assessment will provide input for developing the tool.

#### Challenges in progress toward sub-objective 4.1

Current Value: (**Sep 2012**) - Dearth of data resulting from the fact that financing has not been a critical component of the TB program. The following step has been taken to address this challenge: The assessment team had to use various sources of data and meet with several key informants to gather data.

Quarterly progress toward sub-objective 5.1

Current Value: (**Sep 2012**) - SIAPS was asked to present at the Institute of Medicine's workshop titled, "Developing and Strengthening the Global Supply Chain for Second-Line Drugs for Multidrug Resistant TB" in July 2012. The SIAPS presentations focused on setting quality standards for second-line medicines and innovative approaches for financing second-line medicines. 1 GI request for technical assistance was addressed: a GDF monitoring mission was conducted to Uzbekistan; and 1 GDF TRC supported.

Deliverables: Sub-Objective 5.1

Current Value: (**Sep 2012**) - GDF mission report to Uzbekistan.

Quarterly progress toward sub-objective 5.2

Current Value: (**Sep 2012**) - There was substantial progress in Public Private Mix activities in Kenya, Tanzania, and Pakistan during quarter 4; country-specific updates are below:

**KENYA:** -In August, inputs were sought from Kenya Association for the Prevention of Tuberculosis and Lung Diseases (KAPTLD) and the Division of Leprosy, Tuberculosis, and Lung Diseases (DLTLD) on the design of the SIAPS TB Core supported activities in Kenya, documenting lessons learned from KAPTLD's experience in engaging the private sector, and finalizing options for hiring a local consultant for core-supported PPM TB work. -14 interviews with key stakeholders were conducted, transcribed, and are now ready for processing into a report for sharing lessons learned. -Four candidates were shortlisted in collaboration with KAPTLD for a one-year consultancy agreement to work on engaging private hospitals for MDR-TB treatment. Interviews will be conducted in October-November

**PAKISTAN:** -Finalized baseline survey data analysis and developed a draft report. - Finalized procurement process for a company to develop training materials (in multi-media video format) and selected Interactive Resource Group (IRC). First story board draft expected end of October.

**TANZANIA:** -Draft training materials - aimed at improving the knowledge and skills of pharmacies and ADDOs attendants to increase TB case detection in Tanzania - and various tools (including TB symptoms checklist, cough register, and reporting and referral forms) initiated in May 2012, were finalized at the end of July and shared with the NTLP. -Training of 595 Dispensers from Morogoro region on August 13 – 18, 2012. -Development of health workers sensitization materials, adapted MOHSW community based TB trainers guide and hosted technical committee meeting to review the training and HWs sensitization materials before dispenser training. - Sensitization of facilities health workers (including receptionists, OPD clinicians, laboratory staff, DOT nurse, Health Facility) on the proposed referral system. 186 health workers from Morogoro were sensitized on August 13 -18; and 276 from Dar es Salaam on Aug 29 -31. -Training of Dispensers from private pharmacies in Dar es Salaam on September 12 and 17- 19, 2012. -Development and printing of 1100 posters capturing TB diagnostic centers operating in Dar es Salaam and Morogoro (and their location) for displaying in drug outlets and printing of 1100 referral forms.

-Attendance of the five-day annual meeting for National Tuberculosis and Leprosy Program (NTLP) during the 3rd week of September, where SIAPS was invited to share progress on engagement of private drug outlets in TB case finding in Tanzania.

#### Challenges in progress toward sub-objective 5.2

Current Value: (**Sep 2012**) - PAKISTAN- the primary challenge is the delay in the development of training materials. TANZANIA – the initial training of pharmacy workers in Dar es Salaam had low turnout; with attendance at less than 50% of the 400 expected. The following steps have been taken to address these challenges: PAKISTAN - the pace of the intervention will be increased following the finalization of training materials in order to catch up to the scheduled timeframe. TANZANIA - Plan to conduct a second training for pharmacy workers Dar es Salaam in the coming months; will request the Ministry of Health to send out invitation letter (as opposed to the pharmacy council as was done for the first training) to maximize interest and participation.

#### Deliverables: Sub-Objective 5.2

Current Value: (**Sep 2012**) - KENYA - 14 transcribed interview notes, Trip Report from August-2012. PAKISTAN - finalized baseline survey data analysis and draft report. TANZANIA - health worker sensitization materials including the development and printing of 1100 posters capturing TB diagnostic centers operating in Dar es Salaam and Morogoro, Tanzania.

#### Quarterly progress toward sub-objective 5.3

Current Value: (**Sep 2012**) - RISK MANAGEMENT ACTIVITY - SIAPS has completed the analysis to categorize TB medicines according to their level of risk, based on predefined risk criteria. The first draft of the protocol has been completed; internal review of protocol for procedure and technical content is underway. The next step is to revise and finalize the first draft based on reviewer's comments and then send to external reviewers to validate research technique and content.

ACTIVE SURVEILLANCE ACTIVITY - Swaziland was identified as one of the countries where the TB/HIV active surveillance protocol will be implemented. The initial visit has been made to the country to map out the TB system flow for the development of the protocol/implementation guide. During the mapping visit, it was decided with key stakeholders to utilize existing tools in country for data collection and reporting. As a result, SIAPS has organized a meeting with the tool developers to work together to ensure tools are compatible for import and export of data to the systems. The first draft of the implementation plan has been developed. Next steps include adapting the DCAT tool for analysis of adverse drug reactions (ADR) to incorporate TB and HIV elements for Swaziland content; adapt and incorporate ADR forms in RX solution tool used in Swaziland for data collection and plan for in-country implementation of protocol.

#### Deliverables: Sub-Objective 5.3

Current Value: (**Sep 2012**) - RISK MANAGEMENT ACTIVITY - first draft of the protocol.  
ACTIVE SURVEILLANCE ACTIVITY - first draft of the implementation plan in Swaziland.

## **USFDA CORE**

USFDA Core work plan details for Year 1 of the SIAPS Program

### **Quarterly Report Background**

Studies have reported the huge impact that poor product quality, adverse drug reactions (ADRs), and medication errors have on health system in general and on patients' health in particular. Few developing countries, however, have the structures, systems, or resources in place to support medicine safety activities, and countries often lack unbiased, evidence-based information to help guide regulatory and patient safety decisions. Pharmacovigilance activities in many developing countries are fragmented and often do not include all components of a comprehensive pharmacovigilance and medicine safety system. Medicines safety monitoring or post-marketing surveillance (PMS) is crucial to quantify previously recognized ADRs, identify unrecognized ADRs, and evaluate the effectiveness of medicines in real-world situations to decrease mortality and morbidity associated with medicine-use-related adverse events. There is a need to develop a comprehensive pharmacovigilance system that includes not only adverse event data collection but also risk evaluation, minimization, and communication, thereby serving as safety net to prevent the majority of adverse events. To build this safety net, there is also a need to strengthen regulatory capacity, develop strong mechanisms for communication and information sharing, and target for improvement those areas of the safety net with the largest vulnerabilities.

The SIAPS program continues and expands upon the work of SPS in the areas of pharmacovigilance and regulatory systems. The USAID-funded SPS program implemented by MSH recently published the seminal paper, Supporting Pharmacovigilance in Developing Countries: The Systems Perspective. The systems approach provides a conceptual framework and operational approach for strengthening pharmacovigilance systems and stresses the intersection of people, functions, and structures to arrive at local decisions that prevent medicine-related problems and reduce associated morbidity and mortality. This approach highlights the need for building capacity to undertake both passive and active surveillance activities and the complementary role of the two approaches in ensuring a robust pharmacovigilance system. The SPS program also developed the Indicator-based pharmacovigilance assessment tool (IPAT) for the systematic and longitudinal monitoring of country's capacity and performance in ensuring the safety and effectiveness of health products registered in the country. The SIAPS program applies a broad regulatory systems framework and systems perspective to strengthen regulation of pharmaceutical personnel, premises, practices, and products and ensure timely access to quality, safe, and effective health products and technologies in developing countries.

In 2010, the U.S. Food and Drug Administration (FDA) and USAID signed an Interagency Agreement, implemented through the SPS program. The objective of the agreement was to foster collaboration between the two agencies on the task of strengthening those systems that ensure the quality and safety of FDA-regulated products. The FY10 funding of the agreement was used for the conduct of the assessment of pharmacovigilance systems and their performance in sub-Saharan Africa. FY11 funding will produce deliverables to: 1) Assess of pharmacovigilance systems and their performance in Asia and dissemination of findings; 2) Hold conference to disseminate findings of the Sub-Saharan Africa Study and workshop to identify needs related to the development of pharmacovigilance tools; and 3) Develop and disseminate framework and tools for pharmacovigilance systems.

### **Goal: USFDA Core Year 1 Work Plan Goal**

Strengthen regulatory systems to ensure the quality and safety of products in the supply chain

#### **Objective 1**

Assess and disseminate findings on the pharmacovigilance and post-market surveillance systems performance in the Asia/Pacific region

**Sub-Objective 1.1**

Assess pharmacovigilance systems and performance in selected Asia/Pacific countries

**Activity 1.1a**

Develop methodology and data collection tools for the assessment of the Asia/Pacific pharmacovigilance systems and their performances

**Activity 1.1b**

Inform and engage national regulatory authorities (NRAs) and other stakeholders in selected countries on the assessment

**Activity 1.1c**

Conduct the assessment in the selected countries

**Sub-Objective 1.2**

Document and disseminate results of the study

**Activity 1.2a**

Develop a report on the findings of the assessment

**Activity 1.2b**

Disseminate findings of the assessment

**Objective 2**

Conduct a workshop for the development of pharmacovigilance tools and conduct a conference for the dissemination of findings of the SSA study

**Sub-Objective 2.1**

Conduct workshop for the development of pharmacovigilance tools

**Activity 2.1a**

Organize a workshop for the mapping of current practices to inform the development of the pharmacovigilance framework and tools that will assist countries to implement the systems perspective

**Sub-Objective 2.2**

Disseminate findings of the SSA study

**Activity 2.2a**

Conduct a conference for the dissemination of the report of the SSA study

**Activity 2.2b**

Present findings of the study at related conferences and through publications

**Objective 3**

Develop and disseminate framework and tools for pharmacovigilance system

**Sub-Objective 3.1**

Develop pharmacovigilance framework and tools

**Activity 3.1a**

Analyze feedback from the tools workshop and develop operational tools for the implementation of pharmacovigilance and post-marketing surveillance systems in selected countries

**Activity 3.1b**

Field-test the tools with selected NRAs. The field testing will involve that the tools be sent for use and/or installed for the local NRAs

**Sub-Objective 3.2**

Disseminate pharmacovigilance framework and tools

**Activity 3.2a**

Engage NRAs, regional harmonization groups, WHO and other stakeholders to disseminate the tools developed

**Activity 3.2b**

Develop web-based portals and dashboard where non-confidential and non-proprietary data from the countries using the tool will be disseminated

**Goal: Quarterly Report Fields**

These are the fields that will be used to collect information for quarterly reports.

Overall Quarter Progress

Current Value: **(Sep 2012)** - Quarter 4 objectives focused on implementation of the Asia Pharmacovigilance Assessment in Bangladesh, Cambodia, Nepal, the Philippines, and Thailand (Objective 1), finalizing the meeting report for the 2012 Africa Pharmacovigilance Meeting held in Nairobi, Kenya from April 18-20, 2012 (Objective 2), and furthering development of existing SPS/SIAPS pharmacovigilance tools (Objective 3).

Key challenges faced during the quarter

Current Value: **(Sep 2012)** - The key challenges that was encountered during the quarter under review with the implementation of the activity include - delays in the approval of the assessment in Vietnam which ultimately prevented Vietnam from participating in the assessment,

challenges with consultant preparing the individual country reports and reviewing with national regulatory authorities according to anticipated timeline, and budgetary challenges due to higher costs of implementing the assessment in the selected Asia countries compared to the Africa study. Timelines have been moved along as quickly as possible with study countries and communicated with the client. The budgetary issues are not unconnected with the additional costs incurred in the Africa PV meeting. The meeting was extended by one day and more persons participated. The development of the PV tools has now been scaled down and there are plans to leverage SIAPS country portfolio funding and expand the features of existing tools to include important PV features identified as priorities.

#### Key activities planned for next quarter

Current Value: **(Sep 2012)** - Activities planned for the next quarter include finalization of the Asia Pharmacovigilance Assessment in Bangladesh, Cambodia, Nepal, the Philippines, and Thailand; The Africa PV Meeting 2012 meeting report will be submitted early next quarter.

#### Technical Activity Coordination

Current Value: **(Sep 2012)** - No activities or expenditures were charged to Technical Activity Coordination.

#### Office management

Current Value: **(Sep 2012)** - No activities or expenditures were charged to Office Management.

#### **Quarterly Report Fields (Objective)**

Objective-level fields for collecting information for quarterly reports.

#### Quarterly Progress for Objective 1

Current Value: **(Sep 2012)** - Implementation for the Asia Pharmacovigilance assessment was conducted in Q4 in the five study countries: Bangladesh, Cambodia, Nepal, the Philippines, and Thailand. In all countries, local consultants appointed by the national regulatory authorities collected assessment data and drafted individual country reports.

#### Quarterly Progress for Objective 2

Current Value: **(Sep 2012)** - The Africa Pharmacovigilance Meeting 2012 was held in Nairobi, Kenya from April 18-20, 2012. The meeting included a dissemination conference and workshop for the development of pharmacovigilance tools, which identified a priority package of tools and guidance documents that could be developed and deployed to address some of the assessment findings and for overall strengthening of pharmacovigilance and regulatory systems. The meeting also included training conducted by the US FDA Center for Biologics Evaluation & Research on active surveillance for vaccine pharmacovigilance.

#### Quarterly Progress for Objective 3

Current Value: **(Sep 2012)** - The development of the pharmacovigilance tools identified during the Africa Pharmacovigilance Meeting 2012 has been constrained by lack of sufficient funding. During previous meetings with FDA and USAID, it was agreed to reduce efforts

in the development of the tools because of the lack of funding. However noting that the SIAPS program has pharmaceutical management-related tools in use across several sub-Saharan African countries, efforts are being made to incorporate pharmacovigilance modules into existing tools that are already widely deployed. For instance, the SIAPS program has eTB manager, which is an online based tool for the management of tuberculosis. An E2B compliant ADR form is being incorporated into the eTB manager. Likewise, the ADR form is being added to the SIAPS electronic dispensing tools (EDT and Rx Solution), and the drug regulatory tool, Pharmadex, is being enhanced to collect and disseminate safety information on medicines. These four tools are currently being used in more than 20 countries many of which are in Africa. The incorporation of ADR and pharmacovigilance related modules into these tools will be accomplished by end of March 2013.

### Quarterly Report Fields (Sub-Objective)

Fields for reporting quarterly progress at the sub-objective level.

Quarterly progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - Implementation of the Asia Pharmacovigilance Assessment was conducted in Bangladesh, Cambodia, Nepal, the Philippines, and Thailand including data collection, data cleaning, and key documentation review in Q4. Local consultants and a team of data collectors were engaged in each country through the respective national regulatory authorities. The assessment includes review of key documentation and semi-structured interviews based on the Indicator Based Pharmacovigilance Assessment Tool (IPAT) with key informants representing the Ministry of Health, National Regulatory Authority, national public health programs, health facilities, industry, pharmacies, academia, professional associations, and clinical research organizations.

Challenges in progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - There were delays in the approval of the assessment in some countries, however data collection and individual country report drafting for the Asia Pharmacovigilance Assessment has otherwise gone well, factoring in such delays. There have been challenges particularly related to timing and budget due to the complexities of working in Asian countries where SIAPS has little or no presence. In order to maximize use of funds, cost leveraging has been utilized whenever possible with existing SIAPS programs. This has been successful particularly in Bangladesh and the Philippines.

Deliverables: Sub-Objective 1.1

Current Value: **(Sep 2012)** - Datasets have been collected from all country consultants and cleaned. Individual country reports have been drafted by local consultants for review by MSH technical staff and country national regulatory authorities.

Quarterly progress toward sub-objective 1.2

Current Value: **(Sep 2012)** - Dissemination of results of the pharmacovigilance systems and performance assessment in selected Asian countries is planned for 2012. During this quarter the country specific reports were drafted and the review process was initiated, to ensure consistent quality in the reports to be generated from the assessment. Also literature review to support the report was conducted.

Challenges in progress toward sub-objective 1.2

Current Value: **(Sep 2012)** - The key challenges that was encountered during the quarter under review included delays in the approval of the assessment in Vietnam which ultimately prevented Vietnam from participating in the assessment and challenges with consultants preparing the individual country reports and reviewing with national regulatory authorities according to anticipated timelines. Timelines have been moved along as quickly as possible with study countries and communicated with the client.

Deliverables: Sub-Objective 1.2

Current Value: **(Sep 2012)** - [None]

Quarterly progress toward sub-objective 2.1

Current Value: **(Sep 2012)** - The two-day workshop was conducted in Q3 April 19 – 20, in conjunction with the sub-Saharan Africa assessment dissemination conference held on April 18, 2012. The workshop approach included mapping of current pharmacovigilance practices through administration of a pre-meeting survey and guided workshop discussion groups, practices to inform the development of the pharmacovigilance framework and pharmacovigilance tools that will assist countries to implement the pharmacovigilance systems perspective. This systems approach was published in the seminal paper, Supporting Pharmacovigilance in Developing Countries: The Systems Perspective, produced by SPS through MSH with funding from USAID. The five key pharmacovigilance tools identified were: • Template of a local pharmacovigilance database to collate data from all sources • Templates for protocols, SOPs, and model software for conducting active surveillance • Protocol and operational guide for requesting and monitoring risk management plans to prevent or minimize known serious risks • Website for real-time sharing of global medicine safety alerts, local safety and quality issues, and regulatory decisions • Model of comprehensive pharmacovigilance guidelines

Challenges in progress toward sub-objective 2.1

Current Value: **(Sep 2012)** - All anticipated progress towards conducting the workshop was achieved in Q3. No challenges were experienced related to conducting the workshop in Q3.

Deliverables: Sub-Objective 2.1

Current Value: **(Sep 2012)** - The Africa Pharmacovigilance Meeting 2012 conference materials and survey analysis was completed in Q3. The workshop report was drafted in Q3 and will be submitted in FY12 Q1, including a summary of the various sessions and technical conclusions.

Quarterly progress toward sub-objective 2.2

Current Value: **(Sep 2012)** - The Africa Pharmacovigilance Meeting 2012 conference and workshop report was drafted in Q3 and will be published in FY12 Q1.

Challenges in progress toward sub-objective 2.2

Current Value: **(Sep 2012)** - Delays in finalization of the Africa Pharmacovigilance Meeting 2012 conference and workshop report were experience in Q4. The Africa Pharmacovigilance Meeting 2012 conference and workshop report will be finalized in FY12 Q1.

Deliverables: Sub-Objective 2.2

Current Value: **(Sep 2012)** - The Africa Pharmacovigilance Meeting 2012 conference and workshop report was drafted in Q3, including a summary of the various sessions and technical conclusions. It will be published in FY12 Q1.

Quarterly progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - Included in the plan for the 2012 Africa Pharmacovigilance Meeting submitted to USFDA and USAID in Q1 were details on the proposed approach for mapping of current practices to inform the development of the pharmacovigilance framework and operational tools that will assist countries to implement the pharmacovigilance systems perspective. During subsequent meetings with FDA and USAID, however, it was agreed to reduce efforts in the development of the tools because of the lack of funding.

Challenges in progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - The development of the pharmacovigilance tools identified during the Africa Pharmacovigilance Meeting 2012 has been constrained by lack of sufficient funding. Noting that the SIAPS program has pharmaceutical management-related tools in use across several sub-Saharan African countries, efforts are being made to incorporate pharmacovigilance modules into existing tools that are already widely deployed.

Deliverables: Sub-Objective 3.1

Current Value: **(Sep 2012)** - [None]

Quarterly progress toward sub-objective 3.2

Current Value: **(Sep 2012)** - Efforts are being made to incorporate pharmacovigilance modules into existing tools that are already widely deployed in more than 20 SIAPS country, many of which are in Africa. The incorporation of ADR and pharmacovigilance related modules into these tools will be accomplished by end of March 2013.

Challenges in progress toward sub-objective 3.2

Current Value: **(Sep 2012)** - Included in the plan for the 2012 Africa Pharmacovigilance Meeting submitted to USFDA and USAID in Q1 were details on the proposed approach for mapping of current practices to inform the development of the pharmacovigilance framework and operational tools that will assist countries to implement the pharmacovigilance systems perspective. During subsequent meetings with FDA and USAID, however, it was agreed to reduce efforts in the development of the tools because of the lack of funding. The development of the pharmacovigilance tools identified during the Africa Pharmacovigilance Meeting 2012 has been constrained by lack of sufficient funding.

Deliverables: Sub-Objective 3.2

Current Value: **(Sep 2012)** - [None]

## **ANGOLA**

Angola work plan details for Year 1 of the SIAPS Program

### **Quarterly Report Background**

Malaria is a major cause of morbidity and mortality in Angola, accounting for an estimated 60% of hospital admission, 35% of the overall mortality in children under five, and 25% of maternal mortality. In 2004, Angola's Ministry of Health introduced artemisinin-based combination therapies (ACT) to improve malaria case management. The first-line treatment of malaria is artemether-lumefantrine (AL-Coartem®). The prevalence of HIV in Angola is estimated at 2% in a total population of 18 million. TB/HIV co-infection is a major concern. HIV/AIDS prevention, treatment and care activities under the National Strategy Plan on HIV/AIDS 2011-2014 are implemented under the MOH's National HIV/AIDS Control Program (Instituto Nacional de Luta Contra o Sida-INLS). USAID provides funding and logistic support for procurement and distribution of condoms and rapid test kits for HIV/AIDS prevention. The INLS has also received support in its treatment and care efforts by the USAID-supported Essential Health Services program that has now become the Strengthening Angolan Systems for Health Systems (SASH) program. The total fertility rate of Angola averages 5.8 births per woman. The high fertility is associated with high infant mortality rates and a high maternal mortality ratio of 1,400 per 100,000 live births. Access to contraceptives is low, with frequent stock-outs of RH/FP commodities at health facilities. The Government of Angola considers FP an important strategy to improve the health of women and children, under the National Road Map to accelerate the reduction of maternal, newborn and child mortality.

USAID's PEPFAR support for HIV/AIDS activities is channeled through the INLS. USAID-funded condoms are distributed via the INLS and USAID implementing partners. PMI support is channeled through the National Malaria Control Program, and population (POP) support goes through the National RH/FP Program. The MOH's National Directorate of Medicines and Equipment (Direcção Nacional de Medicamentos e Equipamentos –DNME) and the National Essential Medicines Program (Programa Nacional de Medicamentos Essenciais–PNME) oversee and coordinate all pharmaceutical supply management activities in Angola. The annual DNME/PNME Plans of Activities generally follow the 5-year strategic plans, currently for 2009-2014. With USAID/ PMI support, MSH/SPS program and its predecessor RPM Plus have collaborated with other USAID Implementing Partners and NGOs and other local partners to assist the Angolan MOH to implement pharmaceutical management strengthening interventions at central and lower levels of the health care delivery system since 2005.

USAID/Angola has provided SIAPS/Angola with \$1,450,000 in FY11 funding (PMI-\$650,000, PEPFAR-\$500,000 and POP-\$300,000). SIAPS/Angola will use this funding to implement the pharmaceutical management-strengthening activities from October 2011 to September 2012. SIAPS will work to strengthen Angola's health system by assuring the availability and safe use of quality pharmaceutical products, in line with USAID/Angola's goal to improve health service delivery through systems strengthening, integration and creating partnerships with local organizations. The program will ensure a seamless transition between SPS and SIAPs. Remaining SPS pipeline will be used to continue implementing activities from the SPS FY10 work plan that remained unaccomplished due to challenges associated with delayed MSH in-country registration.

### **Goal: Angola Year 1 Work Plan Goal**

Improved and sustainable health service delivery and impact

#### **Objective 1**

Medicines policy governance strengthened

#### **Sub-Objective 1.1**

DNME capacity to regulate medicines strengthened

**Activity 1.1a**

Strengthen the DNME's capacity to regulate medicines

**Sub-Objective 1.2**

Coordination and collaboration among local pharmaceutical management stakeholders at the central level improved to promote knowledge exchange

**Activity 1.2a**

Support local coordination and collaboration among MOH and partners for improved pharmaceutical management

**Objective 2**

Local capacity for pharmaceutical supply management enhanced

**Sub-Objective 2.1**

Health facility human resource pharmaceutical management capacity improved

**Activity 2.1a**

Support the MOH to build HR capacity for pharmaceutical management

**Sub-Objective 2.2**

Capacity of DNME/PNME and key MOH program central-level staff to conduct follow up supportive supervision of peripheral health units improved

**Activity 2.1b**

Support MOH supportive supervision

**Objective 3**

Information for pharmaceutical management decision-making improved

**Sub-Objective 3.1**

LMIS strengthened to enable evidence-based decision-making

**Activity 3.1a**

Support the DNME and CECOMA to improve the national LMIS

**Sub-Objective 3.2**

Strategic monitoring tools implemented to improve pharmaceutical management decision-making

**Activity 3.2a**

Provide TA support to implement strategic monitoring tools

**Objective 4**

Pharmaceutical services strengthened to achieve desired health outcomes

**Sub-Objective 4.1**

Public procurement and supply chain management system strengthened to improve availability of pharmaceuticals

**Activity 4.1a**

Assist strengthen the public sector procurement and supply management system and CECOMA

**Activity 4.1b**

Assist the MOH to receive, store and distribute USAID-funded commodities

**Sub-Objective 4.2**

MOH PV system strengthened to improve safety and use of medicines

**Activity 4.2a**

Support MOH to strengthen national PV system

**Goal: Quarterly Report Fields**

These are the fields that will be used to collect information for quarterly reports.

Overall Quarter Progress

Current Value: **(Sep 2012)** - During the reported quarter, USAID/SIAPS continued to assist the Ministry of Health/DNME to coordinate all the stakeholders in pharmaceutical management in order to improve the availability of medicines and enhance pharmaceutical services. Preliminary activities focused on conducting the medicine regulatory functions assessment to provide evidence-based information on the current status of the Angola medicine regulatory authority and recommendations to improve its regulatory functions. SIAPS also worked with consultants from LMI to agree on the dates and tools to be used in the CECOMA and LMIS baseline assessment which will help in identifying the current gaps in medicine supply chain and in Logistics Management Information System in Angola so that interventions can be formulated to improve both CECOMA functions and LMIS as a whole for increased availability and the use of evidence-based information in decision making. Preparations for the strategic monitoring tools of antiretroviral and malaria products were undergone to inform decisions in availability and improved use of USAID-funded HIV/AIDS and malaria commodities.

Key challenges faced during the quarter

Current Value: **(Sep 2012)** - 1. Delays in office registration and banking and building renovations have

affected full functionality of the office. 3. Lengthy visa process have delayed key staff recruitment and hindered full implementation of the work plan.

#### Technical Activity Coordination

Current Value: **(Sep 2012)** - During this reporting period, a FY13 SIAPS work plan was prepared and submitted to the technical clusters, health team leaders and SIAPS management for review and inputs. Training in budgeting was provided to the new STA. Pending the Angola work visa approval, the new STA for Angola was tasked to conduct a Short term technical assistance in Angola to advance the implementation of the current work plan while setting the new office. A travel Country Clearance was submitted to and approved by USAID. The local team of consultants was coordinated remotely in the implementation of the work plan. An office manager newly recruited was oriented in his new assignment.

#### Office management

Current Value: **(Sep 2012)** - The local team supported by staff from the corporate level followed up closely the Renovation for new office. Some equipment were identified and purchased pending the occupation of the new office. Signatories on the corporate accounts were identified and the needed documents submitted to the bank. The recruitment process of a driver, an accountant and a finance manager continued with the support from home office. The office continued to seek external Payroll and Health Insurances companies to be used once the office is well established.

#### Key activities planned for next quarter

Current Value: **(Sep 2012)** - Implement some of the recommendations from the baseline assessment in medicine regulatory functions Implement some of the recommendations from the baseline assessment in Medicine Supply Chain and LMIS in Angola Finalization of the End-User Verification survey in 10 provinces

#### **Quarterly Report Fields (Objective)**

Objective-level fields for collecting information for quarterly reports.

#### Quarterly Progress for Objective 1

Current Value: **(Sep 2012)** - An STTA was provided to conduct a baseline assessment on medicine regulatory system in Angola to identify the current gaps and provide the needed recommendations and plan to strengthen Angola medicine policy and governance through a well-functioning medicine regulatory system.

#### Quarterly Progress for Objective 2

Current Value: **(Sep 2012)** - SIAPS provided technical assistance to DNME to organize 1 technical meeting to coordinate and share best practices within MOH Essential Medicines Program, HIV/AIDS Program, RH/FP Program, USAID,ESD/Pathfinder and other relevant local partners. In addition, a semiannual pharmaceutical management activity review and planning meeting with above-mentioned MOH departments and provincial warehouse managers and supervisors was held from 31 July to 1st August to facilitate communication and problem-solving among provincial and national-level representatives from the key MOH programs and pharmaceutical warehouses. Participants also exchanged information on stock status, distribution plans and

processes, and explored the integration of the supply system for condoms and test kits into the supply system for MOH essential medicines.

#### Quarterly Progress for Objective 3

Current Value: **(Sep 2012)** - Consultants from LMI specialized in logistics management information systems and supply chain were contracted to assess the pharmaceutical supply system and information system. SIAPS supported the production of 4 types of manual tools identified as key tools to improve pharmaceutical management at facility level and monitored their distribution by CECOMA (the Medical Central Store). Logistics preparations were undertaken prior to the conduction of an End User verification to be conducted in 10 provinces.

#### Quarterly Progress for Objective 4

Current Value: **(Sep 2012)** - SIAPS supported the Pharmacovigilance department within the DNME to conduct a 2 day PV Awareness training in Lubango, Huila province to provide key health care staff with necessary information in pharmacovigilance system and how they can be actively involved in ADR spontaneous reporting and medicines with poor quality reports. PV contact persons at Provincial and municipal levels were also identified for further collaboration and follow up after the training.

#### **Quarterly Report Fields (Sub-Objective)**

Fields for reporting quarterly progress at the sub-objective level.

#### Quarterly progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - An STTA was provided to conduct a baseline assessment on medicines regulatory systems in Angola.

#### Deliverables: Sub-Objective 1.1

Current Value: **(Sep 2012)** - Draft report of assessment.

#### Quarterly progress toward sub-objective 1.2

Current Value: **(Sep 2012)** - An Interagency Coordination Committee meeting for logistics was held under the coordination of DNME in July 2012 and with the facilitation from USAID/SIAPS as a forum to coordinate information sharing among partners on planned and realized activities and for the improvement of pharmaceutical management which will result on an increased availability of pharmaceuticals. Past recommendations were reviewed and planned activities in the coming quarter were presented by all participants. It has been decided that this meeting will be held on monthly basis. In July 31-Aug 1, a 2-day workshop on Supply Chain Management was organized by DNME with technical and financial support from USAID/SIAPS and was chaired by the deputy director of DNME. In total, 68 participants attended among them Provincial Warehouse Managers, Malaria provincial supervisors, PNME supervisors, representatives of vertical public health programs like Reproductive Health program, the National TB/Leprosis control program, EPI/MoH, Assessor Cubano –Luanda, Head departments of DNME, National trainers and Supervisors of PNME. Other stakeholders of DNME and PNME also participated, namely Pathfinder, USAID, UNFPA, and SASH.

#### Challenges in progress toward sub-objective 1.2

Current Value: **(Sep 2012)** - Due to the presidential elections in Angola, the planned meeting of ICC logistics committee was postponed.

Deliverables: Sub-Objective 1.2

Current Value: **(Sep 2012)** - Activity report for the semi-annual workshop in pharmaceutical management Minutes for the coordination meeting of ICC-Logistics

Quarterly progress toward sub-objective 2.1

Current Value: **(Sep 2012)** - No progress in this reported quarter

Current Value: **(Sep 2012)** - The integrated supervision tool developed with the technical assistance from USAID/SIAPS is waiting its validation and approval by the Ministry of Health before being implemented.

Challenges in progress toward sub-objective 2.2

Current Value: **(Sep 2012)** - Delayed validation of the integrated supervision tool by all the programs and stakeholders in pharmaceutical management before being submitted to higher authorities in the ministry for approval.

Deliverables: Sub-Objective 2.2

Current Value: **(Sep 2012)** - Draft integrated supervisory tool.

Quarterly progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - LMI conducted the assessment on medicine supply chain and LMIS in Angola.

Challenges in progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - Significant delay in issuing of visas to the SIAPS technical advisor as well as the LMI consultants and difficulties to find Portuguese-speaker consultants affected the timely conduction of the assessment.

Deliverables: Sub-Objective 3.1

Current Value: **(Sep 2012)** - Draft preliminary presentation of the Medicine Supply Chain and LMIS assessment

Quarterly progress toward sub-objective 3.2

Current Value: **(Sep 2012)** - Logistics preparations for conducting the next EUV survey were done in terms of getting the approval for the activity at PNME/DNME level, sampling sites to be visited, re-training of data collectors and sending the invitations ahead of the time to the selected people. EUV was also conducted.

Challenges in progress toward sub-objective 3.2

Current Value: **(Sep 2012)** - The current online data collection tool had some issues of not responding and the team agreed to use manual forms in data collections which are more

cumbersome especially during data analysis.

Deliverables: Sub-Objective 3.2

Current Value: **(Sep 2012)** - Draft EUV report.

Quarterly progress toward sub-objective 4.1

Current Value: **(Sep 2012)** - LMI conducted an assessment on medicine supply chain and LMIS in Angola.

Challenges in progress toward sub-objective 4.1

Current Value: **(Sep 2012)** - Significant delay in issuing the visa to the SIAPS senior technical advisor who was to be in the country to support the LMI team in this activity and difficulties to find Portuguese-speaker consultants affected the timely conduction of the assessment.

Quarterly progress toward sub-objective 4.2

Current Value: **(Sep 2012)** - A 3 day workshop to raise the awareness on pharmacovigilance was held in Huila province by the department of pharmacovigilance of DNME with the support from USAID/SIAPS. In total 33 participants from Central Hospital of Lubango, Hospital Sanatorio, Psychiatric Hospital and Municipal Hospital attended. Key contacts among the team were identified to further boost ADR and medicine with poor quality reporting to the central level. The reporting forms were also distributed to standardize the reporting.

Challenges in progress toward sub-objective 4.2

Current Value: **(Sep 2012)** - Difficulties in finding a Portuguese speaking consultant to conduct an option analysis for the pharmacovigilance and medicine safety in Angola affected the implementation of a more structured interventions to strengthen the pharmacovigilance system in the country.

Deliverables: Sub-Objective 4.2

Current Value: **(Sep 2012)** - PV awareness training report in Huila

## **BANGLADESH**

Bangladesh work plan details for Year 1 of the SIAPS Program

### **Quarterly Report Background**

After the successful introduction of the web-based procurement and logistics management tool “DGFP Supply Chain Information Portal – SCIP” which includes an online procurement tracking system, logistics management information system (LMIS), and interventions to support the procurement management systems of the DGFP, the MOHFW had requested the SPS Bangladesh program to provide support to strengthen its capacity for procurement and supply chain for the entire DGHS. Following a meeting on October 13, 2010 with the Secretary of the MOHFW, USAID, and Health Secretary and Joint Secretary, several priority areas were identified for support including building the capacity of the MOHFW and component procuring entities to better manage the procurement and supply chain management systems.

Following the recent assessment of the procurement and supply chain management systems of the MOHFW and the CMSD, one of the main recommendations was to transform the CMSD into a strategic procurement organization. In addition, as part of the new 5 year (2012-2016) ‘Health, Population and Nutrition Sector Development Program (HPNSDP)’ one of the main goals is to set up a Procurement and Logistics Management Cell (PLMC) within the MOHFW to oversee the procurement functions of all procuring entities under the Ministry.

The goal of the expanded support to the MOHFW and DGHS includes the strengthening of policy decisions and increasing the capacity for commodity management by health care providers and institutions with an emphasis on good governance, procurement, institutional capacity building and other system strengthening initiatives aimed at ensuring continuous availability of goods required to support health care delivery and the timely availability of reliable data to support evidence based decision making. In addition SIAPS will collaborate with other stakeholders to implement selected options to ensure that the capacity of the MOHFW and other indigenous institutions are developed to carry out the required procurement and supply chain management functions in a sustainable manner.

Based on lessons learned working with DGFP, a general consensus among key stakeholders was made that there is a need to strengthen the medicine registration process under the Drug Administration. The development of a simple and effective medicine registration process is a substantial contribution to the successful completion of procurement processes of any procurement package. Considering the that the Drug Administration plays a key role in the procurement process SIAPS will provide technical support to the Directorate General of Drug Administration (DGDA) to strengthen the medicine registration process.

Based on the success of the SPS program interventions in DGFP, the USAID Bangladesh Mission has also requested the assistance of SIAPS to strengthen the pharmaceutical management system of the National TB Program (NTP) in Bangladesh.

### **Goal: Bangladesh Year 1 Work Plan Goal**

To build the capacity of the Ministry of health and family Welfare to effectively manage the supply chain management of health commodities

#### **Objective 1**

Improve the availability of commodities to support care and treatment of priority health conditions by strengthening procurement management systems of the MOHFW and component procuring entities

#### **Sub-Objective 1.1**

Provide TA to strengthen MOHFW and its procuring entities to effectively plan, forecast, procure and manage the procurement processes of health commodities

**Activity 1.1.1**

Provide support to develop annual procurement plan and consolidated procurement plan for 32 Operational plans of MOHFW and its procuring entities

**Activity 1.1.2**

Facilitate develop the strategic plan for MOHFW procurement management system

**Activity 1.1.3**

Support for the development of online procurement tracking/monitoring systems for MOHFW

**Activity 1.1.4**

Facilitate monthly procurement meeting with DGFP and DGHS/CMSD

**Activity 1.1.5**

Facilitate annual procurement/ tender conference with the potential suppliers to the MOHFW

**Activity 1.1.6**

Support the review and update of existing Procurement Primer

**Activity 1.1.7**

Support to effectively manage the procurement processes (tender, bid reviews, and contract management) followed under the MOHFW

**Activity 1.1.8**

Facilitate the trainings on the DGFP procurements procedure manual

**Activity 1.1.9**

Support for the development of annual forecasting and quantification for DGFP based on five year national forecasting

**Sub-Objective 1.2**

Support the establishment and functioning of the procurement and logistics management cell (PLMC) within the Ministry of Health and Family Welfare

**Activity 1.2.1**

Support to review and agree the proposed structure, function and mandate of PLMC

**Activity 1.2.2**

Provide logistics support in establishing PLMC

**Activity 1.2.3**

Provide support for the development of PPM for MOHFW

**Sub-Objective 1.3**

Provide support to the MOHFW to analyze options available for e-procurement management system

**Activity 1.3.1**

Review existing initiatives and develop a roadmap towards implementation of e-procurement

**Activity 1.3.2**

Share and agree with the stakeholders the newly developed e-procurement system

**Objective 2**

Strengthen warehousing, distribution and logistics management systems of DGFP to improve availability and access

**Sub-Objective 2.1**

Provide TA to DGHS/CMSD and DGFP on good storage, warehousing and logistics management system

**Activity 2.1.1**

Review existing condemnation process and propose revised process for effective disposal of unwanted (obsolete/unusable) items for DGFP

**Activity 2.1.2**

Support de-junking of the unwanted stock/items in the warehouses

**Activity 2.1.3**

Embed a Senior Technical Advisor at CMSD to provide support warehousing, distribution and logistics management system for the MOHFW

**Activity 2.1.4**

Provide support to conduct a feasibility and options analysis for selection of a suitable electronic warehouse and inventory management solution for DGHS warehouses

**Sub-Objective 2.2**

Develop Standard Operating Procedures/Guidelines to support a comprehensive and sustainable Warehousing, Distribution and Logistics management system under MOHFW

**Activity 2.2.1**

Review and update the current DGFP supply manual

**Activity 2.2.2**

Provide training/orientation to relevant DGFP staff on revised supply manual

**Objective 3**

Support evidence-based decision making by strengthening commodity management information systems

**Sub-Objective 3.1**

Improve availability of data and information by providing support for the maintenance and optimal functions of electronic logistics management information tools (e.g. SCIP, procurement tracker, LMIS, UIMS, WIMS, Pipeline, Quantimed, etc.)

**Activity 3.1.1**

Contract Softworks (a local IT firm) to update and maintain the SCIP

**Activity 3.1.2**

In collaboration with Softworks, SIAPS will provide TA to the DGFP for the roll out of the UIMS to 155 new sites and support for adequate functioning of Upazila Inventory Management System (UIMS) in 300 sites under DGFP

**Activity 3.1.3**

Provide basic training on UIMS for 155 new sites and refresher training to existing 145 sites

**Sub-Objective 3.2**

Improve transparency by establishing the procurement management portal

**Activity 3.2.1**

Review and finalize the product catalogue in collaboration with stakeholders

**Activity 3.2.2**

Finalize and launch the MOHFW procurement management portal

**Sub-Objective 3.3**

Generate and disseminate Supply Chain Information to stakeholders

**Activity 3.3.1**

Facilitate the preparations and circulation of quarterly newsletter (SIAPS newsletter)

**Activity 3.3.2**

Provide monthly reports on procurement, stock status and distribution information

**Objective 4**

Promote commodity security by building capacity of MOHFW and its directorates including national institutions and networks to coordinate and manage information relating to health commodity management

**Sub-Objective 4.1**

Support for the development and implementation of capacity building framework and strategy under the leadership of PLMC to build the capacity of relevant personnel of the MOHFW and its key directorates to sustainably manage their supply chains and also of indigenous institutions to provide supply chain technical assistance and training

**Activity 4.1.1**

Facilitation commodity management working group with MOHFW and development partners working on health commodities

**Activity 4.1.2**

Develop training modules and facilitate training in-country for relevant staff of MOHFW and its directorates

**Activity 4.1.3**

Collaborate with indigenous institutions/universities to organize training /short term certificate courses and professional courses on Supply Chain Management and provide necessary technical assistance

**Activity 4.1.4**

Sponsor participation of relevant staffs of MOHFW and its directorates in local and international courses/seminar/workshop on supply chain management issues to enhance technical knowledge and capacity

**Sub-Objective 4.2**

Provide technical leadership and coordination in procurement and supply chain management of Health commodities

**Activity 4.2.1**

Facilitate quarterly meetings of DGFP Logistics Coordination Forum that oversees reproductive health supply chain management systems

**Activity 4.2.2**

Facilitate the MOHFW supply chain management conference to share success, challenges and innovative ideas in improving the health commodities supply chain management

**Objective 5**

Improve drug registration system by providing technical assistance to the Directorate General of Drug Administration

### **Sub-Objective 5.1**

Provide support to review the processes and systems for drug registration management of the DG-DA and make recommendations for strengthening including required technical assistance

#### **Activity 5.1.1**

Conduct a comprehensive pharmaceutical systems assessment (including the drug assessment/review the processes and systems of medicines registration under DG-DA) and provide specific recommendations

#### **Activity 5.1.2**

Support the implementation of recommendations to strengthen medicines registration management process

#### **Activity 5.1.3**

Introduce a management software for drug registration e.g. PHARMADEX

### **Objective 6**

Strengthen pharmaceutical management systems for TB

#### **Sub-Objective 6.1**

Improve TB program performance through strengthening management information systems in collaboration with WHO, URC and other key stakeholders

##### **Activity 6.1.1**

Organize a technical review of the TB commodity management system and develop the TB commodity management plan for the NTP

##### **Activity 6.1.2**

Transition e-TB manager technical coordination to SIAPS Bangladesh

##### **Activity 6.1.3**

Support existing sites using e-TB manager to make it functional and plan for roll-out

##### **Activity 6.1.4**

Develop web-based TB-LMIS linking with e-TB manager based on the experience of DGFP in collaboration with SoftWorks

#### **Sub-Objective 6.2**

Provide support to the TB Program to develop a comprehensive supply chain management system to support, forecasting, quantification, supply planning, procurement management and distribution of TB commodities including lab

##### **Activity 6.2.1**

Review and update existing SOP for drugs and supply management developed by National TB Program (NTP)

**Activity 6.2.2**

Develop the comprehensive training plan on logistics management systems for relevant staff of NTP and provide TOT

**Activity 6.2.3**

Establish a coordinated mechanism to introduce national level forecasting, quantification and supply planning for TB commodities

**Activity 6.2.4**

Introduce pipeline monitoring system using appropriate tools based on DGFP experience

**Activity 6.2.5**

Initiate the process of streamlining the vertical procurement process followed by GFATM in to the national procurement mechanism of CMSD/DGHS under current health sector program.

**Activity 6.2.6**

Embed TB pharmaceutical management specialists in the TB Control Program to facilitate development and implementation of institutional and individual capacity building activities while providing on the job training, mentoring and technology transfer to local counterparts

**Goal: Quarterly Report Fields**

These are the fields that will be used to collect information for quarterly reports.

Overall Quarter Progress

Current Value: (**Sep 2012**) - SIAPS BD Program has continued providing technical assistance to the MOHFW and its component directorates e.g. DGFP, DGHS etc. to build the capacity and strengthen the procurement and supply chain management system. During this quarter besides DGFP, SIAPS BD continued focusing its working areas to DGHS, DGDA and the MOHFW using systems strengthening approach. SIAPS provided support to the MOHFW to finalize the structure and TOR of the Procurement and Logistics Management Cell (PLMC).

SIAPS BD facilitated the process of further upgrading the MOHFW Supply Chain Management Portal (SCMP) to strengthen procurement management system. For having a long-term vision within the MOHFW, the strategic plan for MOHFW procurement management system has been finalized in consultation with key stakeholders. The SIAPS BD also provided support to the MOHFW in drafting the Procurement Procedures Manual for efficient and effective procurement system. The supply manual of DGFP has been revised and published to support a comprehensive and sustainable warehousing, distribution and logistics management system of DGFP.

As part of capacity building and systems strengthening of the MOHFW, SIAPS also started working with the Directorate General of Drug Administration (DGDA) to strengthen its regulatory system (e.g. medicines registration and licensing systems) and

Pharmacovigilance system. SIAPS BD has been providing technical support to National TB Control Program (NTP) in forecasting, quantification, supply planning, procurement management and distribution of TB commodities using e-TB Manager.

In addition to build the capacity of the MOHFW and its directorates, SIAPS BD facilitated the process of working with national indigenous institutions e.g. engineering staff college of Bangladesh to offer basic training (5 days course) on procurement for GOB counterparts.

Key challenges faced during the quarter

Current Value: **(Sep 2012)** - The following key challenge SIAPS BD faced during the reporting period:

- It took a long time to finalize the report on the quantification of RH commodities and TB drugs as there was a coordination gap between local and international consultant and also delayed response from HQ;
- Vehicle condemnation process couldn't be possible to include in the GO/notification issued by the DGFP.
- Delayed in getting Government approval and feedback in the drafted SOPs/guidelines/reports;
- Lack of initiative from the Ministry side to foster monitoring activities;
- Discontinuation of local IT firm (subcontractor);
- Training of e-TB Manager delayed due to discontinuation of IT firm (subcontractor); and
- Slow internet speed at e-TB Manager sites hampered updating data on time.
- 

Key activities planned for next quarter

Current Value: **(Sep 2012)** - 1) Continued roll out of Upazila Inventory Management System Training 2) Training on RSAT and pharmacovigilance assessment 3) Annual work plan technical review 4) Dissemination session on RSAT & Pharmacovigilance System Assessment report 5) Orientation on PLMC (Procurement Meeting) 6) Procurement operational plan workshop 7) Lead time review workshop 8) Participation in National Digital Fair organized by the Government 9) User acceptance training on procurement and use of the on-line portal for PLMC, DGFP, and CMSD staff 10) Final dissemination of strategic plan for MOHFW 11) Sponsor international training on procurement for the MOHFW staff

Technical Activity Coordination

Current Value: **(Sep 2012)** - i. Bi-weekly coordination meeting ii. Monthly staff meeting iii. Three days' workshop to develop work plan for the year of 2012-13

Office management

Current Value: **(Sep 2012)** - During this quarter SIAPS BD installed electronic office attendance and access control system.

### **Quarterly Report Fields (Objective)**

Objective-level fields for collecting information for quarterly reports.

Quarterly Progress for Objective 1

Current Value: **(Sep 2012)** - During this quarter, SIAPS has played vital role to improve the health

condition by strengthening procurement management systems for MOHFW and its component procuring entities. SIAPS has set an example involving 17 line directorates' of DGHS in a workshop for clear perception on fund required under Carried-over Procurement and finalization of items under new Procurement Plan for consolidation. Another initiative was to facilitate the process of drafting the strategic plan for MOHFW procurement management system. The portal has been developed for online procurement tracking/monitoring systems for MOHFW.

Additionally, DGHS is now following the model of DGFP regular monthly procurement meeting. The Procurement Procedure Manual (PPM) for MOHFW has also been developed during this period. A review of the Lead-time for processing the packages have completed for effective management of the procurement processes under MOHFW. The report of annual forecasting and quantification for DGFP based on five year national forecasting was prepared and shared with HQ/editorial team for their input.

In order to ensure the availability of products at service delivery points; SIAPS facilitated to prepare the forecasting exercise of RH commodities for the next ten years with different scenarios and funding gap analysis in consultation with the relevant stakeholders. An orientation workshop has organized on the revised system of the proposed structure, function and mandate of PLMC under MOHFW. Finally, extensive technical and logistics support have been provided in establishing PLMC to establish a functional PLMC within the MOHFW during the reporting period.

#### Quarterly Progress for Objective 2

Current Value: **(Sep 2012)** - During this quarter, remarkable progress was made with DGFP towards meeting this objective. The supply manual of DGFP was revised and printed to support a comprehensive and sustainable warehousing, distribution, and logistics management system. An effective disposal system of unwanted (obsolete and unusable) items for DGFP was introduced and practiced which contributed to increased available storage space, and improved warehousing and logistics management. Moreover, an annual SIAPS and DGFP joint monitoring plan was developed and implemented involving DGFP staff to develop a monitoring and supervision system.

#### Quarterly Progress for Objective 3

Current Value: **(Sep 2012)** - To support evidence-based decision making, SIAPS is supporting the MOHFW to build capacity in the Upazila Inventory Management System (UIMS) by creating a pool of trainers capable of rolling out the training and supporting is an extensive tool for commodity management system which supports evidence based decision making. During this period, a TOT manual for UIMS was developed and 15 DGFP people and 5 SIAPS staff participated in a TOT to create a resource pool for of trainers at Upazila level. These trainers will provide basic training on UIMS for new sites and refresher training to existing sites in the 1st quarter of FY13. The draft product catalogue has been reviewed and finalized in collaboration with stakeholders to improve transparency for evidence based decision making. The developed list is under review by bio-medical engineer for finalization. A portal with four modules has finalized for the MOHFW procurement management. Quarterly SIAPS Newsletter and monthly report on procurement, stock status and distribution information has been preparing and circulating on regular basis.

#### Quarterly Progress for Objective 4

Current Value: **(Sep 2012)** - To achieve this objective, two sub-objectives set on capacity building of relevant personnel of MOHFW and its key directorates and Provide technical leadership and coordination in procurement and supply chain management of health commodities. A significant achievement made under capacity building initiative. A Memorandum of Understanding (MoU) has signed between SIAPS and Engineering Staff College, Bangladesh to organize training/short term certificate courses and professional courses on Procurement and Supply Chain Management. However, during this period, a course of 5 days on Procurement Management have been started. SIAPS BD has planned to sponsor four relevant persons from the MOHFW and its directorates in international procurement training in Kuala Lumpur (22 October – 09 November). The team visited Malaysia for a comprehensive training on Procurement Management. However, the study tour yet to arrange to support relevant staffs under MOHFW and its directorates to promote experience sharing and networking.

#### Quarterly Progress for Objective 5

Current Value: **(Sep 2012)** - SIAPS has been working with the Directorate General of Drug Administration (DGDA) to strengthen its medicines registration and licensing systems. In collaboration with the US Food and Drug Administration (FDA) and SIAPS partner, the University of Washington, SIAPS conducted an assessment of the pharmacovigilance system and a second assessment of the national medicines regulatory system in Bangladesh. These assessments will assist the DGDA to strategically outline next steps.

#### Quarterly Progress for Objective 6

Current Value: **(Sep 2012)** - The e-TB manager has been playing a key role in strengthening pharmaceutical management systems for TB. During the reporting period, a commodity management plan has been developed in collaboration with NTP. The e-TB manager has been rolled out in 20 new sites. To strengthen pharmaceutical management systems for TB, SIAPS set up a mechanism with NTP and other stakeholders to follow the Global Fund mechanism in a coordination manner for national level forecasting, quantification and supply planning for TB commodities. A 5 year quantification exercise also completed to develop a comprehensive supply chain management system to support, forecasting, quantification, supply planning, procurement management and distribution of TB commodities. The process of streamlining the vertical procurement process followed by GFATM in to the national procurement mechanism of CMSD/DGHS under current health sector program has been initiated. There are some challenges faced while making these remarkable progresses. Discontinuation of IT firm (subcontractor) has delayed the training of e-TB manager and the low speed of internet were creating problem to manage the software.

#### **Quarterly Report Fields (Sub-Objective)**

Fields for reporting quarterly progress at the sub-objective level.

#### Quarterly progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - Under this sub-objective, SIAPS progress was outstanding. SIAPS has provided fundamental support to develop annual procurement plan for 32 Operational plans of MOHFW and its procuring entities. SIAPS also provided support to consolidate the plans for respective entities. The process of developing these plans was fully participatory and the ministry people were very keen to work with SIAPS technical team. SIAPS was able to convince them to make a realistic plan. This is the first time a workshop for 17 line directorates' offices of DGHS worked together for clear perception

on fund required under Carried-over Procurement and finalization of items under new Procurement Plan for consolidation. In this endeavor, GOB ownership was remarkable. The first draft of the strategic plan for MOHFW procurement management system is now with the MOHFW for approval. The process was facilitated by SIAPS BD.

The portal has been developed for online procurement tracking/monitoring systems for MOHFW. User acceptance training (UAT) on the portal is planned in mid-December. Furthermore, SIAPS facilitated the monthly procurement meeting with DGFP which is now organized regularly and the same process initiated in DGHS. An international consultant has been working on the development of Procurement Procedure Manual (PPM) for MOHFW. To support for effective management of the procurement processes (tender, bid reviews, and contract management) under MOHFW, a review of the Lead-time for processing the packages have completed in this quarter. The Additional Secretary has fixed the date for launching the DGFP procurements procedure manual in January 2013 which will facilitate the training on the same.

The report of annual forecasting and quantification for DGFP based on five year national forecasting was prepared and shared with HQ/editorial team for their input. In order to ensure the availability of products at service delivery points; SIAPS facilitated to prepare the forecasting exercise of RH commodities for the next ten years with different scenarios and funding gap analysis in consultation with the relevant stakeholders.

#### Challenges in progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - Every year new government staff is involved in the procurement planning process, which means every year SIAPS team has to provide fresh orientation to new set of staff. Additionally, ensuring consistent use of the standard templates for orientating staff on how to prepare Procurement plan by trained Line Directors continues to pose a challenge.

#### Deliverables: Sub-Objective 1.1

Current Value: **(Sep 2012)** –

- SCM Portal
- 32 Procurement plans
- Draft strategic plan for MOHFW procurement management system
- Monthly procurement meeting minutes with DGFP
- Procurement tracking/monitoring Portal for MOHFW
- Draft Procurement Procedure Manual (PPM) for MOHFW
- Draft annual forecasting and quantification for DGFP

#### Quarterly progress toward sub-objective 1.2

Current Value: **(Sep 2012)** - The review process of the proposed structure, function and mandate of PLMC was completed and agreed by the MOHFW. By this time, an orientation workshop was organized on the revised system. Also extensive technical and logistics support has provided to establish a functional PLMC within the MOHFW.

#### Deliverables: Sub-Objective 1.2

Current Value: **(Sep 2012)** - •Government Order •Structure and ToR of PLMC

Quarterly progress toward sub-objective 2.1

Current Value: **(Sep 2012)** - A notification/ Government Order (GO) was issued on 12th August 2012 on the revised process for effective disposal of unwanted (obsolete/unusable) items for DGFP. SIAPS provided technical assistance to document this process in the revised supply manual. Since the issuance of the GO, 70% of unwanted commodities have already been disposed of.

Challenges in progress toward sub-objective 2.1

Current Value: **(Sep 2012)** - It was not possible to include the Vehicle condemnation process in the GO/notification.

Quarterly progress toward sub-objective 2.2

Current Value: **(Sep 2012)** - The supply manual of DGFP has been reviewed and updated. Director L&S played the vital role in this initiative while SIAPS BD team facilitated the process very efficiently and smoothly. It was a huge task but SIAPS BD successfully finished the task. The revised supply manual has been printed and handed over to DGFP. A cover letter from the Director-L&S was issued in this regard.

Challenges in progress toward sub-objective 2.2

Current Value: **(Sep 2012)** - • The process took a long time

Deliverables: Sub-Objective 2.2

Current Value: **(Sep 2012)** - • Printed copy handed over to DGFP • A cover letter from Director (L&S) issued

Quarterly progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - Extensive support was provided for functioning of UIMS in existing 173 sites under DGFP. According to the plan, an action matrix was developed to roll out in new sites with a pool of resource persons. A request letter has been sent to DGFP to organize UIMS training regionally. A manual for TOT on UIMS at Upazila level has been developed and during this period, 20 DGFP people including 5 SIAPS technical staff have been provided TOT. However, providing basic training on UIMS for 310 new sites and refresher training to existing 173 sites has been shifted to 1st quarter of FY13. The ToR has developed for contracting local IT firm.

Challenges in progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - • Roll-out was hindered because of discontinuation of local IT firm (subcontractor)

Deliverables: Sub-Objective 3.1

Current Value: **(Sep 2012)** - • Operational status report • TOT Manual • TOT Report

Quarterly progress toward sub-objective 3.2

Current Value: **(Sep 2012)** - The draft product catalogue has been reviewed and finalized in collaboration with stakeholders. The developed list is under review by biomedical engineer for finalization. The portal with four modules was finalized for the MOHFW procurement management.

Current Value: **(Sep 2012)** - • draft product catalogue • Draft MOHFW procurement management portal

Quarterly progress toward sub-objective 3.3

Current Value: **(Sep 2012)** - A draft version of SIAPS Newsletter for this quarter is under process. It will send to HQ for their feedback soon. Also the monthly report on procurement, stock status and distribution information has been preparing on regular basis and circulating widely.

Current Value: **(Sep 2012)** - • Draft Newsletter • The draft report on procurement, stock status and distribution information

Quarterly progress toward sub-objective 4.1

Current Value: **(Sep 2012)** - A Memorandum of Understanding (MoU) has signed between SIAPS and Engineering Staff College of Bangladesh to organize training/short term certificate courses and professional courses on Procurement and Supply Chain Management. However, during this period, a five-day course on Procurement Management was started.

SIAPS/BD planned to sponsor four relevant persons from the MOHFW and its directorates in international procurement training in Kuala Lumpur (22 October – 09 November). SIAPS will work with participants to promote sharing and networking upon their return from the training.

Challenges in progress toward sub-objective 4.1

Deliverables: Sub-Objective 4.1

Current Value: **(Sep 2012)** - • MoU between SIAPS and Engineering Staff College, Bangladesh • Course outline on Procurement management training with Engineering Staff College started.

Quarterly progress toward sub-objective 4.2

Current Value: **(Sep 2012)** - No progress made on this sub-objective this quarter.

Challenges in progress toward sub-objective 4.2

Current Value: **(Sep 2012)** - It is needed to complete the setup of PLMC and assign a dedicated staff who will coordinate the activities.

Quarterly progress toward sub-objective 5.1

Current Value: **(Sep 2012)** - During this quarter, data was collected and cleaned for the regulatory system assessment and the pharmacovigilance assessment. A stakeholder meeting was planned for the upcoming quarter to review the findings and recommendations of both draft assessments and to work with stakeholders to develop action plans for strengthen the pharmacovigilance and medicine registration processes.

Current Value: **(Sep 2012)** - • SOW of the assessments (RSAT and PV)

Quarterly progress toward sub-objective 6.1

Current Value: **(Sep 2012)** - A technical workshop on ‘Review of the TB commodity management system and developing TB commodity management plan for the NTP’ was organized and a commodity management plan developed. A user guideline in Bangla was developed for implementation and utilization of e-TB manager at all levels and English version customized according to BD perspective. Field visit was conducted for functional e-TB manager and a roll out plan developed in collaboration with NTP. By this time, roll out and training on e-TB manager has been completed in 20 new sites. However, strategy of developing TB LMIS has been changed in consultation with HQ which will be incorporated in Medicine Management Module of e-TB manager.

Challenges in progress toward sub-objective 6.1

Current Value: **(Sep 2012)** - •Discontinuation of IT firm (subcontractor)

Deliverables: Sub-Objective 6.1

Current Value: **(Sep 2012)** - • Technical Review Report • Commodity Management Plan • User Manual • Customized user manual • Roll-out plan of e-TB manager

Quarterly progress toward sub-objective 6.2

Current Value: **(Sep 2012)** - The National TB Program (NTP) and other stakeholders agreed to follow the Global Fund mechanism to establish a coordination system for national level forecasting, quantification and supply planning for TB commodities. In this regard, a 5 year quantification exercise was conducted and the report is forthcoming. The process of streamlining the vertical procurement process followed by GFATM into the national procurement mechanism of CMSD/DGHS has been initiated under the current health sector program.

Deliverables: Sub-Objective 6.2

Current Value: **(Sep 2012)** - • Concept paper of quantification exercise. • Spreadsheet for drug management of central TB WH. • TB-LMIS and e-TBM.

## **BRAZIL**

Brazil work plan details for Year 1 of the SIAPS Program

### **Quarterly Report Background**

Since 2007, SPS has helped strengthen the nationwide diagnosis and treatment of multidrug resistant (MDR)-TB patients, management of second-line medicines, and overall drug-resistant (DR)-TB surveillance. For example, the number of DR-TB treatment centers has expanded from 62 to 167, which has increased geographic accessibility. Also, an innovative tool was developed, the web-based e-TB Manager© information management tool, which was implemented in all DR-TB centers. SPS supported the adoption of new evidence-based guidelines for TB and DR-TB control and developed MDR-TB guidelines and training-of-trainers materials. In addition, SPS conducted nationwide capacity building programs in all 167 reference centers focusing on case management, diagnostic capacity, monitoring of MDR-TB cases, and information sharing at all levels. These interventions contributed to a 12 percent increase in DR-TB cure rate between 2004 and 2010, and more than doubled the number of DR-TB case notifications between 2004 and 2011.

SPS strengthened DOTS and overall TB drug management by institutionalizing a permanent product quality assurance-testing program for first- and second-line drugs. As a result, Brazil has been recognized by international organizations, including the Green Light Committee/Global Drug Facility at Stop TB Department/WHO, for promoting the use of quality assured medicines. SPS also has supported the transition to fixed dose combination (FDC) products for TB by training providers in all 27 states in rational use of FDCs and by providing technical assistance in the development and manufacture of the new FDC dosage forms. In addition, SPS supported the national public health laboratory network to achieve international standards, implement quality systems according to ISO norms, and promote accreditation processes through innovative methodologies in ten public health laboratories.

As a result of these achievements, SPS is recognized for its expertise among local TB partners and has been nominated for a second mandate to the new MoH TB advisory committee created in 2011 to provide input into national TB policies. During all these years, MSH has been able to leverage substantial human and financial resources. Using the same collaborative model that was used by the Government of Brazil, MoH is committed to continue its support for all proposed activities in this work plan on a cost-share basis of approximately 50 percent.

### **Goal: Brazil Year 1 Work Plan Goal**

Strengthen TB / DR- TB control allowing MSH and partners key activity achievements to be fully sustainable within the Brazilian Health System

#### **Objective 1**

Strengthen TB pharmaceutical management and information systems

#### **Sub-Objective 1.1**

Support incorporation of key drug management achievements and policies within the public health system

#### **Activity 1.1a**

Support local production of quality assured pharmaceutical forms for first-line TB treatment

#### **Activity 1.1b**

Consolidate new treatment guidelines implementation and 4 in 1 fixed dose combination uptake at primary health care level countrywide

**Activity 1.1c**

Disseminate good pharmaceutical practices implementation / management for SLDs at state level

**Activity 1.1d**

Provide logistical support for DM to MoH and consolidate tools incorporation

**Activity 1.1e**

Support a sustainable framework to ensure a supply of quality assured TB drugs (Quality Control Program and WHO pre-qualification)

**Sub-Objective 1.2**

Support SITETB (Brazilian e-TB Manager specific version) long term sustainability, management and use countrywide

**Activity 1.2a**

Support SITETB implementation countrywide

**Activity 1.2b**

Support best surveillance practices through regular data mining/analysis, evidence-based management and decision making

**Activity 1.2c**

Continue exploring interoperability between SITETB and São Paulo-SP TB electronic system (TBWEB)

**Objective 2**

Support TB state programs in strengthening DOTS and community DOTS implementation

**Sub-Objective 2.1**

Support local ONGs for community DOTS activities

**Activity 2.1a**

Evaluate outcomes and impact of FY10 activities and define the way forward with partners

**Sub-Objective 2.2**

Support DOTS implementation with RJ State TB Program

**Activity 2.2a**

Evaluate outcomes and impact of FY10 activities and define the way forward with partners

### **Sub-Objective 2.3**

Support the SP State TB program in implementing specific TB control activities

#### **Activity 2.3a**

Support project's design and implementation of TB control in key areas for intervention (co-morbidities such as diabetes... and long term hospitalization)

### **Objective 3**

Strengthen Helio Fraga National TB Reference Center activities and the Public Health TB Laboratory network

#### **Sub-Objective 3.1**

Support Helio Fraga Center in delivering its key mandate as National TB Reference Center

##### **Activity 3.1a**

Continue to provide technical support to Hélio Fraga Center to consolidate its quality management system and move towards accreditation (including minor physical renovations and equipment acquirement for CRPHF's pharmacy)

##### **Activity 3.1b**

Consolidate National TB Reference Laboratory activities for the TB Lab network (smear microscopy, culture and DST External Quality Assurance Program; Culture decentralization; State TB program supervision)

#### **Sub-Objective 3.2**

Support Public Health Laboratory Network in using Labmost methodology to strengthen Laboratory Quality Management Systems and accreditation process

##### **Activity 3.2a**

Organize and conduct two Labmost TOT workshops with participation of NTP/CGLAB, GGLAS/Anvisa representatives and INCQS staff

##### **Activity 3.2b**

Explore incorporation of Labmost methodology by CGLAB and GGLAS/ANVISA as an official tool to support lab quality management initiatives and Anvisa financial support to public health lab network

##### **Activity 3.2c**

Provide support for six additional Labmost workshops in cooperation with CGLAB and GGLAS/ANVISA

#### **Sub-Objective 3.3**

Support a pragmatic clinical trial to evaluate the potential use of new rapid TB tests within the Brazilian

public Health System

**Activity 3.3a**

Continue ensuring coordination activities within the steering committee

**Activity 3.3b**

Continue ensuring diagnostic kits strategic supply with partners

**Activity 3.3c**

Explore the potential use of current research platform for new rapid TB test for extra pulmonary and Pediatric TB

**Goal: Quarterly Report Fields**

These are the fields that will be used to collect information for quarterly reports.

Overall Quarter Progress

Current Value: **(Sep 2012)** - SIAPS has achieved in average around 90% of all planned activities for all 3 objectives designed in our workplan. Due to restrictions and limitations from our partners some activities will not be completed, so last quarter was important to aligned the priorities and overall the activities that will be fully delivered by the end of our project in Brazil. Important to mention that according to our internal discussions and in agreement with Brazilian government, our key deliverable will be the full transition of SITETB system to Brazil's NTP, so goals for covering all Brazilian states were established.

Key challenges faced during the quarter

Current Value: **(Sep 2012)** - SIAPS had many difficulties on implementing some of our technical activities due to political issues or even lack of capacity of Brazilian government to take the ownership on specific areas. Helio Fraga Center has many barriers to solve basic problems (human resource issues, technical capacity, implementation of their part on the joint planned achievements) making impossible the implementation of key objectives of our work plan, specifically on the accreditation of the Pharmacy, Outpatient Department and Laboratory.

Key activities planned for next quarter

Current Value: **(Sep 2012)** - SITETB training for 7 new states of Brazil (Sergipe, Rio de Janeiro, Ceará, Rio Grande do Norte, Minas Gerais, Maranhão and Piauí) achieving around 91% of all states. Elaborate final report measuring the impact of SIAPS support given to Rio de Janeiro state municipalities Implement activities according to the agreement with São Paulo State TB Control program Conduct second LABMOST workshop in Adolf Lutz Institute, Brazilians largest public health laboratory Finalize all planned activities within SIAPS scope for the accreditation of Hélio Fraga Reference Center Pharmacy, Outpatient Department and Laboratory Meeting scheduled for December with physicians and pharmacists that will be part of the NTP's TB team in charge of validating cases and managing medicines through SITETB

**Quarterly Report Fields (Objective)**

Objective-level fields for collecting information for quarterly reports.

#### Quarterly Progress for Objective 1

Current Value: **(Sep 2012)** - SIAPS and NTP had agreed that in order to have a complete transmission of SITETB system ownership, trainings provided by SIAPS should involve all 27 Brazilian States (first goal was to cover 11 states). Aiming the accomplishment of that new goal, SIAPS has expanded the trainings for the entire country. SITETB implementation will be prioritized for all remaining SIAPS funding linked to strengthening TB pharmaceutical management and information systems to guarantee its sustainability with Brazilian MoH. Among all other planned products, around 95% of them were already delivered; other 5% are still pending basically due to reasons that aren't under SIAPS control.

#### Quarterly Progress for Objective 2

Current Value: **(Sep 2012)** - SIAPS continued to support DOTS implementation for 9 municipalities of Rio de Janeiro's metropolitan region through car rental. Activities planned proposed by São Paulo State TB Control Program (PEC-TB SP) were finally defined, consultants were hired and activities are on-going.

#### Quarterly Progress for Objective 3

Current Value: **(Sep 2012)** - SIAPS provided technical support for strengthening CRPHF's capacity specifically linked to its accreditation, all issues under SIAPS control were fully completed. SIAPS support linked to Laboratory activities is facing many constraints due to the lack of capacity/initiative/counterpart from Brazilian MoH partners.

### **Quarterly Report Fields (Sub-Objective)**

Fields for reporting quarterly progress at the sub-objective level.

#### Quarterly progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - Anvisa opened a public consultation for further authorization to market products containing more than 3 drugs in FDCs, according to Brazilian legislation only up to three components are currently allowed to be used in a FDC, results of this public consultation still under evaluation; . Registration dossier for 2 in 1 FDC still under evaluation for approval at Anvisa. Public network manufactures representative and Farmanguinhos participated to 26th of April meeting to assess current capacity to start producing 2 in 1 FDCs when registration will be conceded. Farmanguinhos facility is still in process of obtaining renewal of its GMP certificate and need to have a dedicated line for TB products manufacturing before production can start.

Decision was taken to organize a meeting with all public manufacturers involved in TB products production to further assess their production capacity and transfer to other public manufactures the new 2 in 1 tablet FDC formulation developed by Farmanguinhos with SIAPS support after successful bioequivalence studies were conducted in 2011. Pool procurement of quality assured API is considered between public network manufacturers to facilitate production of final quality assured products. SIAPS will convene another meeting with public network manufacturers to discuss these issues when registration will be conceded by Anvisa. Additional information was requested to Farmanguinhos to give an update of current status of technology transfer process for 4 in 1 FDC production with the WHO pre-qualified supplier Lupin.

Capacity building plan for new treatment guidelines and 4 in 1 fixed dose combination uptake at primary health care level elaborated, approved (by NTP and partners) and implemented, all 27 states are currently following 100% of new guideline and treatment recommendations using 4 in 1 FDCs for 1st treatment;

- SIAPS has supported TB Clinical Management training performed in Minas Gerais, completing 26 out of 27 states targeted for new treatment guideline implementation and 4 in 1 FDCs use.
- Training for strengthening TB reference conducted in Minas Gerais, completing all Brazilian states.
- SIAPS has accomplished all activities under its governance towards Helio Fraga Center accreditation process (Laboratory, Outpatient department and Pharmacy), activities still pending due to difficulties with issues not linked to SIAPS governance.

#### Challenges in progress toward sub-objective 1.1

**Current Value: (Sep 2012)** - In April 2012, SIAPS participated in a meeting to confirm the switch from caps to tablet (meeting minutes as a product), final decision still pending on MoH approval. Issues linked to Helio Fraga Center governance not yet addressed turning impossible the completeness of all planned activities (biosafety analysis report still pending, not allowing completeness of all accreditation process). TB Clinical Managements training couldn't be conducted in Mato Grosso, due to TB state reference center internal problems.

#### Deliverables: Sub-Objective 1.1

**Current Value: (Sep 2012)** - 54 professionals trained (21 male and 33 female) on good pharmaceutical practices SIAPS conducted supervisory visits at 2 DR-TB reference centers (Alagoas +Rio Grande do Sul) totaling 7(3 Rio Janeiro + 1 Piauí + 1 Minas Gerais + Alagoas +Rio Grande do Sul). Reports and recommendations elaborated and disseminated to NTP for further monitoring. Supervision checklist elaborated by SIAPS has been approved and incorporated by NTP to be used for regular supervision. Work plan target of conducting 20 DR-TB reference centers supervisory visits with SIAPS decreased to only 7 to match with NTP's plans/schedule.

SLD Inventory model (SOP and tracking tool) was elaborated, approved by NTP and implemented in 10 DR-TB reference centers (Distrito Federal, Alagoas, Paraná, Sergipe, Rio Grande do Sul, Espírito Santo, Rio de Janeiro (3) and Piauí)2 preliminary meetings to define forecast and procurement timelines for SLD acquisition were conducted with SIAPS support. SIAPS tools and methodology were shared and incorporated with CRPHF and NTP for procurement purposes. Final meeting conducted in September 2012 to finalize all SLD procurement process for year 2013 with CRPHF and NTP. Baseline information to assess past consumption and define future forecasts was based on SITETB data (reports).

SIAPS provided support to MoH pharmacy department and NTP to monitor procurement cycle and elaborate technical procurement documents, such as: forecasts/consumption monitoring, terms of reference, technical notes, customs clearance and distribution. SIAPS elaborated 3 Monthly SLDs Movement Reports and distribution worksheets including graphic charts from CRPHF to all DR-TB centers countrywide. Information disseminated to CRPHF, NTP and Pharmacy Department. SIAPS elaborated 3 Monthly SLDs Movement Reports and distribution worksheets including graphic charts from CRPHF to all DR-TB centers countrywide. Information disseminated to CRPHF, NTP and Pharmacy Department. SIAPS provided trainings and technical support to CRPHF

pharmacy staff to transfer full responsibility for managing medicine orders from all DR-TB reference centers and ensure timely SLDs distribution countrywide. Quarterly reports were elaborated and disseminated.

#### Quarterly progress toward sub-objective 1.2

Current Value: **(Sep 2012)** - • Meeting was held with the SIAPS team, CVE (PECT-SP) and Prodesp, where they discussed the technical possibilities of interoperability between systems (SITETB and TBWEB system) and operational use of both by reference centers from São Paulo state. Meeting minute and document for the systems interoperability were done.

- Assessment instrument for DR-TB reference centers (case and medicine management) developed by SIAPS were evaluated during the review meeting of the monitoring visits. Instrument was discussed, and its contents, were incorporated and are now official for NTP. Next monitoring visits will also involve issues linked to reference centers, DR-TB control and rational SLD management will be part of the routine evaluation and agreement with municipal and state managers.

- NTP is not yet managing SITETB. Professionals from NTP are participating in all trainings for the states, evaluating all needs linked to each working area and planning strategies to incorporate these activities within NTP. Professionals of PCTs are participating in all training state, assessing the needs of each particular area of expertise and planning strategies incorporating these management activities for the NTP. Already scheduled for December, a meeting with medical professionals and pharmacists who will be part of the team that will validate the cases and the management of medicines.

#### Deliverables: Sub-Objective 1.2

Current Value: **(Sep 2012)** - • Reference centers SITETB units using case management and medicine management: 44 (95% of the planned 46 total) • States using SITETB: 10 (62.5% of the planned 16 total) • Percentage of registered cases in SITETB regarding MDR-TB cases reported in the System:  $2485/5849 \times 100 = 42.5\%$  • Number of professionals trained in SITETB during current quarter: 158 (22 men and 136 women) • Number of registered users in SITETB: 27 (cumulative total: 150) • Number of registered institutions in SITETB: 44 (cumulative total: 107) • No. of transactions: 12,824 (cumulative total: 30,524) • Number of cases of DR-TB managed by SITETB: 966 (cases on treatment) • Attendance on meetings held: 4. Meetings planned 4 – total: 100% • Two meetings with the NTP's information working group to discuss issues relating to Sinan system's new version and the SITETB cases inputs and outputs. • # of cases of RS, PR and AL migrated from TBMR System: 552 • # Number of cases of RS, PR and AL notified directly in SITETB: 31 • # Cases migrated from TBDR system and those that were reported directly in SITETB: 2485.

#### Challenges in progress toward sub-objective 2.1

Current Value: **(Sep 2012)** - Final report couldn't be delivered since all requested information from all municipalities weren't yet sent to SIAPS technical team.

#### Quarterly progress toward sub-objective 2.2

Current Value: **(Sep 2012)** - SIAPS continued supporting 9 municipalities in Rio de Janeiro's metropolitan region, by supporting DOTS strategy through car rental for development of routine program control activities. The municipalities included: Rio de Janeiro, Nova Iguaçu, Duque de Caxias, Belford Roxo, Mesquita, Itaboraí, Queimados, Itaguaí and

Magé. Searching for respiratory symptoms within communities 74. Searching for respiratory symptoms in health units 122. Activities in health education / promotion of TB in the community 24. Activities in health education / promotion of TB in schools 10. Activities in health education / dissemination of TB to health facilities with 72. Integration activities between TB and HIV / AIDS programs 4. Delivery of incentives and facilitators for DOT 70. Delivery of laboratory test results 146. Meetings with PCT's staff 68 . Meetings with health facility managers 48. Meetings with PECT (State Program for TB Control) 10. Meetings with PMCT (Program Municipal TB Control) 20. Transporting samples to laboratories 138. Medicine transportation 60. In-service training (hospitals / emergency units) 6. In-service training (basic health units / Family Health teams) 192. Training for application and reading Tuberculin test 0. Monitoring visits (information recording instruments) 286. Supervisory visits to health facilities 286 . Home visits for strengthening adherence 102. Home visits to rescue defaulters 140. Home visits to patients under DOT 116

Quarterly progress toward sub-objective 2.3

Current Value: **(Sep 2012)** - • 3 activity lines were proposed by PECT-SP: 1 - control of TB comorbidity and diabetes comorbidity, 2 - control of TB comorbidity and smoking comorbidity, and 3 - control of TB patients with long-stay in hospital . Activities were initiated, scheduled agreed and on-going. • Products were defined as well as the indicators for all three activities. Documents will be delivered till December 2012.

Quarterly progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - Out of the 15 SOPs for Outpatient department identified, 8 were finalized, other 7 still under development. All SOPs for the pharmacy were completed as well as all planned trainings conducted. The guideline for Pharmaceutical Care was partially developed. Helio Fraga Center new Quality Committee was named, with two members from SIAPS technical (Jorge Rocha and Renata) SIAPS continuous to support the elaboration of BSL3 Laboratory Operational plan as well as BSL3 Laboratory Accreditation.

Challenges in progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - Lack of response from Helio Fraga Center professionals responsible for elaborating and sending SOPs, SIAPS technical team has already reported to Helio Fraga Center direction Guideline for Pharmaceutical Care not yet finalized by SIAPS consultant due to her high level of workload Biosafety's report still pending, turning impossible the achievement of all planned steps for Helio Fraga accreditation

Deliverables: Sub-Objective 3.1

Current Value: **(Sep 2012)** - 10 SOPs elaborated and implemented for Helio Fraga Center Pharmacy 1 guideline with standards and routines procedures elaborated for Pharmaceutical Care elaborated 10 trainings conducted for Helio Fraga Center pharmacist on Good Pharmaceutical Practices Biosafety check list developed to prepare NRL/CRPHF BSL3 to prepare to accreditation to BSL3. Quality management system check list/framework and recommendations for Lab accreditation developed and agreed with partners for implementation Technical support for SOPs and quality system manual elaboration provided Lab staff trained in quality system and biosafety according to international standards Support for accreditation dossier submission provided (considering that all technical/managerial requirements have been met) Annual culture proficiency testing report = done for 2010/2011 Annual DST proficiency testing report

= done for 2010/2011 Culture decentralization plan evaluated and endorsed by NTP/CGLAB 1 technical supervision visit for Rio Grande do Norte state TB program conducted by NTP's task force (with CRPHF/NTLR and CGLAB) 1 Spreadsheet for Lacens and CRPHF/NTRL Lab supplies inventory control developed

Quarterly progress toward sub-objective 3.2

Current Value: (**Sep 2012**) - SIAPS has discussed and agreed with São Paulo state to conduct new LABMOST methodology for Adolfo Lutz Institute

Quarterly progress toward sub-objective 3.3

Current Value: (**Sep 2012**) - Activities linked to pragmatic clinical trial for the introduction of rapid tests for resistance are still ongoing.

## **BURUNDI**

Burundi work plan details for Year 1 of the SIAPS Program

### **Quarterly Report Background**

Malaria is considered a major public health problem in Burundi and places a heavy burden on the health system. According to Ministry of Public Health (MOPH) statistics, malaria is responsible for up to 60% of all outpatient visits and up to 50% of deaths occurring in health facilities among children under five years of age. Almost the entire population of Burundi lives in areas at risk of malaria. Plasmodium falciparum accounts for more than 90% of all infections.

The malaria control strategy in Burundi includes: Improving accessibility to effective antimalarial drugs; prevention of malaria through the use of insecticide-treated nets (ITNs) and indoor residual spraying and; early detection and control of epidemics. Ensuring prompt, effective, and safe ACT treatment to a high proportion of patients with confirmed or suspected malaria in Burundi continues to represent one of the greatest challenges for the PNILP given the weaknesses in the country's pharmaceutical management system, poor access to health services, and the lack of accurate laboratory diagnostic capabilities.

The Strengthening Pharmaceutical Systems (SPS) Program received field funding from USAID/Burundi in 2009 and 2010 to address pharmaceutical management challenges in malaria control in Burundi, build capacity of the PNILP, provide assistance to develop strategic and policy documents and their implementation as well as play a coordination role for all USAID short-term assisted technical assistance in Burundi.

With FY11 funding, SIAPS will continue to build upon the work carried out with FY09 and FY10 funding to ensure that pharmaceutical sector governance is strengthened, the capacity for pharmaceutical supply management and services is increased and enhanced, information for decision-making challenges in the pharmaceutical sector are addressed and that pharmaceutical services improved to achieve desired health outcomes. All the above objectives will contribute to the SIAPS intermediate results and objectives as well as USAID/Burundi's objective of reducing the mortality and morbidity due to malaria in Burundi.

### **Goal: Burundi Year 1 Work Plan Goal**

Strengthen pharmaceutical management to reduce mortality and morbidity due to malaria

#### **Objective 1**

Governance in the pharmaceutical sector and the PNILP strengthened

#### **Sub-Objective 1.1**

Intermittent Preventive Treatment for the prevention of Malaria in Pregnancy (IPTp) adopted

#### **Activity 1.1.1**

Development and adoption of the policy and implementation plan

#### **Activity 1.1.2**

Quantification of SP and distribution plan to health facilities

#### **Activity 1.1.3**

Training of healthcare providers

**Sub-Objective 1.2**

Community case management of malaria (CCM) improved

**Activity 1.2.1**

Evaluation of the pilot study implementation

**Activity 1.2.2**

Supportive supervision of CHWs

**Objective 2**

Organizational and functional capacity of the PNILP developed

**Sub-Objective 2.1**

Technical managerial capacity of the PNILP strengthened

**Activity 2.1.1**

Follow up on MOST evaluation

**Activity 2.1.2**

Provide trainings in leadership and management

**Activity 2.1.3**

Conduct a second MOST

**Activity 2.1.4**

Provide PNILP with other developmental opportunities

**Objective 3**

Information generation for decision-making in the pharmaceutical sector increased improved

**Sub-Objective 3.1**

Monitoring and Evaluation within PNILP improved

**Activity 3.1.1**

Support the PNILP to implement the M&E plan

**Activity 3.1.2**

Aggregate data submitted to EPISTAT, CAMEBU and PNILP to analyze and interpret them

**Sub-Objective 3.2**

Strategic information collection using PMI tools strengthened

**Activity 3.2.1**

Organize, analyze and disseminate data collected from EUV, PPRM and PMISS

**Objective 4**

Pharmaceutical services to achieve desired health outcomes improved

**Sub-Objective 4.1**

Pharmaceutical management for malaria strengthened

**Activity 4.1.1**

Follow up on training and organize refresher trainings on pharmaceutical management

**Activity 4.1.2**

Conduct quarterly supervision of health facilities and districts pharmacies

**Sub-Objective 4.2**

Quantification of malaria products strengthened

**Activity 4.2.1**

Provide training in quantification

**Activity 4.2.2**

Institute a yearly quantification exercise

**Sub-Objective 4.3**

Case management of malaria (including diagnosis and rational use of antimalarials) improved

**Activity 4.3.1**

Organize the dissemination of the new protocol

**Activity 4.3.2**

Formative supervision of healthcare providers to ensure adherence to the new protocol

**Activity 4.3.3**

Training in case management

**Goal: Quarterly Report Fields**

These are the fields that will be used to collect information for quarterly reports.

#### Overall Quarter Progress

Current Value: **(Sep 2012)** - To support USAID/Burundi's objective of reducing mortality and morbidity due to malaria in Burundi, SIAPS worked with counterparts to strengthen pharmaceutical sector governance, build capacity for pharmaceutical supply management and services, address decision-making challenges in the pharmaceutical sector, and improve pharmaceutical services.

To enhance pharmaceutical sector governance, SIAPS assisted the PNILP (National Malaria Control Program) to organize a workshop for Roll Back Malaria stakeholders to track progress toward goals and update the plan of activities. SIAPS also supported the Executive Board for Malaria to conduct a gap analysis of funding necessary to implement 2013 malaria activities.

SIAPS continued to provide assistance to the PNILP to improve its organizational structure and managerial skills. SIAPS supported PNILP to implement the Management and Organizational Sustainability Tool (MOST), resulting in recommendations for strengthening PNILP's structure. Also during the reporting period, SIAPS supported PNILP to improve their internal and external communication by facilitating the development of a Manual of Operations and PNILP staff links via a network.

To strengthen the supervision system of health facilities, SIAPS assisted the Ministry of Health and the PNILP to design a harmonized supervision system. A harmonized supervision guide was developed including a supervision check-list. The supervision guide was approved by the Ministry of Health and is ready for dissemination. SIAPS worked with Global Fund recipients to leverage logistics funding for supervision field visits.

Also during quarter four, SIAPS further reinforced the supply management system for malaria commodities. SIAPS supported partners to develop a pipeline analysis and anticipate upcoming challenges that might cause stock outs or expired commodities. SIAPS continued to advocate for a quantification committee through the leadership of the Directorate of Pharmacy, Medicines, and Laboratories (DPML). The SIAPS quantification training module was adapted for Burundi and translated into French.

SIAPS also assisted the DPML to complete the dissemination of standard operating procedures for pharmaceutical management to 26 districts at the peripheral level. The dissemination provided a good opportunity for refresher training on pharmaceutical cycles and quantification.

SIAPS also worked with partners to conduct End Use Verification surveys at 63 health facilities in 17 provinces. The survey showed an improvement in laboratory diagnostics, case management, and supply chain.

Through a review of the national malaria treatment protocol, SIAPS assisted the PNILP and other stakeholders to form a strong foundation for strengthening case management.

SIAPS continued to work closely with the ESD project on the implementation of a malaria community case management pilot in two districts. The pilot will help support the PNILP and partners in evaluating the potential contribution of a community case management approach in Burundi.

Key challenges faced during the quarter

Current Value: **(Sep 2012)** - - Several activities, originally planned for the quarter, were delayed or will not happen in 2012 due to delays or changes in priorities within the Government of Burundi. For example, intermittent preventive treatment of pregnant women ( IPTp) is not yet a priority for the GoB. Likewise, the development of an improved and costed M&E plan is not yet a priority for the GoB. M&E plan development is postponed until the PNILP strategic plan for 2012-2015 is completed (planned for early 2013). -During quarter 4, other activities were delayed due shortage of skilled staff within the DPML and PNILP.

Key activities planned for next quarter

Current Value: **(Sep 2012)** - 1. Disseminate findings on supervision in a feedback meeting to districts for adopting strategies to reinforce capacity building at the peripheral level 2. Organize supervision visits in the remaining 15 districts 3. Conduct a quantification training workshop at the central level and develop a quantification report for the malaria commodities needed in 2013 (ACTs, RDTs, laboratory reagents, etc.) including the new modules added for a 2nd treatment of uncomplicated and severe malaria 4. Assist PNILP and DPML to develop its joint annual operational plan for 2013 5. Continue to support the dissemination of the new STG for malaria and organize the TOT on case management of malaria at central level 6. Conduct a qualitative study on deep roots of stocks outs of ACTs/RDTs at peripheral level while stocks are available at central medical stores

**Quarterly Report Fields (Objective)**

Objective-level fields for collecting information for quarterly reports.

Quarterly Progress for Objective 1

Current Value: **(Sep 2012)** - Several activities that were originally planned for in quarter four of the SIAPS FY 2011 work plan have been delayed or will not happen this year due to delays or changes in priorities within the Government of Burundi. For example, intermittent preventive treatment of pregnant women (IPTp) is not yet a priority for the GoB.

**Quarterly Report Fields (Sub-Objective)**

Fields for reporting quarterly progress at the sub-objective level.

Quarterly progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - Several activities that were originally planned for in the quarter SIAPS FY 2011 work plan have been delayed or will not happen this year due to delays or changes in priorities within the Government of Burundi. Intermittent preventive treatment for pregnant women (IPTp) is not yet a priority for the GoB.

Quarterly progress toward sub-objective 1.2

Current Value: **(Sep 2012)** - SIAPS continues to work closely with the ESD Project, managed by Pathfinder International to follow-up on the implementation of a malaria community case management (CCM/PECADOM) pilot in two districts (Kayanza and Muyinga). During quarter 4, SIAPS in close collaboration with the PNILP, supervised the implementation

of the PECADOM seven health centers. At the end of September, 21 health centers out of the 25 received supervision visits. The supervision visits coincided with the monthly meeting that health centers hold with all CHWs in their catchment areas. From these visits, 132 CHW at health centers received a refresher orientation on recording stock movement through filling stock cards correctly while managing ACTs and RDTs, as well as on good dispensing practices focusing on proper counseling to mothers to improve adherence to malaria treatment. Starting October 2012, the pilot community case management of malaria activity will be fully transitioned from Pathfinder to SIAPS.

#### Quarterly progress toward sub-objective 2.1

**Current Value: (Sep 2012)** - During the reporting period, SIAPS assisted the PNILP to organize 2-day workshop aimed at coordinating Roll-back malaria (RBM) stakeholders. The meeting's main objective was to track progress and challenges towards the 2012 road map. At end of September 2012, the PNILP has implemented 54% of planned activities. The main deliverable of the meeting was an update and adjusted plan of activities from October to December 2012. The meeting also highlighted the need to organize a retreat in October to develop the 2013 joint work plan. Delays in implementation of several activities, especially in developing policies such as the strategic plan for 2013-2016, were due to a dependence on external technical assistance.

Prior to this coordination meeting, SIAPS assisted the PNILP, WHO, and SEP/CNLS-Malaria (Permanent Secretariat Executive Board for Malaria) to conduct a gap analysis on funds necessary to implement all activities aiming to reduce malaria in 2013. The gap analysis document was shared with the RBM secretariat during a retreat held in Tanzania in September 2012. The Burundi gap analysis document was reviewed and approved, and will be used to advocate for funds, especially for mobilizing funds for indoor-residual spraying (IRS). SIAPS continued to provide technical assistance to the PNILP to improve its organizational structure and managerial skills.

In July 2011, an evaluation of the organizational structure of the PNILP was conducted using the MOST evaluation tool. From the evaluation recommendations were made to strengthen the PNILP structure by (1) revising its legal status to upgrade the institution to an autonomous entity with an updated organogram; (2) building the capacity of staff by providing local trainings: in leadership management, communication, basic computer skills, data management, and English; and (3) equipping the PNILP with IT equipment, office equipment, and communication means (internet, telephone, etc.).

During the reporting period, SIAPS improved both internal and external communication by facilitating all PNILP staff to be on easy network. A list of additional equipment needed was identified and are under procurement. SIAPS assisted the PNILP to identify domains and develop content, as well as SOW for the development of a manual of operations. The recruitment of a capable consultant is planned in December 2012. The manual will be available in February 2013. Due to a conflict of agenda, the local trainings identified and planned (in leadership and management, English, computer skills, human resources management, and project management based on MS Project) were postponed to early 2013.

#### Quarterly progress toward sub-objective 3.1

**Current Value: (Sep 2012)** - The development of an improved and costed M&E plan is not yet a priority for the GoB. M&E plan development is postponed until the PNILP strategic plan for 2012-2015 is completed (planned for early 2013).

Quarterly progress toward sub-objective 3.2

Current Value: **(Sep 2012)** - During the quarter 4, SIAPS continued to reinforce the supply management system of malaria commodities to ensure an uninterrupted availability at all levels. SIAPS completed and submitted the PPMRm for the period of July to September 2012. A pipeline analysis was performed, together with PNILP and SEP/CNLS- Malaria to identify and anticipate problems of stock out/expiries. From the analysis, all formulations of ACTs are available in sufficient quantities to cover needs from 2012-2013. During the reporting period, SIAPS also conducted the EUV survey in 63 health facilities randomly sampled in all 17 provinces. Data collection and data entry were completed. The report of the EUV survey is available. Findings showed areas of improvement in strengthening laboratory diagnostic of malaria, case management of malaria at facility level, as well as improvement of the supply chain of malaria commodities, especially availability of RDTs. The availability of RDTs is especially important as Burundi is scaling up the use of RDTs as a preliminary requirement to confirm malaria before treating a patient.

Deliverables: Sub-Objective 4.1

Current Value: **(Sep 2012)** - To strengthen the supervision system of health facilities, SIAPS assisted the various departments within the Ministry of Health and the PNILP to design a strong and harmonized the supervision system. In June 2012, SIAPS collaborated with UNICEF, Global Fund, and AMAGARA MEZA to support the Ministry of Health/Directorate of Service Delivery and the PNILP to develop a harmonized supervision guide for district teams while conducting formative supervision at the health center level. A check-list for supervision customized for the needs of the PNILP was developed that integrates all aspects of malaria (vector control, case management, M&E, communication, management, and administration). This checklist is included as an annex to the supervision guide.

The harmonized supervision guide was validated by a larger group of MOH partners and representatives from provincial and districts teams in August 2012. Seventy participants at this validation meeting represented various departments of the Ministry of Health, NGOs, and international organizations (MSPLS, PNILP, DPML, PRONIANUT, PNLs, SNIS, DODS, EIP, PNLT, BPS, BDS, IMAD, SIAPS, PATHFINDER, PSI, AMAGARA MEZA, WHO, and UNICEF). The harmonized supervision guide was officially signed by the Ministry of Health and ready for wide dissemination.

SIAPS continued to assist the DPML to complete the dissemination of the SOPs on pharmaceutical management at peripheral level to the 26 districts supported by SIAPS (the other 19 districts are supported by the project AMAGARA MEZA). During these dissemination sessions, presentations were made on each element of the pharmaceutical cycle and all corresponding SOPs were explored through group work activities and plenary sessions. Further, a refresher training on quantification of all medicines in general and specifically on ACTs was also conducted and included hands-on exercises. At the end of each dissemination session, SOPs were officially distributed to all participants.

Quarterly progress toward sub-objective 4.2

Current Value: **(Sep 2012)** - SIAPS leveraged funds from the SEP/CNLS-Malaria (managing the Global Fund malaria money) to organize appropriate logistics for successful field supervisions visits. Findings will be discussed with district management teams in form of a feedback meeting to adopt strategies to strengthen the capacity of health care providers. The

meeting will be held in October, at the PNILP FY 13 work planning retreat. As an immediate outcome of the supervisions at district level, stock managers together with the manager of HMIS, have conducted an analysis of consumption and morbidity data from their catchment areas and ensured the average monthly consumption in all health centers has been updated.

SIAPS continued to advocate for the establishment of a formal national quantification committee with all stakeholders involved in the pharmaceutical sector through the leadership of DPML (Directorate of Pharmacy, Medicines, and Laboratories). SIAPS assisted the DPML to organize meetings of the “Thematic group of medicines” where all stakeholders discuss pharmaceutical management and adopt appropriate decisions. During the reporting period, SIAPS Burundi worked closely with the in-country SCSM Field officer and HQ staff to translate and make available the quantification training module and the guide for quantification in French. SIAPS Burundi shared the quantification training module, agenda of the four-day training, the list of trainees and facilitators, and started to organize the logistics for the training planned for November.

#### Challenges in progress toward sub-objective 4.3

**Current Value: (Sep 2012)** - To strengthen case management of malaria, SIAPS assisted the PNILP and its stakeholders to update/review the national malaria treatment protocol as per recent recommendations from WHO. During the reporting period, SIAPS organized the printing of 1,200 copies of the new STG and algorithms to support the dissemination in all 650 health facilities. According to the dissemination plan developed by the PNILP with assistance from SIAPS, refresher training on the new STG will be provided to all healthcare providers nationwide.

During the quarter 4, SIAPS organized two retreats with key facilitators to adapt/review of the training material to be used during the refresher trainings. Training materials included: a facilitator guide, a trainee guide for healthcare providers, an agenda, and all power points presentations with case studies and practical exercises. A four-day TOT at the central level for 25 experts and at the district level for 242 persons will be conducted in November and December. The trainees from the TOT will organize cascade trainings for all health facilities starting January 2013. During the reporting period, the check-list for supervision integrating all aspects of malaria developed in June 2012 was field tested in 30 districts out of the 45 (the remaining 15 districts will be supervised later in October- November 2012).

Prior to the field visits, SIAPS assisted the PNILP, DPML, and the SEP/CNLS-Malaria to develop (1) the methodology of the supervision aiming for capacity building of district teams, (2) criteria for selecting a supervisor, (3) key points to emphasize on during the supervision, and (4) guidance for refresher orientation on the requisition process of ACTs and RDTs, analysis of consumption and morbidity data and on how to calculate and update the average monthly consumption (AMC).

Supervisors were identified as representatives from various institutions and constitute a multidisciplinary team of supervisions at national level: PNILP, DPML, SEP/CNLS-Malaria, Directorate of Service Delivery/MOH, National Institute of Public Health (INSP), MOH/HMIS department, IMAD, PSI, and SIAPS. An orientation for the selected 30 supervisors (meeting the criteria defined) was organized on July 12th and covered the different topics. The plan for the field visits in the 45 districts was also defined.

SIAPS continued to assist DPML, CAMEBU, and PNILP to establish a strong

pharmacovigilance system in Burundi. A meeting of “Thematic group of medicines” members to share best practices and tools needed to support the establishment of a pharmacovigilance system in Burundi was planned for December due to unavailability of members at an earlier date. SIAPS proposed the agenda and content of the meeting which will focus on an evaluation of current status, immediate next steps, and mapping of stakeholders involved in the establishment of a pharmacovigilance system. A draft of immediate next steps with a clear roadmap was defined and will be discussed and approved during the stakeholders meeting.

## CAMEROON

Cameroon work plan details for Year 1 of the SIAPS Program

### Quarterly Report Background

SIAPS has been provided with \$3.5 million in field support from the USAID Regional Office in Accra to implement within 3 years, a package of interventions aimed at strengthening the pharmaceutical sector in Cameroon at the central level of the health system as well as in four USAID-focus regions (Adamawa, East, North West and South West). SIAPS did not have an office in Cameroon, but plans to establish one with three technical staff and one administrative staff by the second quarter of Year 1.

An assessment of Cameroon's public pharmaceutical sector conducted by MSH's Strengthening Pharmaceutical Systems (SPS) program in October 2011 identified key weaknesses and priority interventions to address them. The SIAPS Year 1 work plan is based in part on the recommendations of this assessment. Additionally, PEPFAR's FY11 operational plan has identified capacity building of key public sector actors in the pharmaceutical system in procurement, distribution and pharmaceutical management information systems as priority activities. Under SIAPS's first year of activity in Cameroon, interventions will be implemented to both address immediate supply chain bottlenecks in four USAID selected regions, and build the foundation for sustainable nationwide improvements in the functioning of Cameroon's public pharmaceutical sector.

### JUSTIFICATION

The assessment conducted by MSH/SPS in October 2011 identified a number of weaknesses and variations in the quality of pharmaceutical management within the public pharmaceutical sector which could generally be summarized as:

- Poor coordination existing between the central level of Ministry of Health (MoH) and Cameroon's regions to ensure implementation of the national pharmaceutical policy. For instance, there is absence of a functional national coordinated mechanism for collecting, transmitting and analyzing consumption data on pharmaceuticals across various disease programs.
- Paucity of pharmaceutical management data for quantification, forecasting and supply planning
- Lack of national standards, guidelines and standard operating procedures to govern various areas of pharmaceutical management in the public and private sector
- Poor inventory management and storage practices existing at pharmaceutical warehouses and dispensing points
- Inadequate training and supervision of dispensing staff in health facilities
- Varying financing and governance arrangements exist at the regional level with respect to funding and payment for pharmaceuticals, with resulting variation in the availability of products.

The FY 11 PEPFAR Country Operational Plan identifies capacity building of Cameroon's Central Medical Stores, CENAME (Centrale Nationale d'Approvisionnement en Médicaments Essentiels), the National Commission for fighting AIDS (CNLS), regional pharmaceutical supply centers (Centre d'Approvisionnement Pharmaceutique Régional, or CAPRs) as well as district hospitals in procurement and distribution of HIV/AIDS, STI and NTD supplies and, in management of logistics information as priority activities.

Additionally PEPFAR expressed interest that funds be used to build capacity of these actors of the pharmaceutical sector in recording, transmitting and using pharmaceutical management information. SIAPS is proposing phased implementation of interventions to incrementally address these issues. This will start with a focus on rendering functional the national coordination mechanism for quantification/forecasting/procurement planning and redesigning the existing pharmaceutical management information system in Year 1. In subsequent years, SIAPS will increasingly focus on strengthening pharmaceutical services such as prescribing and dispensing.

**Goal: Cameroon Year 1 Work Plan Goal**

Ensure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes

**Objective 1**

Pharmaceutical sector governance strengthened

**Sub-Objective 1.1**

Improved medicines policies, legislation, regulations, norms and standards

**Activity 1.1.1**

Collaborate with MOH/DPM and WHO to support the development of STGs that govern various components of the pharmaceutical system

**Sub-Objective 1.2**

Transparent and accountable pharmaceutical management systems are created

**Activity 1.2.1**

Support the DPM in establishing mechanism for quantification, forecasting and supply planning, and provide technical inputs during meetings of this mechanism

**Objective 2**

Capacity for pharmaceutical supply management and services increased and enhanced

**Sub-Objective 2.1**

Pharmaceutical management capacity of individuals, institutions, organizations and networks strengthened

**Activity 2.1.1**

Assist in the development of an action plan for the implementation of improvements to regional pharmaceutical supply centers (CAPRs)

**Activity 2.1.2**

Support the reorganization of products in the warehouses following good storages practices

**Activity 2.1.3**

Facilitate agreement between CAPRs and CENAME on standardized approaches to information

**Activity 2.1.4**

Conduct TOT of pharmaceutical managers in supply chain management and development of a training plan for rolling out nationwide using cascade training

**Activity 2.1.5**

Provide TA to the National Disease for NTD, HIV/AIDS, Malaria, TB and RH and to Regional Delegeue to improve the management of medicines

**Objective 3**

Utilization of information for decision making

**Sub-Objective 3.1**

Pharmaceutical management information available and used for decision at different levels of the health system

**Activity 3.1.1**

Develop a strategic plan for the implementation of an efficient pharmaceutical management system for ARVs and other HIV AIDS commodities

**Activity 3.1.2**

Provide TA to DPM to redesign/ develop tools and forms used for collecting and transmitting pharmaceutical information at different levels of the health system

**Objective 4**

Financing strategies and mechanisms to improve access to medicines strengthened

**Sub-Objective 4.1**

Financial resources available to the pharmaceutical sector increased

**Activity 4.1.1**

Assist CNLS and the CENAME in meeting conditions to access grant from the Global Fund Round 10 HIV/AIDS

**Objective 5**

Pharmaceutical services improved to achieve desired health outcomes

**Sub-Objective 5.1**

Pharmaceutical services standards defined, adopted and implemented

**Activity 5.1.1**

Work with DPM to develop and implement harmonized standards for pharmaceuticals services

**Goal: Quarterly Report Fields**

These are the fields that will be used to collect information for quarterly reports.

### Overall Quarter Progress

Current Value: **(Sep 2012)** - During Q4, the SIAPS Cameroon program mainly made progress toward three SIAPS Cameroon work plan objectives (Objectives 2, 3 and 4). SIAPS also completed all the objectives related to meeting Global Funds (GF) precedents conditions (CPs) and therefore SIAPS had helped in securing funding for the National HIV/AIDS Program through the Round 10 HIV AIDS grant. Under Objective 2, SIAPS Cameroon completed the assessment on the management capacity of the 10 regional pharmaceutical warehouses (CAPRS) and central medical stores (CENAME). During the same quarter, SIAPS used outputs from the assessment to develop an action plan to improve the storage capacity, storage conditions and management practices of those entities. (25th June to 11th July and 5 to 10 August 2012).

Additionally, outputs from this assessment will enable SIAPS to progress on Objective 3 (pharmaceutical management information available and used for decision making at different levels of the health system). The information will make it possible to develop a strategic plan for the implementation of an efficient pharmaceutical management system for ARVs and other HIV AIDS commodities.

Under Objective 4, SIAPS supported the Comité National de Lutte contre le Sida (CNLS) in the revision of its Procurement Manual with updated procedures ensuring compliance with Global Fund procurement policies (August 20th to September 6th, 2012). Outputs from Objective 2 and 4 was used in the same quarter to produce a strategic plan for the improvement of patients and stock information system necessary to manage HIV AIDS program, and therefore to complete SIAPS Cameroon Objective 3. During Q4, SIAPS/Cameroon developed its Year 2 work plan based on lessons learned from implementation during Year 1.

### Key challenges faced during the quarter

Current Value: **(Sep 2012)** - MSH is still not yet registered in country to operate as an international non-governmental organization. SIAPS staff in country (Country Project Director and Senior Technical Advisor) initiated the process of registering MSH as an NGO in Cameroon during Q3, but registration had still not been obtained by the end of Q4.

### Key activities planned for next quarter

Current Value: **(Sep 2012)** - During the next quarter, SIAPS Cameroon will continue the implementation of the warehouse reorganization by directly supporting the CENAME and CAPRs through the purchase of warehouse equipment. SIAPS will work with the DPM and CNLS to develop standard operating procedures (SOPs) for drug management in the ART program at facilities level. SIAPS will implement training of trainers (TOT) on SOP implementation and drug management (with focus on HIV Aids commodities management for pharmacy managers) and will subsequently work with trainers to begin implementing the training plan developed during Q4.

### Technical Activity Coordination

Current Value: **(Sep 2012)** - During Q4, SIAPS participated in 2 meetings with development partners that work in pharmaceutical management in Cameroon (GIZ, UNFPA, UNICEF, ESTHER, USAID, PEPFAR, CHAI). These partners procure health products or equipment, conduct training, or provide technical assistance. These meetings occurred on July 19th and August 17th, 2012. The main purpose for those meetings was for each

partner present to share work plans and to identify areas for collaboration and coordination.

#### Office management

Current Value: **(Sep 2012)** - During Q4: • An Office & Finance Manager and an Administrative Assistant officially started working full time with SIAPS. • SIAPS continued with the recruitment for a Senior Technical Advisor for Pharmaceutical Services. • SIAPS continued to set up the office through purchase of office equipment and IT installation. • SIAPS continued to follow up on its registration file (for official registration of MSH in Cameroon) which allow MSH to effectively function as a project in country.

#### Quarterly Report Fields (Objective)

Objective-level fields for collecting information for quarterly reports.

#### Quarterly Progress for Objective 1

Current Value: **(Sep 2012)** - There was no progress made under this objective during Q4. However, SIAPS did provide financial support to the Direction de la Pharmacie et du Medicament (DPM) to organize a planning and coordination meeting of pharmaceutical activities with DPM key partners (such as CHAI, WHO, GIZ, USAID, CDC and ESTHER). The outputs from this meeting will allow DPM and partners to map out technical and financial assistance available and therefore provide DPM with information for planning and coordination of efforts and interventions. This work is being done to promote stakeholder involvement, coordination and oversight in order to facilitate availability and accessibility of medicines at all levels of the health system.

#### Quarterly Progress for Objective 2

Current Value: **(Sep 2012)** - Interventions under this sub objective focus on improving the functioning of CAPRs so that high quality commodities can be available at distribution points and so that coordination and information-sharing between the CENAME and CAPRs is improved. During Q4, SIAPS Cameroon completed the development of an action plan to improve warehouse management and storage capacities. This plan addressed: - the reorganization of products in the warehouses using good storages practices; - the standardized approaches to information management between CAPRs and CENAME; - and the training plans for pharmaceutical managers at all levels in supply chain management, as well as for National Disease Control Departments.

#### Quarterly Progress for Objective 3

Current Value: **(Sep 2012)** - During Q4, SIAPS, based on the outputs from the assessment done under objective 2 as well as knowledge of CNLS procurement procedures revised under Objective 4, and requirements set by the Global Fund as precedents conditions to meet before accessing grant money for the procurement of HIV AIDs commodities, had developed a plan to improve information systems for successful management of pharmaceutical systems for HIV AIDs program.

#### Quarterly Progress for Objective 4

Current Value: **(Sep 2012)** - In May 2012, USAID requested that SIAPS accelerate its provision of technical assistance to the CNLS to fulfill the precedents conditions (CPs) to disbursing funds for the procurement of pharmaceuticals and medical supplies for the Global Fund

Round 10 HIV AIDS grant to Cameroon. During Q4, SIAPS, succeeded in achieving Objective 4, whose focus was to assist the Global Fund Round 10 HIV/AIDS grant Principal Recipient with meeting procurement and supply management-related conditions precedent in order access grant funds needed to procure ARVs and other HIV/AIDS commodities.

The conditions that were met were the following: • Provide technical assistance to revise the CNLS's procurement manual in order to ensure that it complies with Global Fund policies. • Provide technical assistance to develop a plan for improving storage and distribution capacity to ensure that conditions are adequate for handling the volume of the products beings managed through the National HIV/AIDS program (see objective 2.1 for additional details). • Collaborate with the CENAME and the DPM to develop a strategic plan to upgrade and improve systems in place to manage patient and commodity management data in the national HIV/AIDS program.

It should be noted that the activities conducted to achieve this success are precursors to other activities that will contribute to the attainment of Objectives 2 and 3 of the work plan. The SIAPS team was also instrumental in conducting quantification needed to organize for an emergency shipment of ARVs to Cameroon through the PEPFAR Emergency Commodity Fund mechanism (see attached). Our team has also advised the Ministry of Health on a procurement strategy (since ARVs in Cameroon are being purchased by the Ministry from multiple funding sources) that should be implemented immediately in order to avert stock outs in 2013.

#### Quarterly Progress for Objective 5

Current Value: **(Sep 2012)** - There was no progress toward achieving Objective 5. However, discussion with the DPM and CNLS during Q4 will help link interventions under Objective 5 with interventions that will take place under Objective 1 through the development of standards procedures for pharmacy operations, SOPs), and under Objective 2 through strengthening capacity of health care workers in drug management. It is therefore feasible to expect progress on this objective during Q1 of Y2.

#### Quarterly Report Fields (Sub-Objective)

Fields for reporting quarterly progress at the sub-objective level.

#### Quarterly progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - SIAPS began making progress on Objective 1.1 (Improved medicines policies, legislation, regulations, norms and standards) by helping the Ministry of Health mobilize key partners to discuss approaches to improving the performance of the pharmaceutical sector, including coordinating approaches to developing and/or updating norms and standards. During Q4, SIAPS provide financial support to the Direction de la Pharmacie et du Medicament (DPM) to organize a planning and coordination meeting of pharmaceutical activities with key stakeholders (CHAI, WHO, GIZ, MSH, USAID, CDC and ESTHER) and MOH local institutions.

The purpose of the meeting was to agree with various partners in their involvement in supporting the DPM in various pharmaceutical areas. SIAPS involvement in supporting DPM was confirmed during the meeting through the following points: Ø development and implementation of standards procedures for the management of health products including HIV Aids commodities, Ø improvement of storage conditions and capacity of the CAPRs and CENAME to effectively manage HIV Aids commodities, Ø support of

the establishment of the National Quantification coordination committee, Ø and, finalization of the National Pharmaceutical Policy.

Quarterly progress toward sub-objective 1.2

Current Value: **(Sep 2012)** - SIAPS contributed to Objective 1.2 (Transparent and accountable pharmaceutical management systems) by moving Cameroon closer to establishing a national quantification committee. SIAPS has moved forward with its strategies of mobilizing key technical partners in pharmaceutical management in Cameroon to participate in the development of this committee. During Q4, SIAPS held a meeting with ESTHER Aid in order to discuss and identify collaboration and synergies in support to the establishment of the National Quantification coordination committee. In the absence of a national quantification committee, SIAPS assisted the National HIV/AIDS Program (CNLS) with the quantification of ARVs in order to prepare an order for an emergency procurement through PEPFAR's Emergency Commodity Fund (ECF). The need for this emergency procurement was due to disbursement delays based on USAID request to support CNLS to quantify needs for first lines adults ARV be procured by the PEPFAR Emergency Commodity Fund. The quantification was successfully completed and submitted to USAID in September, 2012.

Deliverables: Sub-Objective 1.2

Current Value: **(Sep 2012)** - Quantification of ARVs submitted with Cameroon's Emergency Contraceptive Fund application to PEPFAR.

Quarterly progress toward sub-objective 2.1

Current Value: **(Sep 2012)** - SIAPS progressed with this sub-objective focused on building capacity of pharmaceutical entities within Cameroon. From August 5th to 10th, 2012, SIAPS led the development of action plans to improve the storage capacity in order to assist the National HIV AIDS program (CNLS) to meet Global Fund precedent conditions, so as to enable the CNLS to access its first disbursement for the HIV AIDS Round 10 grant for the procurement of pharmaceuticals. Action plans were developed for each Cameroon 10 regional pharmaceutical warehouses as well as at Cameroon's Central Medical Stores. The action plans include the following aspects: equipment upgrade, training needs in various supply chain management aspects for pharmaceuticals managers, improvements needed in logistics management systems (LMIS), as well as supervision needs of health facilities (HFs).

Quarterly progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - During Q4, SIAPS helped the CNLS to meet Global conditions precedent to access the first disbursement for the HIV AIDS Round 10 first disbursement, resulting in the disbursement of 3.1 million Euros to the CNLS in September 2012. One of these conditions precedent required the CNLS to develop a plan to upgrade and improve the quality of the systems to manage and report patient data and inventory of health commodities used at HIV/AIDS treatment sites. This plan was developed from August 20th to September 6th, 2012. The following methodology was used to develop the plan: Ø Analyze the existing information system to identify weakness and bottlenecks Ø Identify actions to be implemented immediately in order to update the information system were identified. Actions identified should permit regular follow up of stock status of commodities and of patients both under treatment and patients awaiting treatment. Ø Develop tools (forms, etc.) that when used, would enhance functioning of the system. As next steps, SIAPS will support CNLS to organize a stakeholder consensus workshop to

validate the proposed plan to upgrade and improve the quality of existing systems for managing and reporting on patients and inventories of health products. The plan can subsequently be implemented.

#### Quarterly progress toward sub-objective 4.1

Current Value: **(Sep 2012)** - In May 2012, USAID had requested that SIAPS accelerate a specific aspect of its provision of technical assistance to the National AIDS Program (CNLS), which consisted of helping the CNLS to fulfill the conditions precedent to disbursing funds for procurement of pharmaceuticals and medical supplies under the Global Fund Round 10 HIV/AIDS grant to Cameroon. During Q4, SIAPS supported CNLS to fulfill the following two Global Fund precedent conditions: • Development of an action plan to improve the storage capacity, conditions and overall management of the CAPRs in support of the HIV/AIDS grant. This plan developed includes reorganization of products in warehouses in line with good storage practices.

Additionally, SIAPS facilitated dialogue to enable reaching of consensus among CAPRs and the CENAME on standardized approaches to transmission and management of pharmaceutical information. From 25th June-11th July, 2012, SIAPS led the collection of data and discussions at the CENAME and regional warehouses required for developing action plans to improve the storage capacity, storage conditions and management practices at the 10 regional warehouses as well as at Central Medical Stores. From 5th to 10th August, 2012, SIAPS provided technical and financial support to finalize these action plans in collaboration with key local stakeholders such as the CAPRs, the CENAME and the CNLS.

• Revision of the CNLS procurement manual, including updating procedures to ensure compliance with Global Fund procurement policies. The revision covered procurement procedures, inventory management information systems, stock monitoring and storage management, as well as the implementation of a memorandum of understanding between CNLS and CENAME. From August 20th to September 6th, 2012, SIAPS provided technical and financial assistance to revise the CNLS procurement manual and to develop a plan to upgrade and improve the quality of the systems to manage and report patient data and inventory of health commodities used at HIV/AIDS treatment sites. As a result of this technical assistance provided, both precedents conditions were met to the GF secretariat's satisfaction, resulting in the disbursement of 3.1 million Euros by the GF on September 4th, 2012.

#### Deliverables: Sub-Objective 4.1

Current Value: **(Sep 2012)** - 1. Revised CNLS procurement manual. 2. Plan for improving storage and distribution capacity at National Medical Stores of Cameroon 3. and 10 Regional warehouses to ensure that conditions are adequate for handling the volume of the products beings managed through the National HIV/AIDS program Strategic plan to upgrade and improve systems in place to manage patient and commodity management data in the national HIV/AIDS program. 4. Quantification of ARVs to accompany Cameroon's Emergency Commodity Fund (ECF) application submitted to PEPFAR

#### Quarterly progress toward sub-objective 5.1

Current Value: **(Sep 2012)** - SIAPS provided financial support to the Direction de la Pharmacie et du Medicament (DPM) to organize a planning and coordination meeting with the purpose of coordinating partner efforts to support various pharmaceuticals interventions. SIAPS and DPM agreed to proceed with the activity in the SIAPS work plan focused on developing

for standards (for all pharmaceuticals operations, procedures included for pharmaceuticals services) which will contribute to achieving both Objective 1 and Objective 5 of the SIAPS Y1 work plan.

## **DOMINICAN REPUBLIC**

Dominican Republic work plan details for Year 1 of the SIAPS Program

### **Quarterly Report Background**

The Dominican Republic (DR) Ministry of Health (MoH) is currently receiving support from the USAID mission in Santo Domingo to implement a National Pharmaceutical Management System (SUGEMI, by the Spanish acronym). SUGEMI will improve the supply of medicines currently managed by the TB and HIV/AIDS programs.

SPS activities for FY09 and FY10 included the elaboration of standard operational procedures for all the SUGEMI components, the training of personnel in its procedures, and the initial implementation of two components: the pharmaceutical management information systems and the programming of needs for 2012 procurement. A summary of the activities and documents produced during the SPS program are available at: <http://www.msh.org/projects/sps/Global-Focus/Dominican-Republic.cfm>. SIAPS will follow up on these activities.

SIAPS has received USD 600,000 from the USAID mission in Dominican Republic in FY11 funds to provide technical assistance for the implementation of the SUGEMI and document its impact particularly in public health programs such as TB and HIV/AIDS.

### **Goal: Dominican Republic Year 1 Work Plan Goal**

A continuous supply of quality assured medicines and supplies to all patients attending MoH facilities will be assured through an integrated national pharmaceutical system

#### **Objective 1**

Increase the governance in the Dominican Republic pharmaceutical sector through the implementation of a national pharmaceutical integrated system (SUGEMI)

#### **Sub-Objective 1.1**

Transparent and accountable pharmaceutical management systems in Dominican Republic

##### **Activity 1.1a**

Number of vertical programs incorporated to the SUGEMI

##### **Activity 1.1b**

Support the analysis and implementation of alternative procurement mechanism

##### **Activity 1.1c**

Support good programming and procurement practices of TB and HIV/AIDS medicines and diagnostic materials

#### **Sub-Objective 1.2**

Support the generation of evidence for the development of the pharmaceutical sector in Dominican Republic

**Activity 1.2a**

Participate in national and international conferences to present SUGEMI and internal and external evaluations of the TB and HIV/AIDS Program

**Objective 2**

Increase the capacity of the supply management system in Dominican Republic

**Sub-Objective 2.1**

Strengthen the capacity of individuals and institutions

**Activity 2.1a**

Support the institutional development of the national pharmaceutical management unit

**Activity 2.1b**

Technical assistance for the improvement of storage and transportation conditions and the implementation of good practices

**Activity 2.1c**

Support the training of personnel in all the SUGEMI components and the organization of a certified course on pharmaceutical supply management

**Objective 3**

Improve the performance of the pharmaceutical system through the PMIS

**Sub-Objective 3.1**

Improve the performance of the pharmaceutical system through the PMIS

**Activity 3.1a**

Technical assistance for the implementation of a national pharmaceutical management information system (PMIS)

**Goal: Quarterly Report Fields**

These are the fields that will be used to collect information for quarterly reports.

Overall Quarter Progress

Current Value: **(Sep 2012)** - During this quarter, SIAPS continued to enhance the stock monitoring system which shows an improvement in the availability of TB medicines, but not ARV or medicines for non-communicable pathologies. SIAPS has supported the development of technical documents addressing stockouts of anti-retrovirals and medicines for other programs. These documents will be discussed with national counterparts the next quarter.

Key challenges faced during the quarter

Current Value: **(Sep 2012)** - Studies conducted by SUGEMI with the support of SIAPS have demonstrated that the root problem is the lack of financial resources to cover the demand.

Key activities planned for next quarter

Current Value: **(Sep 2012)** - Based on a SIAP-supported study of the "financial gap" in ARV financing, national counterpart and SIAPS will present to national authorities the technical evidence supporting the lack of financial resources as the major cause of stockouts.

Office management

Current Value: **(Sep 2012)** - There is no country office in DR. All activities are implemented by short-term consultants.

### **Quarterly Report Fields (Objective)**

Objective-level fields for collecting information for quarterly reports.

Quarterly Progress for Objective 1

Current Value: **(Sep 2012)** - During this quarter, SIAPS supported the generation of factual evidence to bridge the gap for the financing of ARV procurement, and medicines and supplies for other diseases. The financial resources may not be immediately available, but the written evidence of the gaps has created transparency and accountability.

Quarterly Progress for Objective 2

Current Value: **(Sep 2012)** - SIAPS continued supporting the on-site training of SUGEMI management team. SIAPS also supported the initiation of the certified course on pharmaceutical management, implemented by the National Autonomous University. The target audience is the managers of regional pharmaceutical systems.

Quarterly Progress for Objective 3

Current Value: **(Sep 2012)** - Ninety percent of the regional health services are already reporting the consumption and availability of medicines. A few glitches in the electronic tool were corrected during this quarter. It is expected that all regional health services will consolidate –electronically- their reports by the end of next quarter.

### **Quarterly Report Fields (Sub-Objective)**

Fields for reporting quarterly progress at the sub-objective level.

Quarterly progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - Technical assistance for the implementation of a national pharmaceutical management system: In July 2012, with USAID/DR resources, SIAPS supported a national workshop for the programming of 2013 procurement of medicines and medical supplies. The estimations were subsequently revised and validated by the MoH administration department and PROMESE/CAL (the public procurement agency). SIAPS also supported the estimation of needs of the two programs already integrated to

SUGEMI: TB and HIV/AIDS. During this quarter SIAPS supported the consolidation of the information/requisition/dispatch sub-system. Support the analysis and implementation of alternative procurement mechanism: SIAPS prepared a summary of the proposal elaboration process and the next steps for its implementation. Current MoH authorities were supposed to present the document to the new MoH administration which took over in August 2012. Up to this date (Sept. 2012), neither the USAID mission nor SIAPS has received communication from the new authorities to continue supporting this intervention. Support good programming and procurement practices of TB and HIV/AIDS medicines and diagnostic materials: During this quarter, and following SUGEMI procedures, SIAPS supported the HIV/AIDS and the TB program in the estimation of needs for next year procurement. SIAPS also supported an external GDF mission evaluation to the TB program. During this mission, SIAPS supported the estimation of needs for the procurement through the GDF.

Challenges in progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - No challenges this quarter.

Deliverables: Sub-Objective 1.1

Current Value: **(Sep 2012)** - No deliverables this quarter.

Quarterly progress toward sub-objective 1.2

Current Value: **(Sep 2012)** - SIAPS supported a GDF monitoring mission to the TB program. A technical report was presented to the GDF and national authorities.

Challenges in progress toward sub-objective 1.2

Current Value: **(Sep 2012)** - No challenges this quarter.

Deliverables: Sub-Objective 1.2

Current Value: **(Sep 2012)** - Henry Espinoza, 2012 GDF monitoring mission report was submitted to the national authorities and GDF coordinator.

Quarterly progress toward sub-objective 2.1

Current Value: **(Sep 2012)** - Support the institutional development of the national pharmaceutical management unit SIAPS continued providing technical assistance to the National Pharmaceutical Unit (UNGM) to perform routine activities and extraordinary demands. SIAPS is still supporting –through three short term consultants - the operations of the UNGM. Technical assistance for the improvement of storage and transportation conditions and the implementation of good practices: Based on a baseline study that SPS carried out last year, SIAPS promoted with national counterparts and the Global Fund project, the financing of a model warehouse in La Vega. During this quarter, the renewed warehouse in La Vega was inaugurated. Remodeling started in two additional regional warehouses. Support the training of personnel in all the SUGEMI components and the organization of a certified course on pharmaceutical supply management: SIAPS supported the training in situ, of personnel for the implementation of SUGEMI procedures. The educational modules of the certified course on pharmaceutical management were edited and published during this quarter.

Challenges in progress toward sub-objective 2.1

Current Value: **(Sep 2012)** - No challenges this quarter.

Deliverables: Sub-Objective 2.1

Current Value: **(Sep 2012)** - No deliverables this quarter.

Quarterly progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - During this quarter, some regional services started the information/requisition routines using the SUGEMI information e-application. Others, however, experienced problems in the consolidation of data.

Challenges in progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - No challenges this quarter.

Deliverables: Sub-Objective 3.1

Current Value: **(Sep 2012)** - No deliverables this quarter.

## DEMOCRATIC REPUBLIC OF THE CONGO

Democratic Republic of the Congo work plan details for Year 1 of the SIAPS Program

### Quarterly Report Background

The Democratic Republic of the Congo (DRC) is a country characterized by numerous public health challenges. This situation follows decades of civil war and unrest, which, coupled with inadequate allocation of human and financial resources to the health sector resulted in a fragmented public health delivery system throughout the country, with an inconsistent availability of essential medicines.

In the past, the absence of an adequate regulatory framework in the form of up-to-date legislation and policy documents for the pharmaceutical sector coupled with a weak Drug Regulatory Authority (DRA), and the absence of a national system for planning pharmaceutical procurements created an environment that allowed multiple donors and technical assistance partners to create parallel systems for procurement and distribution of pharmaceuticals. Additionally, the long distances involved in transporting pharmaceuticals across a large country like the DRC combined with lack of transportation infrastructure, renders distribution of health products difficult, and contributes to the stocks frequently found at health facilities.

To address the challenges mentioned above, the United States Agency for International Development has progressively increased its assistance to activities that strengthen the DRC's pharmaceutical sector by funding successive projects aimed at improving the availability and the appropriate use of essential medicines and key health commodities in the DRC. Prior to the start of the recently-awarded Systems for Improved Access to Pharmaceuticals and Services project (SIAPS), the most recent of these projects was the Strengthening Pharmaceutical Systems (SPS) Program also managed by MSH. Under SPS, the following major achievements were realized on which SIAPS is going to build:

- The National Drug Regulatory Authority is functional.
- The production of norms and guidelines for Maternal, Neonatal and Child Health, achieved in collaboration with partners such as the World Health Organization (WHO), United Nations Population Fund (UNFPA), United Nations Children's Fund (UNICEF), Maternal and Child Health Integrated Program (MCHIP), the International Rescue Committee (IRC), and the Integrated Health Project (IHP), among others.
- A mechanism now exists at the provincial level, which serves as the main mechanism for planning and coordinating pharmaceutical activities and resolving supply chain bottlenecks.
- Drugs and Therapeutics Committees (DTC) have been introduced to the DRC for the first time.
- The DRC has become the 99th country to join the WHO Uppsala Monitoring Centre (UMC) following SPS financial support to members of the National Pharmacovigilance Center (NPVC) to attend the International Pharmacovigilance Conference in Nairobi in 2009. As a result, the DRC has submitted over 500 adverse drug event notifications to the WHO Vigiflow database to date.
- Because of SPS assistance, the National HIV/AIDS Program (PNLS) is now able to report patient and commodity-related data on patients on antiretroviral treatment (ART) for 6 provinces. These data have made it possible for the PNLS to conduct quantification based on consumption data, rather than on morbidity data, as was done in the past.

The following amounts have been provided in FY11 funding for the first year of SIAPS activities:

FP/RH: \$200,000

PEPFAR: \$500,000

PMI: \$550,000

TB: \$300,000

Total: \$1,550,000

### Goal: Quarterly Report Fields

These are the fields that will be used to collect information for quarterly reports.

#### Overall Quarter Progress

Current Value: **(Sep 2012)** - Overall SIAPS progressed with SIAPS/DRC project goal of assuring the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes through the strides forward made on its five country project objectives. SIAPS/DRC progress on IR1 (improved pharmaceutical sector governance) will contribute to making appropriate, quality medicines in the DRC by improving functioning of regulatory institutions, improving the content of the policies, laws and regulations and by improving coordination in the pharmaceutical sector. In Q\$, SIAPS/DRC maintained the progress made on improving the functioning of the drug registration system through support to quarterly drug registration sessions and by ensure that lists of registered drugs continue to be posted.

However, SIAPS/DRC will need to step up its efforts to automate the system in Y2. The change in government in Q3 slowed down the process of revision of the National Essential Medicines List, which truly began in Q4. However, there is a great opportunity to improve governance aspects of the revision process using the enhanced WHO methodology. However, SIAPS/DRC will assist the DRC with introducing this enhanced methodology during Y2.

SIAPS/DRC made progress with improving coordination of medicines at the national level through its assistance to revive of the National Medicines Committee (CNM) and the apparent recognition of pharmaceutical sector stakeholders of the necessity of participating and respecting the decisions of this committee. Additionally, SIAPS continued its assistance to coordination and supervision activities to Provincial Medicines Committees in all four USAID-focus provinces.

SIAPS/DRC contributed to improving individual and institutional capacity (IR 2) to make quality pharmaceuticals available through its training on PMTCT commodity management and its assessment (which will be followed by physical improvements) of CDRs.

The progress made on IR3 will is already making it possible to use consumption information on medicines to take corrective actions to make pharmaceuticals available in health centers and health zones – hopefully these efforts will contribute to the development of a national medicines information system which will make it possible to track consumption information across the entire DRC.

With assistance from SIAPS/DRC, the new DRC government is taking increased responsibility for tracking resources available and mobilizing additional funds for the pharmaceutical sector and for allocating more public resources to this sector (IR 4).

SIAPS/DRC is making significant contribution to improving the use of medicines (IR 5) through the work it is doing to promote rational use of pharmaceuticals through interventions implemented by drugs and therapeutics committees. In Year 2, SIAPS/DRC will be in a position to measure the improvements in use through endline studies. Additionally, SIAPS/DRC's extensive coordination with both the DRC government and the Integrated Health Project in Q4 to implement corrective actions (IR 5) contributed to the mitigation of stock outs in health facilities.

Key challenges faced during the quarter

Current Value: **(Sep 2012)** - Stock outs at health facilities occurred in the course of the implementation year. These were caused primarily by delays in the delivery of medicines purchased by IHP. These delays were in turn due to many factors, most of which, were beyond the control of SIAPS. Of note was that a number of entities contributed to these delays, including Ministries of Health, Foreign Affairs and Finances, as well as the US Embassy in DRC. Solutions to mitigate these delays and to prevent them from recurring in the future centered on communications and meetings with the various entities involved in the DRC pharmaceutical supply. These interventions contributed to mitigating bottlenecks in the supply chain to some extent. However, continued attention to the various bottlenecks in the supply chain will be needed in order to minimize delays and thereby stock outs related to future procurements of pharmaceuticals.

#### Technical Activity Coordination

Current Value: **(Sep 2012)** - The SIAPS DRC team began developing its Y2 work plan in September 2012. The entire DRC technical team of SIAPS participated also in the IHP Y2 work planning exercise in September 2012. A joint visit of the Portfolio Manager and the Deputy Director for Country Programs was conducted in September 2012 to provide support in finalizing the SIAPS Y2 work plan and with reorienting the SIAPS strategy in light of increased funding being provided to SIAPS in Y2 through the USAID/DRC Mission. During Q4, the SIAPS Country Project Director and Deputy Country Project Director participated in the Annual Review of the Ministry of Health's implementation of its implementation plan in Lubumbashi, Katanga Province. The SIAPS Country Project Director maintained regular communication with key technical implementing partners within the DRC through visits to various MoH departments as well as through participation of SIAPS staff in the activities organized by various partners. SIAPS spent a full day with SMCS and the JSI/DELIVER Project to assist SCMS in defining the scope of its activities in the DRC in light of what SIAPS and DELIVER were planning to do in terms of activities for the fiscal year beginning October 2012.

#### Office management

Current Value: **(Sep 2012)** - During Q4, SIAPS hired additional staff to work in two of the provinces. A Provincial Representative (at the level of Technical Advisor) was hired to conduct pharmaceutical management activities in the landlocked health district of Sankuru in Kasai Oriental Province. Another was hired to work out of MSH's new office in Uvira (Sud Kivu). Both of these staff began work on July 9, 2012. A Senior Technical Advisor was hired in August 2012 to focus on TB and pharmacovigilance activities. These personnel will be based in the SIAPS office in Kinshasa.

#### **Quarterly Report Fields (Objective)**

Objective-level fields for collecting information for quarterly reports.

#### Quarterly Progress for Objective 1

Current Value: **(Sep 2012)** - During Q4, the SIAPS DRC team contributed to objective of strengthening pharmaceutical sector governance by providing support to the Department of Pharmaceutical Services to maintain the transparency and efficiency introduced into the process for drug registration through the SPS project in prior years. This occurred through the financial and technical assistance provided to the DPM to hold its quarterly session for registering medicines, which resulted in 85 medicines being registered out of 244 applications received. The list of registered medicines was public posted, a practice which has now become routine.

In September, 2012, the SIAPS DRC team has discussed with WHO and the DPM the need to introduce the enhanced approach to revising National Essential Medicines Lists (NEML) developed by WHO. This approach focuses on making the revision process more transparent and efficient, and addresses issues such as conflict of interest of persons involved in the review process. WHO held a meeting in Brazzaville in October 2012 to finalize this new approach -- the document describing the new approach can be disseminated and used after the Brazzaville meeting.

In the meantime, SIAPS provided its technical expertise during meetings held in September 2012 to organize the process of revising the NEML. SIAPS/DRC also contributed to improving coordination among the partners involved pharmaceutical activities at both the national level and the provincial level. At the national level, SIAPS/DRC has been instrumental in help to reinvigorate the National Medicines Committee (NMC), which is the entity at the central of the DRC's health system that coordinates pharmaceutical activities. This has been done through supporting the organization of NMC meetings which normally including the Ministry of Health, multilateral and bilateral donors and implementing partners. Through these meetings, the NMC has managed to collect data on the financial contributions of all donors and IPs for the purchase of health products, as well as to obtain data on the geographic targets for such procurement. This has permitted the NMC to identify gaps in funding and geographic coverage. In future, SIAPS/DRC will assist NMC in fulfilling its role to coordinate pharmaceutical activities (procurement planning in particular) for the DRC's health system.

At the provincial level of the health system, SIAPS has continued to assist the four USAID-focus provinces of Kasai Orientale, Kasai Occidental, Sud Kivu and Katanga with coordinating pharmaceutical activities for the 4 provinces through the holding of meetings of the Comite Provinciaux de Medicaments (CPMs). A particular focus of CPM meetings during Q4 was to review the NEML and suggest additions or modifications. Additionally, SIAPS assisted the CPMS with determining actions that needed to be taken to address medicines availability of problems with the management of medicines SIAPS/DRC also provided assistance to the FEDECAME and CADIMEK to address the fact that they had failed to meet USAID standards for qualify to procure pharmaceuticals on behalf of the US government. SIAPS/DRC facilitated a study tour whereby the FEDECAME AND CADIMEK visited ASRAMES (which had qualified as a Category C procurement agent) in July 2012 to learn about the good practices that had contributed to ASRAMES' qualification. In addition, SIAPS helped the FEDECAME and CADIMEK to write an action plan to address weaknesses found in their respective USAID assessments which if addressed, will allow both entities to eventually qualify to procure on behalf of the US government

#### Quarterly Progress for Objective 2

Current Value: (**Sep 2012**) - During Q4, SIAPS/DRC made progress towards the objective of building capacity of both individuals and institutions in pharmaceutical supply management. Of note was that joint supervision visits conducted by SIAPS/DRC and MoH staff in August 2012 to PMTCT sites in Bas Congo province noted improvements in the completeness and accuracy of monthly reports concerning PMTCT medicines and commodities. This change followed training and supervision interventions by SIAPS in prior quarters to address incomplete and inaccurate reporting that characterized reports submitted during prior quarters.

In July 2012, SIAPS/DRC laid the groundwork for additional capacity building of

individuals by first assessing the capacity for PMTCT commodity management among ART sites in Katanga in preparation for scaling up of the PMTCT acceleration initiative then by conducting three trainings in Lubumbashi (Katanga Province), Kananga and Luiza (Kasaï Occidental). Trainings benefited staff from 66 treatment sites. Additional staff of HZ depots were trained to ensure compliance with Good Distribution Practice (GDP) and Good Storage Practice (GSP) for their respective structures.

Also in Q4, SIAPS/DRC collaborated with the National Program for the Supply of Medicines (Programme National pour l'Approvisionnement des Médicaments or PNAM) to assess storage capacity and conditions at ART sites, regional pharmaceutical warehouses (known as the centres régionaux de distribution or CDRs) and health zone depots in Lubumbashi, Katanga Provinces. The next step from the assessment will be to implement recommendations to improve storage capacity and conditions.

#### Quarterly Progress for Objective 3

Current Value: **(Sep 2012)** - During Q4, SIAPS contributed to the Objective of ensuring that pharmaceutical management information generated through SIAPS is used for decision-making by assisting the Provincial Ministries of Health in all four USAID-focus with interpreting and using data obtained through the medicines information management systems that had been piloted these provinces which is known as the SNIS-MED. Data obtained allowed the determination (on a monthly basis) of the number of health facilities that were out of stock of specific tracer essential medicines and commodities. Using the SNIS-MED, SIAPS managed to obtain and analyze data on stock availability across all 80 USAID-focus health zones. These data have been discussed with the DRC's Ministry of Health as well as with the USAID-funded Integrated Health Project (IHP), which supplies essential medicines to the 80 USAID-focus health zones, and corrective action taken where possible to address stock outs.

Additionally, SIAPS assisted both national and provincial Ministries of Health to obtain pharmaceutical management data through active collection of data through mechanisms such as the Procurement Planning and Monitoring Report for malaria (PPMRm), the Procurement Planning and Monitoring Report for contraceptives (PPMRc) and the End Use Verification Survey (EUVS). SIAPS provided technical assistance with interpreting data from all of these sources. Data used from the PPMRm and PPMRc were to make recommendations on health product procurement to the US government. EUVS data were used to take immediate corrective action to address problems found with the management and use of malaria commodities. The National Medicines Supply Program (Programme National pour l'Approvisionnement des Médicaments or PNAM) plans to use the lessons learned from the implementation of the SNIS-MED to develop a National Information System for Medicines.

#### Quarterly Progress for Objective 4

Current Value: **(Sep 2012)** - • During Q4, SIAPS/DRC made some progress on the objective of increasing financial resources to the pharmaceutical sector. This was done through assisting to revive the PNAM-led National Medicines Committee (NMC), which is one of the mechanisms set forth by the national health strategic plan to coordinate all activities related to the procurement of medicines. The NMC conducts most of its business through meetings. Five CNM meetings were held during Q4 which focused on a range of topics from improving coordination among implementing partners in health in procurement and supply management to determining the levels of financing available from various donors and implementing partners for procuring pharmaceuticals these items. The main financing related results of these meetings were that the government of

the DRC itself determined how much it would contribute to the financing of pharmaceuticals for the coming year and that the government of the DRC committed to financing the procurement of vaccines for the first time in many years.

#### Quarterly Progress for Objective 5

Current Value: **(Sep 2012)** - During Q4, the area of pharmaceutical services in which SIAPS made the most visible contribution was in promoting rational drug use. In the course of Y1 of implementation, SIAPS had assisted various hospitals where SIAPS had helped establish Drugs and Therapeutics Committees to conduct baseline studies in medicines use. A total of 9 such hospitals conducted such studies. SIAPS has collaborated with the University of Kinshasa to help each of these hospitals where baseline studies have been conducted with selecting interventions to address problems with medicines use and to develop action plans for implementing the interventions. During Y2, SIAPS will conduct end line studies to measure the results of these interventions. The types of findings these interventions include the findings that hospitals use antibiotics in 75% of prescriptions (as opposed to approximately 25% of prescriptions as recommended by WHO), and the finding of a number of errors made in prescriptions (incorrect medication, incorrect dose or incorrect duration).

#### **Quarterly Report Fields (Sub-Objective)**

Fields for reporting quarterly progress at the sub-objective level.

#### Quarterly progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - During Q4, SIAPS continued making improvements in the drug registration process's transparency and efficiency by supporting the quarterly drug registration process of the DPM. As a result of SIAPS support, 244 registration applications were reviewed. Out of these 85 drugs were registered. At the time of this session, 85 medicines out of 244 submitted to the DPM have been approved. Sixty-two (62) applications were found to require more information for review and 4 were rejected. Ninety-two (92) dossiers for which analysis was begun were postponed for completion of review until the next session. However, SIAPS did not progress with the automation of the drug registration process due to unavailability of specialized staff at its HQ to provide technical assistance with introduction of the Web-based version of Pharmadex.

#### Challenges in progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - Unavailability of SIAPS HQ staff specialized in installation and training in the Web-based version of Pharmadex made it difficult to make progress on this activity during Q4.

#### Quarterly progress toward sub-objective 1.2

Current Value: **(Sep 2012)** - SIAPS made progress of this objective of improving policies, legislation and regulations by assisting the Ministry of Health in initiating the process for revising the National Essential Medicines List. On September 12, 2012, SIAPS provided financial support and technical inputs to a meeting to establish the national committee for revising the NEML. During this meeting the improved methodology for NEML revision pioneered by WHO which incorporates elements of good governance was discussed. The guidance document for implementing this new methodology was to be finalized by WHO in October 2012 in Brazzaville before being rolled out to various African countries.

Quarterly progress toward sub-objective 1.3

Current Value: **(Sep 2012)** - Technical assistance from SIAPS to both national and provincial levels of the DRC Ministry of Health during Q4 contributed to the continuous improvement in the coordination of supply chain management activities by national and provincial authorities (Objective 1.3) At the national level, SIAPS provided technical inputs and financial assistance to hold 4 meetings of the National Medicines Committee in July 2012. These meetings resulted in the following: 1. The CNM obtained data from all key donors and implementing partners on funding available to support medicines procurement for the DRC. 2. The CNM also obtain pledges from these partners to use the national procurement and distribution system for their next procurements, rather than using parallel systems as had been common in the past. 3. Minister of Health created a Task Force that included WHO and SIAPS, with the responsibilities, among others, to quantify the needs in essential medicines for all the 515 HZs for 6 months.

SIAPS also contributed in improving and supporting coordination at the provincial level on pharmaceutical activities. In Kasai Oriental, SIAPS assisted the provincial MoH with holding the Comite Provincial de Medicament meeting from 5 to 7 September, 2012. At this meeting, the CPM analyzed the morbidity data of the Kasai Oriental previously collected from a sample of 65 health facilities in order to make recommendations for modifying the Provincial Essential Medicine List (PEML) of Kasai Oriental. The next steps will be to develop the PEML and to participate in the revision of the 2010 NEML.

In Sud Kivu, SIAPS provided technical inputs to a CPM meeting held on 20 September 2012 financial support of CORDAID. The following were important results of the meeting: 1. The Provincial Ministry of Health authorized the IHP to distribute FP commodities that were being held at CDRs by the provincial ministry. The commodities could now be released by health workers in all the health zones had to first be trained in the administration and management of these commodities. The training had taken 6 months to complete for all HZ in the province because of the security problems in this province.

The Provincial Pharmaceutical Inspector presented the results of qualitative analyses of drugs circulating in Sud Kivu. This analysis showed that over 40% of drugs circulating in the province were sub-standard. A recommendation of the CPM is to have the Provincial Pharmaceutical Inspector collaborate with the public prosecutor's office to close drugs outlets in Bukavu town that do not meet minimum standards established by the DPM, as had been done in Uvira Town. In July 2012, SIAPS worked with the Chair of Kasai Occidental's CPM to finalize the first Provincial Essential Medicines List for the province. The PEML was adopted by the Comite Provincial de Pilotage at its meeting on 7-8 September, 2012. The PEML for Kasai Occidental contains 1,641 medicines.

SIAPS provided technical advice at a meeting of the Kasai Occidental CPM held on 26 August, 2012 with financial support from the European Union. This meeting served to analyze the financing and pricing of medicines within the province. It was recommended that more ECZS members participate in conducting physical inventories of medicines and in verifying the reporting of pharmaceutical information.

SIAPS coordinated a study visit to ASRAMES for the FEDECAME and CADIMEK to both to learn from ASRAMES about best practices that made it possible for ASRAMES to qualify as a Category C procurement agent for USAID. It is hoped that the FEDECAME and CADIMEK will use the knowledge acquired during the study visit to improve its practices so that both will qualify as a procurement agent for USAID when

each entity is reevaluated. FEDECAME and CADIMEK will also benefit from technical assistance from the SCMS project in the coming year to improve their storage space, conditions and practices.

Deliverables: Sub-Objective 1.3

Current Value: **(Sep 2012)** - 1. Provincial Essential Medicines List for Kasai Occidental 2. Provincial Essential Medicines List for Kasai Oriental

Quarterly progress toward sub-objective 2.1

Current Value: **(Sep 2012)** - During Q4, SIAPS/DRC made progress on sub-IR 2.1 (HIV/AIDS pharmaceutical management capacity of individuals, institutions, organizations strengthened) by conducting activities to begin the process of strengthening the capacity of regional pharmaceutical warehouses known as CDRs. Additionally, SIAPS/DRC conducted several training activities to improve the capacity of PEPFAR partners in pharmaceutical management of products HIV/AIDS commodities.

From July 1-13, 2012, SIAPS worked with staff from the PNAM and National HIV/AIDS Program to conduct a week-long assessment in Lubumbashi, during which storage conditions at ART sites, regional pharmaceutical warehouses (known as the centres régionaux de distribution or CDRs) and health zone depots were examined. SIAPS submitted a report of the assessment findings and recommendations to USAID/DRC. The next step will be for SIAPS to collaborate with SCMS to assist ART sites, CDRs and health zone depots to improve storage conditions.

In July 2012, SIAPS first collaborated with the National Program for Medicines Supply known as the Programme National pour l'Approvisionnement des Medicaments (PNAM) to conduct an assessment in the Katanga province (Lubumbashi) to determine the capacity of implementing partners and MoH staff to manage pharmaceuticals used in PMTCT. This assessment was conducted to prepare for scaling up of the PMTCT acceleration initiative. Findings included: poor knowledge of the functioning of the pharmaceutical distribution chain; improper storage of medicines; lack of use of forms or other tools used to track pharmaceuticals and poor estimation of needs of PMTCT supplies.

SIAPS/DRC then organized three training sessions in two provinces: Katanga (Lubumbashi), and Kasai Occidental (Kananga and Luiza) to address weaknesses identified. The modules on PMTCT commodity management were integrated into a comprehensive training on clinical management of HIV/AIDS implemented by the Integrated Health Project. A total of 95 staff from 66 treatment sites was trained. In addition various MoH staff working in HZ depots were trained to ensure compliance with Good Distribution Practices (GDP) and Good Storage Practices (GSP) for their respective structures.

In addition to providing trainers in pharmaceutical management, SIAPS/DRC provided the funds for the full cost of the training. Additional trainers from the national and provincial offices of the national HIV/AIDS program participated as well. Training topics were the following: 1. Adequate use of PNAM forms and other tools used to track pharmaceuticals. 2. Estimation of health center and health zone needs in pharmaceuticals and preparation of orders. 3. Keeping stock cards, registers and other pharmaceutical management tools up to date. 4. Develop a pharmaceutical management report to be transmitted to health zone management team, based on a standard form.

Members of the health zones management team should now be capable of: 1. Carrying out supervision on the management of HIV/AIDS medicines and commodities. 2. Analyzing and validating medicines orders from health centers and general referral hospitals through the “Quantification Committees” of the HZs. 3. Compiling and transmitting reports of pharmaceutical management from health facilities to the DPS. Improvements to reporting on PMTCT medicines and commodities were noted following technical assistance that had been provided by SIAPS in prior quarters.

Through joint supervision visits (that included provincial HIV/AIDS officers, staff from the USAID-funded ProVic and SIAPS staff) conducted during Q4 from 16-25 August, to 11 PMTCT sites in 5 health zones in Bas Congo. Prior to this initiative, ART sites reported irregularly, and reports were often incomplete. These same sites now produce complete and accurate monthly reports on pharmaceutical management covering of all PMTCT medicines and commodities.

Deliverables: Sub-Objective 2.1

Current Value: **(Sep 2012)** - 1. Training materials 2. Training report 3. Report from Lubumbashi assessment 4. Bas Congo supervision report

Quarterly progress toward sub-objective 2.2

Current Value: **(Sep 2012)** - During Q4, minimal progress was made on this indicator. Progress on sub-IR 2.2 (Pharmaceutical management capacity of individuals, institutions, organizations strengthened) required that dedicated TB staff be available on the SIAPS/DRC team to conduct key activities of conducting training in management of TB medicines and organizing the transfer of TB medicines from Provincial Offices of the National TB to regional pharmaceutical warehouses (centres regionaux de distribution or CDRs). Hiring a SIAPS/DRC TB focal point only occurred in Q4. This person will play a major role in supporting the National TB program in implementing the recommendations mentioned in the TB medicines storage conditions’ assessment report which concluded that TB medicines should no longer be stored in regional office of the National TB program. The SIAPS/DRC TB focal person will also support both national and provincial level TB activities of SIAPS and will collaborate closely with the TB 2015 project in implementing activities.

Quarterly progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - SIAPS/DRC progressed on the intermediate result 3.1 (Pharmaceutical management information systems (PMIS) support both products and patients) by supporting the MoH in continuing its piloting of the medicines information management system piloted two years earlier and by determining the possibility of scaling up the use of EDT for use by the National HIV/AIDS program. Under Activity 3.1.1, SIAPS supported the National Health Information System Directorate (DSNIS) and the PNAM to hold a work shop focused on harmonizing data collection and transmission forms used by the recently piloted medicines information system (SNIS MED) and integrating them into the SNIS. This work shop resulted in the expansion of the list of tracer medicines to include products from more national programs, as well as an expansion in the list of SNIS-MED indicators to be tracked.

SIAPS/DRC also assisted the Ministry of Health with analysis of the data on stock availability across all 80 USAID-focus health zones obtained from the SNIS-MED. These data were also discussed with the USAID-funded Integrated Health Project (IHP), which supplies essential medicines to the 80 USAID-focus health zones. Corrective action was

taken where possible to address stock outs. SIAPS also supported supervision visits by the District Pharmaceutical Inspector of Kolwezi to health zones. Visits focused on data collection and transmission through SNIS-Med in 4 health zones (Manika, Dilala, Lualaba and Kanzenze).

Under Activity 3.1.2, SIAPS/HQ conducted an STTA visit in Q4 focused on conducting an internal review of the piloting of the Electronic Dispensing Tool (EDT) which had been started under the Strengthening Pharmaceutical Systems program in the prior year. EDT had been piloted in the prior year at four hospitals in Kinshasa (Matete General Referral Hospital, Mama Yemo Hospital, Kingasani Hospital and Camp Kokolo Hospital). In Q4, 3 of the pilot sites were still active. EDT was discontinued at Matete Hospital in April 2012 because of frequent power outages which made consistent use of EDT impossible.

By September 2012, 2,149 patients were being monitored using EDT at the three sites. All 3 hospitals were using EDT as prescribed (entering data directly into the computer at the dispensing point), had taken ownership of use of this software, and had integrated use of EDT into hospital pharmacy operations. The review concluded EDT software could be successfully introduced at both public and private hospitals in the DRC, provided that the site had an adequate supply of electricity and a working generator, in addition to having staff that were adequately trained, as well as an adequate schedule of supervision visits to sites using EDT, particularly during the first 6 months of implementation. For sites experiencing particular difficulties in using the software in the initial phases, mentorship of site users was an important factor that led to sites becoming more diligent and independent in the use of EDT. The government of the DRC wishes to scale up EDT to 4 additional sites in Katanga provinces -- this is therefore planned for Y2 of SIAPS implementation.

Activity 3.1.3 (conduct the End User Verification Survey) was not conducted in Q4. SIAPS/DRC did not progress much on activity 3.1.4 (Facilitating use of adverse drug reaction data for decision-making). For the National Pharmacovigilance Center (NPVC) to coordinate meetings focused on modifying national treatment guidelines or the NEML in light of ADE data, the existing ministerial decree governing the NPVC would need to be revised. At a meeting in September 2012 facilitated by SIAPS, both the DPM and the NPVC strongly expressed the preference to have SIAPS make available an expert in pharmaceutical law and organizations in Y2 to provide advice on the rewording of the decree in order to ensure that the revision would adequately capture the change envisioned to the NPVC's function and role.

#### Challenges in progress toward sub-objective 3.1

Current Value: (**Sep 2012**) - Sub IR 3.1: Pharmaceutical management information systems (PMIS) support both products and patients Activity 3.1.1: Provide support to provinces in supervising the health zones including the implementation of the medicines information system (SNIS-Med) still under pilot and assist the PNAM and the DSNIS in a review of the National Health Information System. (funding: cross-cutting, including PMI, PEPFAR/HVSI, and FP/RH) In Katanga Province, during Q4, SIAPS provided financial and technical assistance to both SNIS Directorate (DSNIS) and PNAM to hold a work shop that served to harmonize different data collection and transmission forms including the SNIS MED and to integrate them in the SNIS.

During this work shop, agreement was reached to include additional tracer medicines from more national programs, and the list of SNIS-MED indicators that was decided at the previous work shop held in Kinshasa during Q3. SIAPS also provided financial and

technical assistance to make it possible for the PID of Kolwezi to do supervision visits with a focus on data collection and transmission through SNIS-Med in 4 HZ (Manika, Dilala, Lualaba and Kanzenze). Below is the data reported through the SNIS-MED during Q4 on the number and percentage of health facilities reporting stock outs of tracer products.

Activity 3.1.2: Finalize EDT pilot launched within four sites in Kinshasa (funding: PEPFAR/HVSI and TB). Under SPS's DRC FY10 work plan, SPS had provided technical assistance to the PNLs to pilot a HIV/AIDS information system using EDT software starting in four anti-retroviral treatment sites in Kinshasa. Users of these sites were trained in how to use EDT. Up to the end of September, so far 2,149 patients are being monitored using EDT at the three operational pilot sites. It should be noted that the fourth EDT site in Matete General Referral Hospital was shut down in April of 2012 due to the inconsistent availability of electricity.

In September, 2012, SIAPS/HQ conducted an STTA visit to, amongst other things, review the progress of the EDT pilot. Generally speaking, the three hospitals where EDT was still operational have taken ownership of use of this software, whose use seems now to be well integrated into the operations at each hospital's pharmacy. Below is a table summarizing the evaluation findings among the three sites: Open forum on October 4, 2012 to share lessons learned throughout the pilot year, and best practices adopted among the various health facilities.

Also to discuss were common challenges encountered and EDT users overcame them. • SIAPS to disseminate results from the internal evaluation to other MOH partners and stakeholders during Q1 of Y2. • The National HIV/AIDS program wishes to pilot EDT at 4 additional sites in Lubumbashi, Katanga Province. SIAPS has therefore incorporated this activity into its Y2 work plan. • Also during Y2, SIAPS will continue providing technical support to the remaining three Kinshasa sites where EDT is being implemented.

Activity 3.1.3: Conduct End User Verification survey (EUVs) for malaria commodities (funding: PMI) • The next EUVS will be implemented in Q2 FY2 in all 4 USAID supported provinces. Activity 3.1.4: Facilitate coordination among DPM, NPVC, WHO, GF and other MoH partners to review and use Adverse Drug Events (ADE) information for decision-making (cross-cutting including: PEPFAR, PMI, TB) support to the National Pharmacovigilance Center (NPVC) to ensure that ADE data would be used for decision-making by the NPVC. However, to date this data has not been systematically used by the Ministry of Health to inform decision-making on standard treatment guidelines or the essential medicines list. SIAPS learned that in order for the NPVC to be able to officially recommend decisions to the MoH on ADE data, the existing ministerial decree describing the functions of the CNPV would need to be revised.

#### Quarterly progress toward sub-objective 4.1

Current Value: (**Sep 2012**) - During Q4, SIAPS/DRC made some progress on the sub-objective 4.1.1 (Provide technical and financial assistance to the CNM to improve its tracking of funds being provided to the public pharmaceutical). This was done by playing a key role in reviving the PNAM-led National Medicines Committee (NMC), which is one of the mechanisms set forth by the national health strategic plan to coordinate all activities related to the procurement of medicines. The NMC conducts most of its business through meetings. Five NMC meetings were held during Q4 which focused on a range of topics from improving coordination among implementing partners in health in procurement and supply management to determining the levels of financing available from various donors and implementing partners for procuring pharmaceuticals these items. The main

financing related results of these meetings were that the government of the DRC itself determined how much it would contribute to the financing of pharmaceuticals for the coming year and that the government of the DRC committed to financing the procurement of vaccines for the first time in many years.

Additional outcomes of the meeting were that the MOH pledged to streamline the public procurement and distribution chain for the DRC and that the MoH committed to ensuring improved availability of medicines at the health center level. The affordability of these medicines to the Congolese population is to be discussed in the next CNM meeting. As next steps, SIAPS will assist the CNM with establishing a firm calendar of meetings for the coming year calendar year. Additionally, SIAPS will continue to provide technical and financial support to holding CNM meetings during its second year of operation. There were no requests for assistance from Global Fund Principal Recipients that could have resulted in increased financial resources accessed through the Global Fund mechanism (Activity 4.1.2).

#### Quarterly progress toward sub-objective 5.1

**Current Value: (Sep 2012)** - Activity 5.1.1 Report on the availability of family planning commodities through the quarterly Procurement Planning and Monitoring Report for contraceptives (PPMRc) system (funding: FP/RH) UNFPA, PSI and IHP are the main partners collaborating with SIAPS in FP. SIAPS collect data from each of these and compiled them for use by the DRC Ministry of Health, as well as for use by USAID/Washington in procurement planning. The table below summarizes all data on contraceptives collected from health facilities assisted by IHP and CDRs in the 4 USAID-focus provinces. This PPMRc report show to the field stakeholders the importance of taking into account the residual stock before confirming any new order. Example: the Q4 PPMRc report showed that IHP commanded 926 IUD while it was still 16-months stock. A simple redistribution of the quantities through the sites was able to solve the problems. In the same report, IHP commanded 15, 810 cycle bead, while the total stock was more than 15 months consumption. These observations have demonstrated weaknesses in coordination within IHP field offices. Corrective measures, in term of better coordination, have been taken during the IHP's annual review in September 2012 and IHP requested training session to SIAPS during the FY2. Next Steps: During Y2: • SIAPS plans to involve the National Reproductive Health Program more in producing PPMRc reports so that the Program can eventually take on submitting the reports and initiating corrective actions on its own. • To make functional a national procurement coordination of FP commodities (UNFPA, USAID) with the lead of the National Program.

#### Challenges in progress toward sub-objective 5.1

**Current Value: (Sep 2012)** - During Q4, SIAPS focused on implementing mitigation strategies to prevent the recurrence of stock outs of essential medicines at health facilities caused primarily by delays in the delivery of medicines purchased by the USAID-funded Integrated Health Project (IHP). These solutions centered on communications and meetings with the various entities involved in the DRC pharmaceutical supply. These interventions contributed to mitigating bottlenecks in the supply chain to some extent. However, continued attention to the various bottlenecks in the supply chain will be needed in order to minimize delays and thereby stock outs related to future procurements of pharmaceuticals. SIAPS/DRC collected data through the Procurement Planning and Reporting Mechanism for Malaria (PPMRm) and the Procurement Planning and Reporting Mechanism for contraceptives (PPMRc) and provided recommendations to USAID on whether or not to procurement malaria commodities and contraceptives. The Q4 PPMRc report demonstrated to DRC stakeholders the importance considering

residual stocks before confirming any new order. Weakness in coordination among IHP field offices resulted in additional stocks of contraceptive products being ordered even though large stocks were available across the 80 target health zones. For example, IHP ordered 926 IUD, even though 16-months stock of this product was still remaining. This overstock was addressed through a simple redistribution of the quantities through among health facilities. Similar overstock/ordering occurred with cycle beads ded 15, 810 cycle bead, while the total stock was more than 15 months consumption. IHP has since taken corrective actions to improve coordination among its offices and prevent these scenarios from recurring.

Deliverables: Sub-Objective 5.1

Current Value: **(Sep 2012)** - 1. Q4 PPMRm report 2. Q4 PPMRc report

Quarterly progress toward sub-objective 5.2

Current Value: **(Sep 2012)** - The first ADE notifications received by the National Pharmacovigilance Center after the national ADE reporting system was established came primarily from Kinshasa hospitals. Since October 2011, however, General Referral Hospitals in the four USAID-focus provinces receiving SPS assistance with establishing and managing Drugs and Therapeutics Committees (DTCs) began submitting ADE notifications. Between October 2011 and the end of September 2012, 142 such notifications were received.

In support of the national pharmacovigilance system's plan to decentralize pharmacovigilance and establish provincial pharmacovigilance centers, SIAPS joined the CNPV in conducting 4 trainings to prepare 81 pharmacovigilance focal points who will be stationed across the 4 USAID-focus provinces. Trainees included provincial medical officers in charge of PNLs, PNLT, PNLP, doctors from main referral hospitals. In addition to including a module on pharmacovigilance, the training also addressed rational use of medicines, and pharmacotherapy of the top ten diseases in DRC. SIAPS provided financial and technical assistance.

The following the training outcomes can be noted: 1. • Eighty-one (81) pharmacovigilance focal points are now capable of guiding ADE reporting from health facilities now exist across all four USAID-focus provinces. 2. • These 81 focal points are also capable of supervising pharmacovigilance activities in health zones referral hospitals, under the supervision of the Provincial Pharmacist and the Provincial Medical Officer. 3. • These focal points also now have the ability to promote rational use of medicines and to teaching ADE notification techniques to health providers. The DRC's CNPV compiles ADE notifications sent from health facilities, analyzes them and enters the data into the Uppsala Monitoring Center Vigiflow system (UMCV).

During Y1, SIAPS assisted the CNPV with the payment of its direct Internet connection monthly fees to enable it to continue submitting this data to the UMCV system, as the University server the NPVC was connected to is no longer functioning. The CNPV has also started producing 2 issues of a newsletter each year on pharmaceutical issues for national and international dissemination. SIAPS provided technical and financial contributions toward the production and distribution costs of this newsletter. The first issue was produced and disseminated electronically by the CNPV. The draft of the 2nd issue of the CNPV newsletter was submitted to SIAPS HQ for editing before publication in French and English.

Deliverables: Sub-Objective 5.2

Current Value: **(Sep 2012)** - 1. Report on pharmacovigilance and pharmacotherapy training conducted during Q4. 2. National Pharmacovigilance Center newsletter

Quarterly progress toward sub-objective 5.3

Current Value: **(Sep 2012)** - SIAPS/DRC contributed to Sub IR 5.3 (Medicines use is improved at hospitals with DTCs) by providing feedback to DTCs on the results of baseline studies and working with them to identify appropriate interventions, and providing training to them to address study findings. During Q4, SIAPS provided technical support to 6 DTCs for conducting interventions to improve medicines use based on results of their baseline studies made in Q1-Q3. In Q4, SIAPS/DRC produced a summary report on results of baseline studies and recommended interventions. The report has been submitted to SIAPS/HQ for editing. A specific training addressing the findings for each DTC was organized concurrently with the training of the pharmacovigilance focal points held in Q4. The training provided in rational use and pharmacotherapy as benefitted DTC members.

Deliverables: Sub-Objective 5.3

Current Value: **(Sep 2012)** - 1. Summary report on baseline studies on medicines use at DTCs.

## **ETHIOPIA**

Ethiopia work plan details for Year 1 of the SIAPS Program

### **Quarterly Report Background**

Ethiopia is Africa's oldest independent country. It is the tenth largest country in Africa, covering 1,104,300 square kilometers and is the major constituent of the landmass known as the Horn of Africa. The major health problems of the country remain largely preventable communicable diseases and nutritional disorders. Despite major progresses in improving the health status of the population in the last one and half decades, Ethiopia's population still faces a high rate of morbidity and mortality.

Despite tangible accomplishments in ARV drugs management in Ethiopia, there are gaps that need to be addressed to further improve pharmaceutical services. Irrational use of medicines, shortage and high turnover of staff, poor record keeping and reporting, poor quality of consumption data for quantification, poor dispensing practice leading to unfavorable treatment outcomes and development of resistance to antimicrobial agents, inadequate training and a lack of reference materials, a lack of pharmaceutical institutional framework that would guarantee "ownership" of interventions by implementing partners, poor tracking of expiry and delayed disposal of obsolete and expired products are some of the challenges that health facilities still face.

As follow-on to Strengthening Pharmaceutical Systems (SPS), the scope of SIAPS is to provide technical assistance to governmental and non-governmental organizations in developing countries to build their capacity so as to enable them to effectively manage their pharmaceutical systems. The ultimate goal of creating strong pharmaceutical systems is to ensure access to essential medicines and improve quality of pharmaceutical services, thereby improving health outcomes. This will contribute significantly to the successful implementation of USAID priority services, and ultimately save lives and protect the public's health by improving access to and use of medicines of assured quality.

SIAPS/E benefits from the strong and successful partnership and collaboration created between SPS and key government agencies & professional associations during the past four years. SIAPS/E will build on the milestones achieved through SPS and expand its interventions in the areas of access to and rational use of medicines, pharmaceutical good governance (to ensure accountability, transparency and operational efficiency) and strengthening of pharmaceutical services to improve health outcomes.

Under COP11, SIAPS/E will continue to support capacity building of national organizations, such as Pharmaceutical Fund and Supply Agency (PFSA); Food, Medicines and Health Care Administration and Control Authority (FMHACA) and Regional Health Bureaus (RHBs); professional associations, teaching institutions and health facilities using the SIAPS framework. Support will be focused around strengthening pharmaceutical management, improving Pharmaceutical Good Governance, policy and practice reform aimed at strengthening national skills and capacity in various areas of pharmaceutical systems, promotion and implementation of rational use of medicines, containing the emergence and spread of antimicrobial resistance, promotion of treatment adherence and medicines safety with the aim to improve treatment outcomes.

### **Goal: Ethiopia Year 1 Work Plan Goal**

Assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes.

### **Objective 1**

Pharmaceutical sector governance strengthened

**Sub-Objective 1.1**

Provide trainings in Leadership, Management, Supervision, and Team Building

**Activity 1.1a**

Provide training on leadership, management, supervision and team building to managers drawn from major stakeholders

**Sub-Objective 1.2**

Support FMHACA in implementing Pharmaceutical Good Governance

**Activity 1.2a**

Support consultative meetings between FMHACA and private pharmacies, medicines manufacturers, importers, distributors and retailers

**Activity 1.2b**

Support Policy/legal documents dissemination workshop pertinent to pharmacy service standards and regulations

**Activity 1.2c**

Support FMHACA to update the Standard Treatment Guidelines (STGs) and national drug list (NDL)

**Activity 1.2d**

Provide Pharmaceutical ethics training to EPA members

**Sub-Objective 1.3**

Strengthen the legal framework of APTS to increase transparency and accountability

**Activity 1.3a**

Support RHBs and other stakeholders to draft proclamation on APTS implementation

**Activity 1.3b**

Support popularization and implementation of the proclamation (Support RHB to institutionalize APTS)

**Activity 1.3c**

Printing and distribution of EHRIG-Pharmacy chapter

**Activity 1.3d**

Support regional forums of experience sharing and exchange of best practices

**Objective 2**

Capacity for pharmaceutical supply management and services increased and enhanced

### **Sub-Objective 2.1**

Strengthening the effectiveness of DTCs

#### **Activity 2.1a**

In collaboration with PFSA and RHBs, conduct supportive supervision to selected sites to strengthen DTCs

#### **Activity 2.1b**

Provide TA to facilities in the preparation of health facility-specific drug lists and support printing of the drug lists

#### **Activity 2.1c**

Support ABC /VEN analysis and prescription review by DTCs

#### **Activity 2.1d**

In collaboration with PFSA and RHBs, organize regional meetings for the exchange of best practices among DTCs; provide incentives (computers/LCD projectors) to best performing DTCs

#### **Activity 2.1e**

Scale up establishment and operation of additional DTCs

#### **Activity 2.1f**

Provide new and refresher/ replacement trainings

#### **Activity 2.1g**

Develop SOPs for implementation of EHRIG-Pharmacy chapter

### **Sub-Objective 2.2**

Scale up the establishment of Drug Information Services (DIS) to provide unbiased information on medicines to providers and patients

#### **Activity 2.2a**

Scale up establishment and operation of Drug Information Services in selected hospitals throughout the regions

### **Sub-Objective 2.3**

Improve dispensing practices of EHRIG sites through supply of furniture (Facility improvement)

#### **Activity 2.3a**

Provide dispensing shelves, filing cabinets, basic dispensing furniture, computers with printers

**Sub-Objective 2.4**

Strengthen pharmaceutical human resource at different levels to ensure proper management and use of pharmaceuticals and related commodities

**Activity 2.4a**

Training of graduating pharmacy students in ARV, Malaria, TB, OI, & rational drug use; containment of antimicrobial resistance, adherence, and pharmaceutical good governance

**Activity 2.4b**

Conduct in-service training on clinical pharmacy/pharmaceutical care to EHRIG-implementing sites in collaboration with schools of pharmacy

**Activity 2.4c**

Train pharmacy professionals from public and private health facilities and RHBs on RDU and ART

**Activity 2.4d**

Provide “gap-filling” trainings to mid-level pharmacy personnel to improve quality of service

**Activity 2.4e**

Organize continuing education sessions to pharmacy practitioners in collaboration with EPA

**Activity 2.4f**

Support EPA to conduct activities related to RUM during its annual scientific conference.

**Sub-Objective 2.5**

Strengthen national capacity for safe, accountable management and timely disposal of pharmaceutical waste.

**Activity 2.5a**

Identify relevant SIAPS/E and related pharmaceutical management conferences, trainings, workshops etc. and support the participation of staffs in such activities

**Sub-Objective 2.6**

Supporting FMHACA to develop national disposal frameworks

**Activity 2.6a**

Popularize the waste disposal framework and directives through workshops

**Activity 2.6b**

Provide trainings to health care providers and other relevant stakeholders

**Objective 3**

Utilization of information for decision-making increased

**Sub-Objective 3.1**

Strengthen Pharmaceutical Management Information System at the dispensing level to improve quality of patient care

**Activity 3.1a**

Roll out of EDT to sites with computerized system (ADT)

**Activity 3.1b**

Collaborate with a local IT firm and partners to customize ADT/EDT to support dispensing of all essential medicines at OPD pharmacies as part of implementing EHRIG –pharmacy chapter

**Activity 3.1c**

Print and distribute different data capturing and reporting forms to all ART sites

**Sub-Objective 3.2**

Produce information related to medicines use patient uptake, lost to follow-up and regimen breakdown reports

**Activity 3.2a**

Provide computers, printers, backup drives and RW-CDs to selected health facilities

**Activity 3.2b**

Actively disseminate reports generated to relevant users (USAID, FHAPCO, RHBs, PFSA, HFs and USG partners)

**Activity 3.2c**

Provide TA to implement real-time dispensing using electronic tool and maintain patient-medication records for chronic diseases in addition to HIV/AIDS

**Objective 4**

Financing strategies and mechanisms to improve access to medicines strengthened

**Sub-Objective 4.1**

Support regional health bureaus and health facilities to implement EHRIG –pharmacy chapter

**Activity 4.1a**

Initiate auditable pharmacy services and transaction systems (APTS)

**Activity 4.1b**

Training on EHRIG-Pharmacy chapter and APTS to DTC sites

**Activity 4.1c**

Printing and distribution of EHRIG-Pharmacy chapter

**Activity 4.1d**

Support regional forums for experience sharing and exchange of best practices

**Activity 4.1e**

Strengthening existing EHRIG sites through mentoring and supportive supervision

**Objective 5**

Pharmaceutical services to achieve desired health outcomes improved

**Sub-Objective 5.1**

Promote rational prescribing of medicines through educational, managerial and regulatory interventions

**Activity 5.1a**

Trainings to doctors, health officers and nurses to rationalize their prescribing behavior

**Activity 5.1b**

Support FMHACA to print and distribution of prescribing aids

**Sub-Objective 5.2**

Rational dispensing of medicines by pharmacy professionals to improve treatment outcomes

**Activity 5.2b**

Support the printing and distribution of dispensing aids (Formularies)

**Sub-Objective 5.3**

Improve medicines use by clients

**Activity 5.3a**

Produce and disseminate electronic and printed IEC materials on ethical (prescription) and over the counter (OTC) drugs for patient education in collaboration with FMHACA

**Sub-Objective 5.4**

Provide technical and material assistance to the National AMR Advisory Committee, RHBs, and universities to implement the National AMR Containment Framework

**Activity 5.4a**

Strengthen the National Advisory Committee on AMR to carry out its mandate effectively (study tour, incentives)

**Activity 5.4b**

Support regular meetings of the National Advisory Committee

**Activity 5.4c**

Conduct the two rounds of trainings on AMR to journalists

**Activity 5.4d**

Pilot regional AMR containment interventions with ORHB, Jimma University and FMHACA

**Sub-Objective 5.5**

Provide technical assistance to strengthen ADR monitoring and Pharmacovigilance (PhV) systems

**Activity 5.5a**

Support printing and distribution of ADR reporting forms (yellow form) to health facilities

**Activity 5.5b**

Provide trainings on medicines safety (recognition, prevention, and documentation, monitoring and reporting of ADR) to health professionals from public and private hospitals

**Activity 5.5c**

Provide support in the development of PhV database

**Activity 5.5d**

TA in the use of information generated from PhV database to solve drug related problems (medication errors, product quality, lack of efficacy and ADR) in collaboration with PQM.

**Activity 5.5e**

Popularize PhV framework through workshops and trainings

**Activity 5.5f**

Provision of TA to FMHACA to strengthen active surveillance system (PhV)

**Sub-Objective 5.6**

Support FMHACA and RHBs to improve the quality of service given by Rural Drug Vendors (RDV)

**Activity 5.6a**

Provide training to RDVs in Oromia and other regions

**Activity 5.6b**

Revise/update RDV training materials

**Activity 5.6c**

Follow-up and support to trained RDVs

**Activity 5.6d**

Conduct assessment to examine RDVs training outcome

**Activity 5.6e**

Printing and distribution of RDV formularies

**Activity 5.6f**

Make an assessment and produce a proposal how to institutionalize the trainings and make them part of the requirement for re-registration

**Goal: Quarterly Report Fields**

These are the fields that will be used to collect information for quarterly reports.

Overall Quarter Progress

Current Value: **(Sep 2012)** - • USAID/SIAPS supported FMHACA to finalize and popularize the Medicines Waste Management and Disposal Directives and the National Strategic Framework on Medicines Waste Management. • USAID/SIAPS supported the Amhara Regional Health Bureau to draft a legal directive for the Drug Management and Pharmaceutical Service Delivery System. • The legal framework for the implementation of the Auditable Pharmacy Transaction System (APTS) was approved as a regulation by the Amhara State Government and Dire Dawa city council.

- Debre-Markos hospital implemented APTS and recorded the following outcomes:
  - o zero expiry of medicines during the budget year (2011-2012)
  - o The cost of slow-moving items decreased by 80%
  - o The number of slow moving medicines decreased 60% from 32 to 13
- The implementation of APTS at Debre-Markos hospital resulted in minimized wastages, effective and efficient utilization of budget, continuous availability of essential medicines, and allowed evidence-based decision making on utilization of current stock and future procurements.

- USAID/SIAPS has shifted hotel-based trainings to health institutions and local universities to promote the sustainability of interventions.
- SIAPS partnered with the School of Pharmacy of Jimma University to conduct in-service training in clinical pharmacy and pharmaceutical care from staff at sites implementing the Ethiopian Health Reform Implementation Guidelines
  - o The trained pharmacists are fully assigned to provide clinical pharmacy service in 28 (93%) of the 30 hospitals.

- USAID/SIAPS interventions and advocacy on clinical pharmacy training and practice has resulted in public hospitals sending their pharmacists to Jimma University for post graduate study in clinical pharmacy and paying for the entire training from their budget.
- USAID/SIAPS supported FMHACA to develop and render fully functional a pharmacovigilance database.
- As a result, FMHACA took regulatory measures on three

medicines (prednisolone and niclosamide tablets, and Ringer lactate intravenous solution 1000ml). FMHACA notified the manufacturer of niclosamide to temporarily stop manufacturing the medicine.

- An assessment of RDVs training in Oromia Region revealed sufficient results in all aspects of DSM and RDU. Overall RDV practice, in light of the training provided, was found to be satisfactory in most of the RDVs and ZHDs surveyed.

Key challenges faced during the quarter

Current Value: **(Sep 2012)** - Delay in signing of MOU with partners led to delayed implementation of joint work plan under COP11 Stakeholders not always responsive to the need for timely implementation of joint work plans Shortage of pharmacy professionals at health facilities as a result of high staff turnover

Key activities planned for next quarter

Current Value: **(Sep 2012)** - Pharmaceutical sector governance strengthened • Conduct pharmacy service standards & regulations dissemination/popularization workshops in collaboration with regulatory units of RHBs • Train RHB staff on standards and inspection to effectively implement the new Pharmacy standards • Produce concept paper to advocate revision/updating of the Ethiopian medicines policy and pharmacy administration in collaboration with EPA • Avail directives and guideline/SOP/tools to RHBs for adopting/adapting for effective implementation of APTS by HFs Capacity for pharmaceutical supply management and services increased • Scale up of in-service clinical pharmacy training • Provide ToRs, SOPs, checklists to RHBs and PFSA to strengthen existing DTCs and establish new ones • Produce document to organize and administer accredited continuing pharmaceutical education (CPE) • Establish Health Regulatory Information Center (HRIC) at FMHACA • Provide dispensing shelves and filing cabinets; and support minor renovation (PMI fund) Utilization of information for decision-making increased • Provide manual and electronic tools, maintain collection and use of ART (patient uptake and treatment regimen) & malaria related information • Provide on-the-job training and mentoring to sites with EDT to implement real time dispensing • Upgrade EDT to serve as a comprehensive dispensing tool for all essential medicines and patient categories, including those with chronic non communicable diseases (C-NCDs) Financing strategies and mechanisms to improve access to medicines strengthened • Provide onsite training and mentoring to health facilities to ensure effective implementation of APTS (optimize resource utilization for pharmaceuticals) • Organize best practice sharing events among target facilities Pharmaceutical services improved to achieve desired health outcomes • Provide supportive supervision and mentoring to promote effective utilization of health facility-specific medicines lists • Provide mentoring to conduct ABC value analysis and ABC/VEN reconciliation activities • Provide SOPs/guidelines and referral materials to scale up establishment and operation of Medicines Information Service (DIS) at hospitals • Develop AMR prescribing and dispensing policy at EHRIG implementing sites • In collaboration with Schools of Pharmacy, provide supportive supervision and mentoring to selected hospitals to implement clinical pharmacy & pharmaceutical care services • Organize face-to-face discussions to RHBs to capacitate facility DTCs to identify, prevent, manage and report ADRs • Organize regular meeting with FMHACA to examine the effective utilization of ADR/PV database, including those from WHO • Carryout cohort event monitoring/active surveillance system on ARVs, TB and Malaria medications in collaboration with WHO and other stakeholders • Distribute prescribing manual and electronic prescription forms to implement good prescribing practice • Provide mentoring to RHBs and HFs to implement good dispensing practice through DTCs using EHRIG sites as a pilot •

Provide IEC materials to PFSA, RHB and HFs to improve knowledge of patients on the use of medicines • Assist the National Advisory Committee on (NAC-AMR) to develop and implement work plan for effective execution of its responsibilities • Engage journalists to produce and disseminate articles on AMR containment for awareness creation among the public • Provide supportive supervision and mentoring to appraise, regulate and improve the service provided by RDVs

#### Technical Activity Coordination

Current Value: **(Sep 2012)** - Year two of USAID/SIAPS Country Operational Plan (COP12/FY13) has been prepared and submitted to SIAPS headquarters for comments. Based on the comments a final draft has been produced.

#### Office management

Current Value: **(Sep 2012)** - Year two of USAID/SIAPS Country Operational Plan (COP12/FY13) has been prepared and submitted to SIAPS headquarters for comments. Based on the comments a final draft has been produced.

#### **Quarterly Report Fields (Objective)**

Objective-level fields for collecting information for quarterly reports.

#### Quarterly Progress for Objective 1

Current Value: **(Sep 2012)** - • An assessment was conducted to identify local institutions that could run the Leadership Management and Governance Program (LMG). This will build the capacity of 60 managers of FMHACA, PFSA, the RHB Pharmacy Department and EPA. The scope of work was developed, a local institution selected, and a contract developed to permit the training to be delivered in the next reporting period • In the meantime, various activities that strengthen transparency, accountability and team work were implemented at FMHACA with financial support from USAID/SIAPS. • USAID/SIAPS also supported a consultative meeting between FMHACA and health professional associations. The meeting discussed professional ethics, continuing education, professional registration and licensing. • The meeting resulted in the signature of Memoranda of Understanding (MOUs) between FMHACA and health professional associations such that professional associations will provide accredited continuing education for registration and licensing.

- USAID/SIAPS supported the Amhara Regional Health Bureau to draft a legal directive for the Drug Management and Pharmaceutical Service Delivery System. The legal framework for APTS implementation approved by the regional council as a regulation. • Twenty four health facilities were selected by Regional Health Bureaus, PFSA and SIAPS for the implementation of APTS during the plan year. • The Dire Dawa Regional Health Bureau drafted a directive for the legalization of APTS, which was approved by the city council of Dire Dawa. • SNNPR and Tigray Regional Health Bureaus have adapted the APTS from Amhara RHB and are in the process of implementing it. • USAID/SIAPS prepared a guide to the implementation of 9 of 12 standards in the pharmacy (APTS) chapter of EHRIG • USAID/SIAPS supported the Oromia RHB to conduct four rounds of advocacy workshops for the Ethiopian health policy (EHRIG) (proclamation, guidelines and standards) for health professionals, judges, policemen, prosecutors and trade and commerce officers.

#### Quarterly Progress for Objective 2

Current Value: **(Sep 2012)** - • USAID/SIAPS supported the establishment of 30 new DTCs for a total of 46 (86% of the annual target) • USAID/SIAPS conducted on-site training of service providers (CEOs, DTC Chair, prescribers and dispensers) to establish drug information services at the hospital level. • USAID/SIAPS established drug information services in 10 facilities for an annual total of 20. (100% of the target). o Reference literature necessary for DIS pharmacists, computers, office furniture and accessories have been handed over to these facilities. • USAID/SIAPS conducted 2 pre-service ART/AMDM trainings at Gondar and Mekele universities and 67 graduating pharmacy students were successfully trained and certified. o The topics presented include: basic ART topics, AMDM; overview of DTC, EHRIG, APTS, and Good Dispensing Practice, new government initiatives and directions in the health sector, i.e., EHRIG, APTS, and DTC.

• USAID/SIAPS conducted two rounds of in-service training in clinical pharmacy/pharmaceutical care for EHRIG-implementing sites in collaboration with the School of Pharmacy of Jimma University o A total of 78 pharmacists were trained (130% of the annual target). • USAID/SIAPS developed and signed an MOU with the Ethiopian Pharmaceutical Association (EPA) to provide training in Pharmaceutical Ethics to 100 members of the EPA. o 48 pharmacists were trained for a total of 87. (87% of the annual target) • USAID/SIAPS finalized the 3 day APTS training curriculum for pharmacy professionals, CEOs, MDs, cashiers and accountants o Three rounds of training were held for 115 participants in the last quarter. • In general, a total of 2,362 professionals attended different in-service training events in this plan period (117% of the target set for the year). 33.1% were drawn from Amhara region, followed by Oromia region 16.9%; 42.4% of those who were trained were pharmacists.

#### Quarterly Progress for Objective 3

Current Value: **(Sep 2012)** - • USAID/SIAPS supported SOP trainings for 94 professionals in collaboration with university partners in various venues • USAID/SIAPS supported EDT training of participants from selected health facilities and some PFSA hubs. o In the reporting period, 108 health facilities received technical assistance on pharmaceutical management information system. This included; updating of antivirus programs; maintenance of computers and tools; fixing database problems and providing TA to improve data quality; on site demonstration of data recording, documentation and reporting using PMIS forms for new data clerks; and collection of monthly pharmacy ART patient up-take reports. • USAID/SIAPS conducted formal training sessions on EDT for 41 pharmacists/dispensers and 2 PFSA staff for a total of 115 (113% of the annual target). • USAID/SIAPS conducted onsite trainings for 34 dispensers on how to manage patient and pharmaceutical information using EDT, real-time dispensing and an orientation on basic functionalities of the tool • Currently, 71 health facilities conduct real-time dispensing using EDT (145% of the target set for the year). • USAID/SIAPS collected patient uptake and cumulative regimen data on a bi-monthly basis from 613 health facilities and compiled this for dissemination to USAID/ECDC, SCMS, Regional Logistic Associates (RLAs), RHB, I-TECH Ethiopia, Clinton Health Access Initiative (CHAI), regional HAPCO and JHU. o As a result of MSH/SIAPS report and presentation, the national ART technical working group is being reactivated to play an active role in monitoring current ART regimen. o USAID/SIAPS alerted partners that an unacceptably large percentage of new patients were being put on stavudine-based regimen as opposed to tenofovir-based regimens.

#### Quarterly Progress for Objective 4

Current Value: **(Sep 2012)** - • USAID/SIAPS organized consultative workshops on EHRIG/APTS in five

regions (Tigray, Dire Dawa, Harari, SNNP and Addis Ababa) to create awareness about EHRIG/APTS among representatives of the Regional Health Bureau (Regulatory core process, Auditing case team head, Curative and Rehabilitative core process, Pharmacy Case team, Deputy Head of RHB); Audit Bureau (Audit core process); Finance Bureau (Senior Finance officer) and from selected model health facilities. • USAID/SIAPS provided training on EHRIG-Pharmacy chapter and APTS to DTC sites to 246 professionals drawn from six regions (Amhara, SNNPR, Tigray, Dire Dawa, Harari and Addis Ababa) (146% of the annual target). • USAID/SIAPS printed and distributed 1,782 copies of the EHRIG pharmacy chapter to 20 hospitals • Debre-Markos hospital implemented APTS and recorded the following outcomes: o zero expiry of medicines during the budget year (2011-2012) o The cost of slow-moving items decreased by 80% from \$33,000 to \$6,700 o The number of slow moving medicines decreased 60% from 32 to 13 • The implementation of APTS at Debre-Markos hospital resulted in minimized wastages, effective and efficient utilization of budget, continuous availability of essential medicines, and allowed evidence-based decision making on utilization of current stock and future procurements. • USAID/SIAPS supported the extraction of the Ethiopian Health Centers Reform and Implementation Guidelines (EHRIG) was extracted from EHRIG by FMOH's Hospital Services Directorate in collaboration with the Ethiopian Pharmacy Association, and Addis Ababa University -Schools of Pharmacy. Once approved by the FMOH, the health center reform –pharmacy chapter will be printed and distributed to all health centers.

#### Quarterly Progress for Objective 5

Current Value: (**Sep 2012**) - • USAID/SIAPS supported FMHACA to draft, print and distribute 30,560 pads of 50 standard prescription forms to 24 EHRIG selected hospitals and briefed facility pharmacists on their use, storage and on-site printing. • USAID/SIAPS organized two meetings of the National Antimicrobial Resistance Prevention and Containment Advisory Committee in collaboration with FMHACA to discuss issues pertaining to different aspects of AMR activities including the national strategic framework for prevention and containment of Antimicrobial Resistance and progresses of AMR containment work, including AMR advocacy. • USAID/SIAPS supported FMHACA to provide training to 37 journalists (93% the target set for the year) to create awareness, sensitize and encourage media personnel to work on the prevention and containment of antimicrobial resistance. The journalists work on health programs of different federal and regional government print and electronic media. Similarly, articles/ IEC materials on RUM/AMR were provided for dissemination through the Drug Information Network Bulletin. • USAID/SIAPS supported awareness creation on pharmacovigilance in the form of face-to-face discussions in 29 public and private health facilities. A total of 478 service providers and 13 fourth-year pharmacy students participated in the discussions. Follow up visits were made to eleven health facilities to identify challenges and take corrective actions. USAID/SIAPS helped FMHACA to compile a Pharmacovigilance newsletter, which was printed and distributed. • During the reporting period, FMHACA received 79 reports of adverse drug events (ADE). Of these 71 were reports of adverse drug reactions (ADR) caused by medicines, two were medication errors, while six were reports attributed to product defect. These included four reports of periodic safety updates from well-known pharmaceutical firms like Roche and Astra Zeneca and two reports of adverse events following immunization. • USAID/SIAPS trained 315 rural drug vendors in seven rounds (105% of targets for the year); of which 16.2% were females and 72 (22.8%) were inspectors from regulatory body. The professional mix of the participants revealed that the majority were health assistants (38%) followed by nurses (24%) and druggists (16%). The training course is expected to build capacity in the areas of rational dispensing and patient counseling, proper management of pharmaceutical supplies (including anti-malarial medicines) as part of improving access to essential medicines,

regulatory affairs and raise the quality pharmaceutical services.

### **Quarterly Report Fields (Sub-Objective)**

Fields for reporting quarterly progress at the sub-objective level.

Quarterly progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - It was planned to provide training in leadership, management, supervision and team building to 60 managers of FMHACA, PFSA, RHB Pharmacy Department and EPA to enhance their leadership and management capacity. It was assumed that the Leadership Management and Governance Program (LMG) would kick off in Ethiopia by the end of the 2nd Quarter and thus SIAPS would use the expertise of LMG staff to conduct the trainings. As the launching of LMG project in Ethiopia was delayed, an assessment was conducted to identify local institutions that could provide training in Leadership and Management. The scope of work was developed and a local institution that provides trainings in Management and Leadership selected. A contract is now ready for signing with the winner company and the training will be delivered shortly. In the meantime, various activities that strengthen transparency, accountability and team work were implemented at FMHACA with financial support from USAID/SIAPS

Quarterly progress toward sub-objective 1.2

Current Value: **(Sep 2012)** - USAID/SIAPS also supported a consultative meeting that was held between FMHACA and health professional associations. The role of civil societies, such as professional associations, in promoting good governance is well established. During this consultative meeting, professional ethics, continuing education, professional registration and licensing were among the key issues raised and discussed. At the end of the consultation, a consensus was reached and MOUs signed between FMHACA and health professional associations that health professional associations should take the responsibility to provide accredited continuing education for registration and licensing. Four rounds of workshops on awareness creation on the Ethiopian health policy (proclamation, guidelines and standards) were organized in collaboration with ORHB for health professionals, judges, policemen, prosecutors and trade and commerce officers drawn from various woredas and zones of Oromia. The workshops discussed findings compiled during inspections of health services that reflected malpractices in clinical, laboratory, and radiology services; standards related to the safety of foods and quality of health services as well as measures for improvement were also discussed

Quarterly progress toward sub-objective 1.3

Current Value: **(Sep 2012)** - Pharmaceutical transactions involve a number of interdependent, multi-step activities, often involving numerous partners. This complexity, coupled with the large amount of money involved, makes pharmaceutical systems susceptible to mismanagement and corrupt practices. Implementation of the Ethiopian Hospitals Reform Guidelines (EHRIG) as a whole, and Auditable Pharmaceuticals Transactions and Services (APTS) in particular, is considered by USAID/SIAPS and government stakeholders to be a key intervention that improves pharmaceutical supply management and brings cost savings to health facilities medicines.

Twenty four health facilities were selected by Regional Health Bureaus, PFSA and SIAPS for the implementation of APTS during the plan year. USAID/SIAPS took the lead in collaborating with the Amhara Regional Health Bureau to draft a directive for Drug Management and Pharmaceutical Service Delivery System. A consultative

workshop was held to enrich the document by professionals in the area of legislation, audit, finance, pharmacy and public health. The draft legal frameworks for APTS implementation that was submitted to the regional council was approved as a regulation.

In a similar attempt, the Dire Dawa Regional Health Bureau drafted a directive for the legalization of APTS, which was duly approved by the city council of Dire Dawa. SNNPR and Tigray Regional Health Bureaus have adapted the APTS from Amhara RHB and are in the process of implementing it. Implementation of this activity was accomplished as planned. USAID/SIAPS facilitated experience-sharing tours to the model APTS-implementing site at Debre-Markos Hospital, Amhara Region, by officials from SNNPR, Harari and Dire Dawa Administration Health, Finance and Audit Bureaus. These visits provided officials from different regions of the country evidence-based solutions to increase accountability, transparency and efficiency during the procurement and dispensing of pharmaceuticals and medical supplies.

Following the visits to Debre-Markos Hospital, five EHRIG/APTS consultative workshops were conducted in collaboration with SNNPR, Harari and Dire Dawa Administration Health Bureaus. During the consultative meetings, drafting of the legal framework and implementation of APTS and EHRIG, designing of APTS vouchers and dispensing registers that are in line with the requirements of the respective regions was discussed. A guide for implementation of pharmacy chapter/APTS has been prepared and serves as a standard operating procedure for 9 standards of the 12 standards stipulated in the pharmacy chapter of EHRIG.

#### Quarterly progress toward sub-objective 2.1

Current Value: (**Sep 2012**) - USAID/SIAPS has been working with PFSA and RHBs to strengthen the establishment and institutionalization of DTCs throughout the country. In the reporting period, a total of 43 (30) new DTCs have been established (86% of the target set for the year), of which 12 DTCs were established in private health facilities. Whereas the setting up of DTCs is a relatively easy task, getting the commitment of health facility leaders and responsible pharmacists to implement the extended role of DTCs to ensure ownership and sustainability requires supportive supervision and mentoring.

USAID/SIAPS in collaboration with PFSA, supported hospital DTCs to develop, print and launch facility-specific medicines lists. In this plan year, USAID/SIAPS provided technical and financial assistance to 22 health facilities in the preparation and printing of health facility-specific medicines lists (110% of the target set for the year) Technical assistances were provided to DTCs to conduct ABC/VEN analysis which helps the facility to evaluate their resource utilization, identify gaps and design intervention through developing systems for proper selection, quantification, procurement, distribution and use of medicines. SOP for compounding was also drafted to help some hospitals strengthen pharmacy services: 18 facilities conducted ABC analysis, 74 facilities VEN analysis, 10 facilities performed ABC/VEN reconciliation, and 17 facilities conducted prescription review.

Eight rounds of regional workshops on selecting and developing a list of pharmaceuticals that hospitals and health centers want to procure from PFSA, along with the different methods used to estimate and quantify facility needs for pharmaceuticals and supplies, were conducted in collaboration with PFSA and RHBs. The workshops helped health professionals to identify gaps and challenges in pharmaceutical supply and services, create awareness on pharmaceuticals selection and quantification and identify next steps on how to improve pharmaceutical supply and services in their facilities. The workshops

further dealt with the extended role of DTCs to own and sustain all medicines-related activities and facility-specific work plan development.

#### Quarterly progress toward sub-objective 2.2

Current Value: **(Sep 2012)** - Similarly, on-site trainings were provided to service providers (CEOs, DTC Chair, prescribers and dispensers) to establish drug information services at the hospital level. In the plan period, drug information services were established in a total of 20 health facilities, (100% of the target set for the year). A set of Reference literature necessary for DIS pharmacists, computers, office furniture and accessories have been handed over to these facilities.

#### Quarterly progress toward sub-objective 2.4

Current Value: **(Sep 2012)** - In the last quarter, 2 pre-service ART/AMDM trainings were successfully conducted at Gondar and Mekele universities and all (67 graduating pharmacy students) were successfully trained and certified. The topics presented include: basic ART topics (as per the standard in-service ART training curriculum); AMDM; overview of DTC, EHRIG, APTS, and Good Dispensing Practice. The trainees were familiarized with new government initiatives and directions in the health sector, i.e., EHRIG, APTS, and DTC. Upon deployment to health facilities, these freshly-graduated pharmacists will join the work force ready to provide services in ART and Anti-malarial medicines management.

Two rounds of in-service training in clinical pharmacy/pharmaceutical care were conducted for EHRIG-implementing sites in collaboration with the School of Pharmacy of Jimma University. The main purpose of this activity was to train pharmacists in clinical pharmacy to kick-start patient-centered pharmacy services in targeted hospitals with the purpose to optimize treatment and improve health outcomes. A total of 78 pharmacists have been trained period (130% of the annual target).

The Ethiopian Pharmaceutical Association (EPA) has prepared a code of ethics and standard of practice for its members to follow. To help EPA's efforts in the implementation of ethical practice, USAID/SIAPS had entered into an MOU to provide training in Pharmaceutical Ethics to 100 members of EPA in the reporting quarter 48 pharmacists were trained bringing the total to 87 trained (87% of the annual plan). In general, a total of 2,362 professionals attended different in-service training events in this plan period (117% of the target set for the year). Of which nearly a quarter (24.8%) were females, and 17.7% and 15.5% of the trainees participated in Standard Operating Procedure-manual (SOPm) and RDV trainings, respectively. The majority of the trainees (33.1%) were drawn from Amhara region, followed by Oromia region (16.9%); 42.4% of those who were trained were pharmacists.

#### Challenges in progress toward sub-objective 2.5

Current Value: **(Sep 2012)** - USAID/SIAPS supported FMHACA to develop medicines waste management and disposal directives and a national framework to implement these directives. Five popularization workshops (83%) were conducted so far to familiarize key stakeholders drawn from Amhara, Oromia, Tigray and Addis Ababa Regional States. The objective of the workshop was to familiarize stakeholders on ways of protecting the health of the public and safeguarding the environment from contamination by hazardous waste. The workshop outlined ways for the safe disposal of medicines waste, cost effective and safe disposal methods based on international best practices, roles and responsibilities of stakeholders working at different levels, importance of complying with the national disposal directives, and the potential role of the private

sector in medicines waste management and disposal.

Quarterly progress toward sub-objective 3.2

Current Value: **(Sep 2012)** - Patient uptake data and cumulative regimen breakdown have been collected on bi-monthly basis from 613 health facilities and compiled for dissemination.. The information generated was shared with USAID/ECDC, SCMS, Regional Logistic Associates (RLAs), RHB, I-TECH Ethiopia, Clinton Health Access Initiative (CHAI), regional HAPCO and JHU. As a result of MSH/SIAPS report and presentation, the national ART technical working group is being reactivated to play an active role in monitoring current ART regimen. SIAPS was able to bring to the attention of USAID, CDC, implementing partners, FMOH and stakeholders that unacceptably large percentage of new patients were being put on Stavudine-based regimen as opposed to tenofovir-based regimen, which is what the guidelines recommends. This intervention by USAID/SIAPS has been highly appreciated both by CDC and USAID.

Quarterly progress toward sub-objective 4.1

Current Value: **(Sep 2012)** - Pharmaceutical transactions and services at health facilities in Ethiopia are not supported with adequate tools and systems that ensure transparency and accountability. The existing system doesn't generate adequate, reliable and consistent information that are relevant for effective auditing of pharmaceutical transactions and services. It also does not allow tracing the quantity and price of medicines that are dispensed, lost or damaged; the same is true to transferred medicines. Consultative workshops on EHRIG/APTS were organized in five regions (Tigray, Dire Dawa, Harari, SNNP and Addis Ababa) to create awareness about EHRIG/APTS among representatives of the Regional Health Bureau (Regulatory core process, Auditing case team head, Curative and Rehabilitative core process, Pharmacy Case team, Deputy Head of RHB); Audit Bureau (Audit core process); Finance Bureau (Senior Finance officer) and from selected model health facilities.

Similarly, training on EHRIG-Pharmacy chapter and APTS to DTC sites was provided to 246 professionals drawn from six regions (Amhara, SNNPR, Tigray, Dire Dawa, Harari and Addis Ababa) using training curriculum and manual developed for the purpose (146% of the plan). The observed achievement over the plan target was due to frequent request and demand for this training by the RHBS. In order to popularize and increase awareness about changes in pharmaceutical services, 1,782 copies of the EHRIG pharmacy chapter booklets were printed and distributed by USAID/SIAPS to 20 hospitals.

As a result of introducing and implementing EHRIG-Pharmacy chapter and APTS in targeted hospitals, the following notable results have been achieved. Debre-Markos hospital experienced no expiry of medicines during the budget year (2011-2012) as a result of frequent stock status analysis using APTS tools. The cost of slow-moving items decreased from Birr 593,502.67 to Birr 120,270.94, while the number of such medicines decreased from 32 to 13. Implementation of the system enabled the health facility to minimize wastages and ensure effective and efficient utilization of budget, ensured continuous availability of essential medicines, allowed evidence-based decision making on utilization of current stock and future procurements.

The Ethiopian Health Centers Reform and Implementation Guidelines (EHCRIG) was extracted from EHRIG by FMOH's Hospital Services Directorate in collaboration with USAID/SIAPS, Ethiopian Pharmacy Association, and Addis Ababa University -Schools of Pharmacy. Once approved by the FMOH, the health center reform –pharmacy chapter

will be printed and distributed to all health centers.

Quarterly progress toward sub-objective 5.1

Current Value: **(Sep 2012)** - Standardized prescription papers are important tools to promote the rational use of medicines and establish responsibility and accountability during the prescribing and dispensing of medicines. The absence or shortage of standard prescription papers in health facilities has been identified as one of the major challenges and gaps preventing the provision of quality services. In some facilities that used official prescription papers, there were inconsistencies and variations in the content of the prescription papers, which demonstrated a lack of standards. Recognizing these facts, FMHACA in Collaboration with USAID/SIAPS drafted standard prescription forms and printed the forms for selected hospitals of the country to use and showcase for further replication. 30,560 pads of 50 pages standard prescription were distributed to 24 EHRIG selected hospitals and brief orientation on the use, storage and on-site production (printing) of the prescription papers was given to facility pharmacists.

Quarterly progress toward sub-objective 5.4

Current Value: **(Sep 2012)** - USAID/SIAPS organized two meetings of the National Antimicrobial Resistance Prevention and Containment Advisory Committee in collaboration with FMHACA to discuss issues pertaining to different aspects of AMR activities including the national strategic framework for prevention and containment of Antimicrobial Resistance and progresses of AMR containment work, including AMR advocacy. To create awareness, sensitize and encourage media personnel to work on the prevention and containment of Antimicrobial resistance, USAID/SIAPS in collaboration with FMHACA provided training to 37 journalists working on health programs of different federal and regional government print and electronic media, such as radio and television(93% the target set for the year).

Objectives of the training were to provide information on prevention and containment of AMR and Rational Use of Medicines practice RUM and AMR information abstraction and dissemination to the public; discuss the challenges faced in educating the public about RUM/AMR using their respective media outlets; develop plan of action to increase awareness of the public on AMR and to agree on follow-up meetings. Similarly, articles/ IEC materials on RUM/AMR were provided for dissemination through the Drug Information Network Bulletin. Awareness creation on pharmacovigilance was carried out in the form of face-to-face discussions in 29 public and private health facilities. A total of 478 service providers and 13 fourth-year pharmacy students participated in the discussions. Follow up visits were made to eleven health facilities to identify challenges and take corrective actions. USAID/SIAPS helped FMHACA to compile a Pharmacovigilance newsletter, which was printed and distributed

Quarterly progress toward sub-objective 5.5

Current Value: **(Sep 2012)** - Awareness creation on pharmacovigilance was carried out in the form of face-to-face discussions in 29 public and private health facilities. A total of 478 service providers and 13 fourth-year pharmacy students participated in the discussions. Follow up visits were made to eleven health facilities to identify challenges and take corrective actions. USAID/SIAPS helped FMHACA to compile a Pharmacovigilance newsletter, which was printed and distributed. The total number of Adverse drug event (ADE) reports received by FMHACA during 2004 E.C were 79, of which 71 were reports of adverse drug reactions (ADR) caused by medicines, two were medication errors, while six were reports attributed to product defect. These included four reports of periodic

safety updates from well-known pharmaceutical firms like Roche and Astra Zeneca and two reports of adverse events following immunization.

## **GUINEA**

Guinea work plan details for Year 1 of the SIAPS Program

### **Quarterly Report Background**

More than 90% of the clinical cases of malaria each year occur in Africa, with much of the burden in children under five years of age. Strategies to address these challenges must be implemented in collaboration with programs aimed at integrated approaches to childhood illness and reproductive health and assuring that quality medicines are available and used appropriately.

Guinea is a West African country where malaria is endemic to the whole territory. In 2005, Guinea changed its malaria treatment policy to include an artemisinin-based combination therapy (ACT), artesunate-amodiaquine (ASAQ) as first-line treatment for uncomplicated malaria. To date, funding for procurement of ASAQ has been through the Global Fund Round 6 grant in 2009 and more recently the President's Malaria Initiative (PMI). The first consignment of approximately three million treatments of ASAQ arrived in country in 2009 with subsequent PMI-procured treatments in 2011. ASAQ has been distributed to almost 1300 public sector health facilities in Conakry and in all 38 prefectures. Treatments have been provided to beneficiaries at no-cost.

Prior to the arrival of PMI-procured ACTs in late 2011, health facilities experienced stock-outs of ASAQ for about 6 months. In addition to political instability in Guinea, there were delays in implementing Global Fund Round 6 planned activities and subsequently delays in fund disbursement for phase 2 of the Round 6 grant, which led to the stock-outs. Furthermore, an inefficient information system which prevented appropriate decision making and limitations of the central medical store (PCG) to provide essential medicines to the health facilities' in a timely and effective manner contributed to the stock-outs.

The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, implemented by Management Sciences for Health (MSH)'s Center for Pharmaceutical Management, has received funds from PMI to provide technical assistance to improve supply chain management and logistics management information systems alongside other partners. In addition, PMI expects SIAPS to support the improved performance of the pharmaceutical system and create conditions for PCG and other key health systems structures to ensure that malaria commodities are distributed to health facilities in a timely manner to avoid recurrent stock-outs. This support is intended to facilitate the implementation of Guinea's national malaria policies. While this is the first support from USAID Guinea directly to SIAPS for assistance in strengthening pharmaceutical systems, SIAPS will build on appropriate lessons and work conducted under its predecessor program Strengthening Pharmaceutical Systems (SPS) in other PMI beneficiary countries, as well as other MSH programs in Guinea, such as Pour Renforcer les Interventions en Sante Reproductive et MST/SIDA (PRISM) and Extending Service Delivery (ESD).

PMI has provided \$1,000,000 to SIAPS for fiscal year 2011.

### **Goal: Guinea Year 1 Work Plan Goal**

Improved Access to pharmaceuticals and services

#### **Objective 1**

Pharmaceutical sector governance strengthened

#### **Sub-Objective 1.1**

Improved ability of the Direction Nationale de la Pharmacie et des Laboratoires (DNPL) to regulate the pharmaceutical system

**Activity 1.1.1**

Conduct an exploratory visit to assess the situation of the pharmaceutical system in the country

**Activity 1.1.2**

Assist the DNPL in performing an institutional assessment, and create an action plan for implementing assessment recommendations.

**Sub-Objective 1.2**

Improved medicines policies, legislation, and regulations

**Activity 1.2.1**

Provide technical assistance to the DNPL to establish a committee and process for revising the National Essential Medicines List.

**Sub-Objective 1.3**

Improved governance in the pharmaceutical management

**Activity 1.3.1**

Organize a roundtable of stakeholders in the pharmaceutical sector, develop an action plan and begin implementing recommendations from the plan focused on improving coordination

**Objective 2**

Capacity for pharmaceutical supply management and services increased and enhanced

**Sub-Objective 2.1**

Inventory and pharmaceutical management capacity of individuals and institutions strengthened

**Activity 2.1.1**

Update pharmaceutical management tools and training materials of the DNPL

**Activity 2.1.2**

Training of trainers at the central level and regional level on inventory and pharmaceutical management and create a plan for cascade training

**Activity 2.1.3**

Establish and render functional a mechanism (committee) for quantifying, forecasting and supply planning of antimalarials

**Objective 3**

Pharmaceutical management information is available and used for decision-making

**Sub-Objective 3.1**

Pharmaceutical management systems (PMIS) support both products and patients

**Activity 3.1.1**

Implement measures to improve the communication capacity of key actors in the pharmaceutical sector

**Activity 3.1.2**

Conceptualize a PMIS that will allow data on stock levels and consumption to flow from health centers to the Central level

**Activity 3.1.3**

Establish and support a regional mechanism for collecting, analyzing and transmitting pharmaceutical management data

**Objective 4**

Pharmaceutical services improved to achieve desired health outcomes

**Sub-Objective 4.1**

Availability of pharmaceuticals improved

**Activity 4.1.1**

Initiate and coordinate corrective actions to address stock outs and overstocks of malaria commodities

**Sub-Objective 4.2**

Improved case management

**Activity 4.2.1**

Assist the NMCP and the DNPL in revising the national clinical case management strategy management

**Quarterly Report Fields (Objective)**

Objective-level fields for collecting information for quarterly reports.

Quarterly Progress for Objective 1

Current Value: (**Sep 2012**) - During Q4 two SIAPS consultants conducted an assessment of the National Medicines Regulatory Authority using the Regulatory System Assessment Tool (RSAT). In the course of the assessment, Hody and Blanchot conducted interviews with DNPL staff, interviews with other key actors in the pharmaceutical sector such as the Pharmacie Centrale de Guinée (PCG), the National Pharmaceutical Society (Ordre National des Pharmaciens Privés de Guinée) the legal counsel of the Minister of Health, and the Health Inspectorate. Donors such as USAID, the European Union were interviewed. Additionally, and technical partners such as the World Health Organization (WHO), the United Nations Population Fund (UNFPA), the United Nations Children's Fund (UNICEF) were also interviewed. These interviews were conducted between July 2-8,

2012.

In the course of these interviews, data were collected and captured into the RSAT questionnaire, and legal, administrative and technical documents relevant to the assessment were collected. The consultants analyzed and critiqued documents collected, and conducted a systemic analysis of the public sector supply chain system for pharmaceuticals with particular emphasis on the DNPL and the PCG. They also conducted a functional analysis of the institutions in Guinea's public sector involved in pharmaceutical regulation (Commission National du Médicament, Laboratoires de Contrôle de Qualité des Médicaments, Pharmacovigilance, Inspection pharmaceutique). The consultants also reviewed the role of non-state actors such as UNICEF and UNFPA in the supply of pharmaceuticals.

On July 12, Hody and Blanchot presented the preliminary results of the assessment to the Ministry of Health at a meeting presided by the Secretary General of the Ministry of Health. Present at this dissemination meeting were the Minister of Health's Chief of Staff, the Inspector General, the Director for the National Quality Control Laboratory, USAID Health Team staff, various Division Directors of the Ministry of Health (Pharmaceutical Services, Hospitals and Health Services, Prevention and Community Health, Human Resources), Directors of the National Malaria and HIV/AIDS programs, the institutions involved in meetings were held with the DNPL staff, Meetings were also held with the Minister of Health, and the Secretary General of the Ministry of Health.

Following the dissemination, the consultants and the SIAPS Country Project Director met with a representative of the European Union and the Minister of Health, Dr. Naman Keita to brief them on the findings. On July 13, the consultants debriefed the USAID/Guinea Health Team on the assessment findings. Present at the debriefing from the USAID Health Team were: Mr. Neil Woodruff, Health Team Leader, Dr. Nashat Hanafi, PMI Advisor, Dr. Lamine Bangoura, PMI Specialist, Dr. Marouf Baldé, Public Health Specialist and Mr. Alpha Diallo, Program Advisor.

#### Quarterly Progress for Objective 2

Current Value: **(Sep 2012)** - SIAPS/Guinea contributed to IR 2 (Capacity for pharmaceutical supply management increased and enhanced) through the review of pharmaceutical management tools used in Guinea's health system, the review of training materials, and through SIAPS/Guinea participation in the training of trainers activity organized by the Medicines for all Initiative. However, much is still to be done to increase the National Malaria Control program's capacity in quantification, forecasting and supply planning. Capacity building activities conducted by SIAPS in Y2 will make this area of capacity building a priority.

#### Quarterly Progress for Objective 3

Current Value: **(Sep 2012)** - Significant progress was made by SIAPS/Guinea toward the IR of ensuring the pharmaceutical management information data are available and used for decision making. This was possible because SIAPS/HQ mobilized a 3-person technical assistance to travel to Guinea between 20 August and 7 September to accelerate implementation of a number of activities under this Objective. The key focus was to conceptualize PMIS/LMIS for Guinea in collaboration with key stakeholders and agree on a plan for implementing it. The team had also planned to provide support for implementing a baseline survey to collect data on malaria commodity management and case management practices.

Upon arrival, however, the team was met with other PMI/NMCP priorities, including the

request for assistance with organizing an emergency distribution of antimalarials procured by PMI. The team therefore provided assistance to the USAID/Guinea mission to prepare for this emergency distribution for which products began arriving in October 2012. The STTA team made the strategic decision to use the emergency distribution should be used as an entry point to jumpstart the creation of a logistics management information system for malaria commodities by. This was to be done by ensuring that an initial tranche of commodities be delivered to health facilities in line with needs expressed by the facilities. In order to receive resupply, health facilities would subsequently have to submit LMIS reports to the Ministry of Health.

With past emergency distributions, the MoH had not insisted on receiving consumption reports from health facilities in order to be resupplied. During the technical assistance trip, SIAPS did manage to discuss options for organizing a malaria commodity LMIS. The team also managed to conduct a review of existing forms, registers and stock cards currently used in Guinea's health system in collaboration with the National Malaria Control Program and the Department of Pharmaceutical Services in preparation for the introduction of a malaria commodity LMIS. The system for quarterly active data collection of malaria commodities is yet to be put in place by SIAPS/Guinea. This can be put in place once implementation of the LMIS is underway. During Y2, SIAPS will conduct the national stakeholder workshop to reach consensus on the LMIS systems option proposed and to agree on next steps and a timeline.

#### Quarterly Progress for Objective 4

Current Value: (**Sep 2012**) - SIAPS/Guinea contributed to IR 4 (Pharmaceutical services improved to achieve desired health outcomes Activity 4.1.1) through its work with USAID/Guinea to prepare the distribution plan for the malaria commodities whose expected arrival dates were in October and November 2012 and to make all arrangements for distribution the products to health zones. Making arrangements for distribution was also to include coordinating corrective actions to address stock outs and overstocks of malaria should these circumstances be encountered once distribution teams were in the field.

#### **Quarterly Report Fields (Sub-Objective)**

Fields for reporting quarterly progress at the sub-objective level.

#### Quarterly progress toward sub-objective 1.1

Current Value: (**Sep 2012**) - SIAPS made significant progress on this sub IR focused on improving the ability of Guinea's National Medicines Regulatory Authority known as the Direction Nationale de la Pharmacie et des Laboratoires (DNPL) to regulate the pharmaceutical sector. During Q4 two SIAPS consultants specialized in regulatory matters and pharmaceutical law conducted an assessment of the National Medicines Regulatory Authority using the Regulatory System Assessment Tool (RSAT). Between July 2-8, 2012, the consultants conducted interviews with DNPL staff, interviews with other key actors in the pharmaceutical sector such as the Central Medical Stores, the National Pharmaceutical Society, the legal counsel of the Minister of Health, and the Health Inspectorate. Donors such as USAID, the European Union were interviewed. Additionally, and technical partners such as the World Health Organization (WHO), the United Nations Population Fund (UNFPA), the United Nations Children's Fund (UNICEF) were also interviewed.

In the course of these interviews, data were collected and captured into the RSAT questionnaire, and legal, administrative and technical documents relevant to the

assessment were collected. The consultants analyzed and critiqued documents collected, and conducted a systemic analysis of the public sector supply chain system for pharmaceuticals with particular emphasis on the DNPL and the PCG. They also conducted a functional analysis of the institutions in Guinea's public sector involved in pharmaceutical regulation (Commission National du Médicament, Laboratoires de Contrôle de Qualité des Médicaments, Pharmacovigilance, Inspection pharmaceutique). The consultants also reviewed the role of non-state actors such as UNICEF and UNFPA in the supply of pharmaceuticals.

On July 12, Hody and Blanchot presented the preliminary results of the assessment to the Ministry of Health at a meeting presided by the Secretary General of the Ministry of Health. Present at this dissemination meeting were the Minister of Health's Chief of Staff, the Inspector General, the Director for the National Quality Control Laboratory, USAID Health Team staff, various Division Directors of the Ministry of Health (Pharmaceutical Services, Hospitals and Health Services, Prevention and Community Health, Human Resources), and Directors of the National Malaria and HIV/AIDS programs. Following the dissemination, the consultants and the SIAPS Country Project Director met with a representative of the European Union and the Minister of Health, Dr. Naman Keita to brief them on the findings.

On July 13, the consultants debriefed the USAID/Guinea Health Team on the assessment findings. Present at the debriefing from the USAID Health Team were: Mr. Neil Woodruff, Health Team Leader, Dr. Nashat Hanafi, PMI Advisor, Dr. Lamine Bangoura, PMI Specialist, Dr. Marouf Baldé, Public Health Specialist and Mr. Alpha Diallo, Program Advisor. The consultants returned to Guinea in September 2012 at which time they disseminated assessment results through a national workshop and obtained stakeholder consensus around the recommendations for improving the functioning of the DNPL. The immediate next step will be to begin implementing the recommendations aimed at improving the basic functioning of the DNPL.

#### Challenges in progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - Although USAID was present for the opening of the dissemination workshop, the USAID representative left the workshop prior to the discussion concerning mobilization of resources for implementing evaluation recommendations. No other donors attended the dissemination meeting. This was therefore a lost opportunity to coordinate priorities among donors in funding various aspects of implementation of recommendations to strengthen the functioning of the DNPL.

#### Deliverables: Sub-Objective 1.1

Current Value: **(Sep 2012)** - 1. Report of the evaluation of the DNPL

#### Quarterly progress toward sub-objective 1.3

Current Value: **(Sep 2012)** - Much progress was made on sub IR 1.3 which focuses on improved coordination of partners in procurement and distribution of malaria commodities. At the beginning of Q4, SIAPS activities in coordination had slowed down considerably, and there had been little follow up in implementing recommendations from the Roundtable discussions that had occurred at the end of Q2. During the TDY conducted by the SIAPS HQ-based Portfolio Manager, dialogue was reestablished with in country partners (such as the National Malaria Control Program, the DNPL and the Central Medical Stores) for whom it is important to coordinate with SIAPS. A clear message from all partners was

the need for SIAPS to be more visible and participatory in the Medicines for All Initiative, an initiative currently led by the Central Medical Stores to improve pharmaceutical management at all levels of the health system by training trainers from the central and regional level of the health system who will in turn execute a cascade training that will extend to all 400+ of Guinea's health facilities. Visit by PM included meetings with CMS Director, PNLP staff and DNPL Deputy Director. SIAPS rededicated itself to participating in Medicines for all initiative.

#### Quarterly progress toward sub-objective 2.1

**Current Value: (Sep 2012)** - During Q4, SIAPS/Guinea made progress on this sub-objective, which focuses on strengthening the inventory and pharmaceutical management capacity of individuals and institutions. Activities that were to be implemented to move SIAPS/Guinea toward achieving this objective included: Updating pharmaceutical management tools and training materials of the DNPL; training of trainers at the central level and regional level on inventory and pharmaceutical management and create and monitor a plan for cascade training and; establishing and rendering functional a mechanism (committee) for quantifying, forecasting and supply planning of antimalarials.

During Q4, SIAPS/Guinea reviewed the existing tools being used to record and transmit health commodity data for Guinea's and shared with key Government of Guinea partners in the course of meetings held during the TDY. However, the finalization of tools and of the LMIS implementation plan through a workshop had to be postponed to a later time (ultimately until December 2012), to define the way forward for Guinea malaria commodity management. SIAPS/Guinea participated in and contributed financially to the training of trainers on inventory and pharmaceutical management. The training activity was led by the Medicines for All Initiative. However, the training plan for cascade training has not been finalized. However, no progress was made on formalizing the committee for quantifying forecasting and supply planning of malaria commodities.

#### Challenges in progress toward sub-objective 2.1

Deliverables: Sub-Objective 2.1

#### Quarterly progress toward sub-objective 3.1

**Current Value: (Sep 2012)** - SIAPS/Guinea's made progress toward achieving Sub-IR 3.1 (Pharmaceutical management information systems (PMIS) support both products and patients) by starting the process of creating a pharmaceutical management information system for malaria commodities during Q4. A team of three persons that travelled to Guinea between August 20 and September 7 was instrumental in starting this process by first conceptualizing a malaria commodity management information system for the Ministry of Health based on the experience with existing tools, potential for enhancement and user-friendliness. The conceptualization of the system was based on the numerous discussions held between SIAPS, the NMCP, the DNPL, the PCG and the NHIMS during a TDY conducted by SIAPS HQ and regional staff in between August 20 and September 7, 2012. By the end of September, this system is remained a proposal which needed to be discussed and agreed to by key stakeholders during a stakeholder workshop (ultimately held in December 2012).

- SIAPS/Guinea reviewed existing tools in use and included in the technical working group (TWG) and Medicines for All project documents. Based on the review of existing

tools prepared tools options analysis document, SIAPS/Guinea made a presentation of the same to the TWG, which the TWG considered as important input to the review process. SIAPS/Guinea established an operational plan for implementing a modified EUV survey. A member of the STTA who had previously led an End User Verification Survey (EUVS) provided a detailed orientation to local SIAPS consultant identified for recruitment on EUV survey methodology. Additionally, the STTA team helped the SIAPS Country Director to identify specific target facilities for the provision of computers and printers.

#### Challenges in progress toward sub-objective 3.1

Current Value: (**Sep 2012**) - Availability of Ministry of Health staff to implement all activities related to establishing the logistics management information system (LMIS) resulted in delays in validating the LMIS concept and thereby proceeding with implementation of the new system. This was particularly true during the STTA that took place from August 20-September 7, 2012,

#### Deliverables: Sub-Objective 3.1

#### Quarterly progress toward sub-objective 4.1

Current Value: (**Sep 2012**) - SIAPS/Guinea made significant contributions to sub-objective 4.1 (Availability of pharmaceuticals improved) by responding to a request from USAID/Guinea to develop a distribution plan for the distribution of malaria commodities (ACTs and rapid test kits) purchased by USAID on an emergency basis for distribution 185 health facilities. This emergency procurement was done by USAID/Guinea to address chronic stockouts caused by delayed disbursement of funds to Global Fund Principal Recipients for malaria grants in Guinea. SIAPS/Guinea will use this distribution exercise as a mechanism to jumpstart reporting on malaria stocks which will be a key element of the malaria commodity information system that SIAPS/Guinea plans to create. Expected arrival dates for the malaria commodities were in October and November 2012.

SIAPS/Guinea developed a concept proposal for supplemental activities to be conducted by SIAPS with a focus on the emergency distribution, monitoring and reporting on PMI provided anti-malaria products. SIAPS/Guinea also developed a detailed emergency distribution plan for the commodities purchased by PMI which were due to arrive in the coming week. SIAPS/Guinea also with the plan tools for baseline data collection and distribution/reporting from all the health facilities. Finally, the scope of work for the local consultant that SIAPS/Guinea was about to hire was revised to include providing support to emergency distribution of malaria commodities, as well as active monthly stock status and consumption reporting and use of continuous results monitoring (CRM) checklist.

#### Challenges in progress toward sub-objective 4.1

Current Value: (**Sep 2012**) - Challenges to implementing this sub-objective centered on slowness by the MoH in validating the iCCM strategy and activating the Steering Committee. Additionally, the currently limited staff in the SIAPS/Guinea team (only 1 full time technical staff recruited by September 30, with another recruitment for a local Senior Technical Advisor underway) made it difficult for SIAPS/Guinea to effectively contribute to iCCM developments and meetings.

#### Deliverables: Sub-Objective 4.1

Current Value: **(Sep 2012)** - 1. Plan for distributing malaria commodities purchased by PMI and arriving in October and November, 2012. 2. Concept note for additional malaria commodity management activities not in current work plan but needed to ensure availability of pharmaceuticals in all USAID-focus areas 3. Revised local consultant scope of work which includes emergency distribution activity.

Quarterly progress toward sub-objective 4.2

Current Value: **(Sep 2012)** - Little progress had been made of this sub-objective (improved case management) in the previous quarter (Q3). During Q4, SIAPS/Guinea made some progress by reestablishing communication with MCHIP which is a key partner on integrated communication case management (iCCM), which includes community case management of malaria. During a TDY implemented by Christine Onyango in August 2012, Christine Onyango and Serigne Diagne held a lengthy discussion with key MCHIP staff to discuss collaboration on integrated community case management (iCCM) activities in Guinea to determine how SIAPS/Guinea should intervene next.

The first element needed to implement iCCM in Guinea was to update the policy on iCCM to ensure that community health workers (CHWs) could engage in both health promotion and curative activities. A workshop to for technical validation of the updated policy was held on July 15, but the workshop for political validation was still to happen in the coming weeks in August. CHWs are to deliver an integrated package for iCCM in Guinea, to address fever, diarrhea, nutrition and pneumonia. Commodities required to deliver this package of services will include zinc and oral rehydration salts (ORS) for treating diarrhea, rapid malaria test kits (RDTs) and ACTs for diagnosing and treating malaria and antibiotics (amoxicillin) for treating pneumonia. The focus on nutrition will be on detection of nutritional problems and appropriate referrals. Additionally, CHWs will be trained to provide injectable contraceptives at the community level.

MCHIP has followed up with the Ministry of Health (Direction Nationale de la Prevention et de la Santé Communautaire) to hold the technical validation meeting. Once this meeting occurs, MCHIP will proceed to training community health workers in September 2012. A Steering Committee (SC) had existed in the past to provide a mechanism for implementing iCCM activities, but the Ministerial decree creating this committee could not be located. The SC therefore had to be reconstituted. A meeting was planned during the week of August 20-24 by the SC to validate the implementation guide for integrated management of childhood illnesses, but this meeting was rescheduled to September (dates were to be announced). A workshop had occurred on June 7-8, 2012 to harmonize tools to be used by CHWs for iCCM, including stock cards, patient records and registers. Training modules for CHWs had already been developed and validated. Once the training was completed, MCHIP would oversee 20 health centers (each with five CHWs).

The next steps in implementing the iCCM strategy are: 1. Training of of 100 CHWs during the first half of September 2012 focused on fever in children (malaria diagnosis using TDRs and in malaria treatment using ACTs). These CHWs are located in Conakry, Boke, Dinguiraye and Fokekaya b. Faions Ensemble (project managed by the RTI) to conduct a similar training in 10 prefectures 2. Training of extended program of immunization (EPI) workers A shipment of RDTs to be used for training purposes was to arrive in September 2012. MCHIP had been asked by PMI to plan supervision visits to reinforce knowledge and skills acquired during September training activities. The supervision visits are to last at least up to December 2012.

MCHIP has developed a system for transmitting data on stock status related to its activities to promote the use of contraceptives using cell phones. The system covers a 280 health facilities (206 health centers and 74 hospitals). MCHIP plans to expand this system to cover malaria activities (including transmission of data on malaria medicines). After considering the information above, the SIAPS MCH Core Portfolio determined that it would conduct a TDY to Guinea in October 2012 to ensure timely involvement in the next steps of the Guinea iCCM strategy. To this end, Jane Briggs and Mbombo Wathum conducted TDYs to Guinea in October 2012.

Challenges in progress toward sub-objective 4.2

Current Value: (**Sep 2012**) - Challenges to implementing this sub-objective centered on slowness by the MoH in validating the iCCM strategy and activating the Steering Committee. Additionally, the currently limited staff in the SIAPS/Guinea team (only 1 full time technical staff recruited by September 30, with another recruitment for a local Senior Technical Advisor underway) made it difficult for SIAPS/Guinea to effectively contribute to iCCM developments and meetings.

## HAITI

Haiti work plan details for Year 1 of the SIAPS Program

### Quarterly Report Background

For over ten years the *Ministère de la Santé Publique et de la Population* (MSPP), donors, foundations, and non-governmental organizations (NGOs) have implemented projects aiming to ensure the availability and accessibility of essential medicines (EM) in Haiti, but to date, major achievements have been lacking. The pharmaceutical sector in Haiti suffers from deregulation. This situation creates a serious anarchy, and poor control of medicines has the potential to cause serious harm to the people of Haiti. The perception of medicine as a source of profit is prominent and medicines are often treated as simple profit making commodities.

USAID/Haiti has been supporting the MSPP and other partners for many years to improve access to quality pharmaceutical products for the Haitian population. It is through this support that USAID/Haiti has requested technical assistance from the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) project to support the *Direction de la Pharmacie du Médicament et de la Médecine Traditionnelle* (DPM/MT).

During FY12, SIAPS teams conducted three visits to Port-au-Prince with the following key objectives:

- To identify the key pharmaceutical sector gaps in Haiti and that need to be addressed in a revised National Medicine Policy (NMP);
- To support the revision of the NMP through a series of stakeholders engagement workshops

### Activities Conducted During the Reporting Period

- **Support the DPM/MT to revise and disseminate the National Medicine Policy**

In the third quarter, SIAPS conducted stakeholder engagement workshops to discuss identified gaps and propose recommendations for the NMP. From May 27 to June 1st, 2012, the SIAPS team facilitated a series of five one-day stakeholder's engagement workshops for the revision of the NMP. Each workshop gathered an average of 20 participants to address specific section(s) of the proposed policy and met for an entire day. SIAPS team facilitated the workshops during the five days. The results from the groups were presented at the plenary session at the end of each workshop.

Following the stakeholders' engagement workshops, SIAPS team worked with the DPM team to elaborate the revised version of the NMP document based upon the recommendations of the series of key stakeholders' engagement workshops that take into consideration recent global trends and WHO recommendations. The first draft of the NMP document was shared with the Head of DPM/MT during the debriefing meeting on Friday June 8, 2012. Comments were further solicited from in-country stakeholders and incorporated into a revised draft of the NMP document. The second draft of National Medicine Policy document including all the initial comments received from stakeholders was sent to the DPM/MT on July 10, 2012.

## LAC AMI

LAC AMI work plan details for Year 1 of the SIAPS Program

### Quarterly Report Background

The Amazon Malaria Initiative (AMI) was launched in March 2002, through USAID LAC/RSD-PHN, to address malaria in the Amazon countries (Bolivia, Brazil, Colombia, Ecuador, Guyana, Peru, and Suriname). This region began to experience a re-emergence of malaria in the early 1990s, including the appearance of *Plasmodium falciparum* and resistance to inexpensive, first-line antimalarial drugs. With technical and financial support from AMI, the seven participating countries conducted in vivo efficacy studies of antimalarials and changed their drug policies for malaria to include new, more efficacious combination therapies. Strengthening the core elements of pharmaceutical management—including the policy and legal framework, selection, procurement, distribution, use and management—is essential to the effective implementation of these new policies.

The USAID funded programs, Rational Pharmaceutical Management Plus (RPM Plus), Strengthening Pharmaceutical Systems (SPS), and currently the Improved Access to Pharmaceuticals and Services (SIAPS), have successively been the technical pharmaceutical management partners for AMI since 2002. The other partners in the Initiative include the Pan American Health Organization (PAHO) Infectious Disease Division, the Center for Disease Control and Prevention (CDC), the United States Pharmacopoeia Promoting Quality of Medicines (USP-PQM) Program, National Malaria Control Programs in the Amazon and Central American regions, and the local USAID Missions. Between 2003 and 2011, RPM Plus and SPS collaborated with these partners to develop and implement strategies to strengthen pharmaceutical management for malaria in the region, particularly related to the new treatment policies. Both programs developed training materials; conducted regional workshops on pharmaceutical management issues to professionals representing all the Initiative countries; developed and disseminated tools; provided country-specific technical assistance to assess and improve their pharmaceutical supply systems for malaria; contributed to the Initiative's technical documents and study protocols; participated in annual meetings, regional workshops and dissemination activities; and, served on the Steering Committee. These activities have resulted in a solid foundation upon which SIAPS can further strengthen pharmaceutical management systems in the region. A summary of the activities supported by SPS and technical reports are available at: <http://www.msh.org/projects/sps/Global-Focus/Amazon-Malaria-Initiative.cfm>.

With FY10 funds SPS supported the elaboration and publication of standard operational procedures for malaria pharmaceutical management; the scale up and monitoring of the supervision system to malaria diagnostic and treatment posts; regional studies on the impact of the introduction of ACTs; regional and national workshops to strengthen good programming and procurement practices in low incidence settings; and support to the pharmaceutical management information systems.

SIAPS has received USD 900,000 in FY11 funds to support pharmaceutical management activities under AMI. These funds will be used to follow up on activities initiated on FY10 with SPS resources. The FY11 focus will be on the institutionalization of activities promoted by AMI and the development and implementation of strategies to improve pharmaceutical management in low incidence settings.

These proposed activities were discussed with AMI partners during the AMI Steering Committee in September 2011, and follow the 2010 - 2015 AMI Strategic Orientations on Drug Access and Use.

### Goal: LAC AMI Year 1 Work Plan Goal

Amazon Malaria Initiative countries will move to advanced phases of malaria control, significantly reducing morbidity and mortality. The achievement of this goal will be possible due to the implementation of innovative pharmaceutical management strategies specifically designed for low

incidence areas and population living under special circumstances

**Objective 1**

Coordinate joint activities with AMI partners to strengthen the governance of the pharmaceutical sector

**Sub-Objective 1.1**

Provide evidence to support the revision of plans and policies

**Activity 1.1a**

Provide direct technical assistance and collaborate with partners in the design and implementation of interventions to improve pharmaceutical management

**Activity 1.1b**

Strengthening of the regional monitoring system of availability of antimalarials

**Activity 1.1c**

Participate in the annual steering committee and other regional meetings with initiative countries and technical partners

**Objective 2**

Support evidence base decision making on malaria pharmaceutical management

**Sub-Objective 2.1**

Pharmaceutical management information will be immediately available to support products and services

**Activity 2.1a**

Provide technical assistance to AMI countries to conduct assessments on their pharmaceutical management systems

**Activity 2.1b**

Communication of research results and dissemination of best practices and illustrative interventions to national and international audiences

**Objective 3**

Provide technical assistance to institutionalize best practices on malaria pharmaceutical management to provide desired outcomes

**Sub-Objective 3.1**

Improve the availability of antimalarials and its correct use to prevent the emerge of resistance

**Activity 3.1a**

Institutionalization of malaria pharmaceutical management guidelines

### **Activity 3.1b**

Inclusion of revised programming criteria in low incidence areas

#### **Goal: Quarterly Report Fields**

These are the fields that will be used to collect information for quarterly reports.

Overall Quarter Progress

Current Value: **(Sep 2012)** - AMI countries have implemented procurement, programming and distribution interventions to confront the challenge of pharmaceutical supply in low incidence regions. Particular progress was evident in the implementation of revised programming and distribution criteria in low incidence areas.

Key challenges faced during the quarter

Current Value: **(Sep 2012)** - There are local administrative constraints to implement the technical alternatives suggested by AMI to deal with pharmaceutical management in low incidence areas.

Key activities planned for next quarter

Current Value: **(Sep 2012)** - SIAPS will start undertaking studies (baseline and impact evaluations) on: competencies for diagnosis and treatment in low incidence areas; impact of revised criteria for programming and distribution in low incidence areas; and results of PM interventions in decentralized areas.

Office management

Current Value: **(Sep 2012)** - No local office in any of the AMI countries. All activities (with exception of the ones in Peru) supported by the Arlington office.

#### **Quarterly Report Fields (Objective)**

Objective-level fields for collecting information for quarterly reports.

Quarterly Progress for Objective 1

Current Value: **(Sep 2012)** - SIAPS conducted a regional workshop in September with the participation of PAHO. Regional AMI activities to support the improvement of malaria pharmaceutical management were agreed during this meeting. Participants in the workshop were provided with evidence and tools to keep the problem of malaria control high in the political agenda.

Quarterly Progress for Objective 2

Current Value: **(Sep 2012)** - SIAPS continued supporting the dissemination of the quarterly bulletin on malaria medicines stock in AMI countries, and in-depth assessments on specific issues. That information has supported the donation/exchange of medicines and the reorientation of malaria control strategies.

Quarterly Progress for Objective 3

Current Value: **(Sep 2012)** - During this quarter, SIAPS supported the introduction of guidelines and manuals to improve malaria pharmaceutical management. Result/impact evaluations were conducted after the implementation of these tools. The revised criteria for programming and distribution of medicines in low incidence areas were immediately used for the redistribution of regional antimalarial stock in two countries. Peru has drafted a ministry decree to institutionalize this practice nationwide.

### Quarterly Report Fields (Sub-Objective)

Fields for reporting quarterly progress at the sub-objective level.

Quarterly progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - SIAPS visited Honduras to participate in a meeting to analyze the results of a pharmaceutical management assessment conducted in collaboration with PAHO in 2011. Based on the results, AMI partners and local counterparts agreed on a short-term plan to confront the problems. During a visit to Lima and Loreto on August 2012, SIAPS agreed with PAHO consultants on a strategy to improve malaria diagnosis in Loreto. On September 2012, SIAPS conducted a regional meeting in Quito, Ecuador to discuss, with national counterparts of eight AMI countries, the situation of malaria pharmaceutical supply and alternatives to confront problems on the availability of antimalarials. A trip report (including work plans for each country) was distributed immediately after. Strengthening of the regional monitoring system of availability of antimalarials: With SIAPS assistance, DIGEMID issued the quarterly bulletin on August 2012. Eight countries (including some in Central America) provided data. SIAPS and DIGEMID revised the MS Excel tool to correct a few glitches. Participate in the annual steering committee and other regional meetings with initiative countries and technical partners: During this quarter SIAPS prepared draft versions of annual and multiannual plans to be presented and discussed on the next AMI regional meeting.

Challenges in progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - The Ecuadorian government –citing a revision of their technical assistance policies- declined the technical assistance proposal drafted by SIAPS consultants and national counterparts during the previous quarter.

Deliverables: Sub-Objective 1.1

Current Value: **(Sep 2012)** - Provide direct technical assistance and collaborate with partners in the design and implementation of interventions to improve pharmaceutical management: In September, 2012, SIAPS conducted a regional meeting in Quito, Ecuador to discuss, with national counterparts of eight AMI countries the situation of malaria pharmaceutical supply, and alternatives to confront problems on the availability of antimalarials. A trip report (including work plans for each country) was distributed immediately after. Strengthening of the regional monitoring system of availability of antimalarials: DIGEMID issued the quarterly bulletin in August 2012 with assistance from SIAPS consultants. During the quarter, SIAPS and DIGEMID revised the MS Excel tool to correct a few glitches and issued an updated version to the AMI countries.

Quarterly progress toward sub-objective 2.1

Current Value: **(Sep 2012)** - During this quarter, SIAPS presented and discussed with partners and counterparts the final and edited versions of various studies ("Adequacy" evaluation of

malaria control strategies in Brazil, Nicaragua and Panama; and "Bottleneck" analysis in the procurement of malaria medicines). If requested by counterparts, these studies will be published and disseminated to a wider audience. During the regional workshop organized in Quito, Ecuador (September 11-13, 2012) SIAPS consultants and national counterparts presented information on the situation of malaria pharmaceutical management in each AMI country, and the progress in the implementation of interventions supported by AMI.

Challenges in progress toward sub-objective 2.1

Current Value: **(Sep 2012)** - The contract of the principal researcher for these two studies was delayed. The contract has been resolved and the researcher will finish those studies.

Deliverables: Sub-Objective 2.1

Current Value: **(Sep 2012)** - "Adequacy" evaluations for malaria control strategies in Brazil, Nicaragua and Panama and the "Bottle neck" analysis in the procurement of malaria medicines.

Quarterly progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - The impact evaluation of the introduction of the guideline was completed in Madre de Dios, Peru. The results were presented and discussed during the meeting in Quito (September 11-13). During this quarter, a final design of the guideline and a baseline evaluation was completed and presented in Guatemala. During this quarter SIAPS organized meetings in Honduras and Bolivia to reach an agreement with national counterparts on the standardization of minimal antimalarial stocks in low and high incidence areas. Similar criteria were already applied for the distribution of medicines in Loreto, Peru. SIAPS elaborated the first draft of a research protocol to assess the implication of the implementation of these criteria on the opportunity of treatment and costs. SIAPS also supported the elaboration of a programming and distribution electronic tool and procedures in Colombia. In Bolivia, SIAPS supported the malaria program's adoption of programming and distribution procedures used by the national pharmaceutical system. During the Quito meeting (September 11-13) representatives from Bolivia, Colombia and Brazil presented the situation of their supervision systems, based on recent assessments supported by AMI. In these countries the coverage is suboptimal, although the supervision contributes to improve the performance of the malaria control strategies in health facilities. Country representatives and SIAPS consultants agreed on the need to strengthen the supervision, considering the limitations imposed by the limitation of national human and financial resources.

Challenges in progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - No challenges for the quarter noted.

Deliverables: Sub-Objective 3.1

Current Value: **(Sep 2012)** - First draft of a research protocol to assess the opportunity of treatment and costs of the standardization of minimal antimalarial stocks in low and high incidence areas.

## **LAC SAIDI**

LAC SAIDI work plan details for Year 1 of the SIAPS Program

### **Quarterly Report Background**

The growing problem of antimicrobial resistance is threatening to undermine the advances achieved through priority health programs including tuberculosis, malaria, acute respiratory infections, sexually transmitted infections and HIV/AIDS, by rendering currently available treatments ineffective. Antimicrobial resistance (AMR) is the result of an increased exposure of microorganisms to antimicrobial medicines and the subsequent development of survival mechanisms in these microorganisms. The consequences of AMR include an increase in mortality, morbidity and in the cost of health care worldwide. An example of AMR of particular concern is multi-drug resistant tuberculosis (MDR-TB). The emergence and spread of MDR-TB has serious implications for a national TB control program: treatment is longer and less effective than treatment of non-resistant tuberculosis and is significantly more costly.

In response to this growing challenge, the USAID Bureau for the Latin America and Caribbean Region (USAID/LAC/SD) has proposed a sub-regional strategy for the Andean countries and Paraguay, called the South American Infectious Disease Initiative or SAIDI. The general objective of this initiative is to contain the emergence and spread of AMR by improving the availability and the use of antimicrobials of assured quality. Thus, the central focus of SAIDI is rational use of antimicrobials and AMR control, with a special emphasis on preventing the emergence of MDR-TB.

Since FY04, the Rational Pharmaceutical Management Plus (RPM Plus), and Strengthening Pharmaceutical Systems (SPS) programs – predecessors to MSH's current Improved Access to Pharmaceutical Services Program (SIAPS) – and the other SAIDI international partners, including the Promoting Quality of Medicines Program from the US Pharmacopeia (PQM USP), Links Media, the US Center for Disease Control and Prevention (CDC), and the Infectious Disease Division of the Pan-American Health Organization (PAHO) have been working with national counterparts in Bolivia, Peru and Paraguay to create a new, evidence-based and stepwise approach to local solutions for containing AMR. This approach considers the factors contributing to AMR within the context of existing systems and not in isolation, and thereby takes advantage of the interaction among stakeholders. Over the past three years, national AMR working groups have been formed in Peru and Paraguay and, in conjunction with SAIDI international partners, have conducted various assessment activities which led to a holistic local view of the factors contributing to AMR in each country. Based on these results, MSH's USAID sponsored programs and national partners have implemented multiple activities to address the problem areas (check SPS/SAIDI Web site: <http://www.msh.org/projects/sps/Global-Focus/SAIDI.cfm> )

In FY10, SAIDI partners decided to concentrate all the technical assistance and resources in the control of TB and MDR-TB in the jurisdiction of Madre de Dios, Peru. Limited resources were still used to document the impact of previous interventions, and transferring capacities to national institutions.

SIAPS has received USD 90,000 in FY11 funds to support pharmaceutical management activities under SAIDI. These funds will be used to follow up on activities initiated on FY10. The FY11 work plan will focus on the implementation of the SAIDI approach in Madre de Dios, Peru.

### **Goal: LAC SAIDI Year 1 Work Plan Goal**

The incidence of TB in populations living under special conditions will be reduced due to the implementation of a health service provision model adjusted to their particular needs. Such a model will influence all the sub-systems including the pharmaceutical management of TB medicines

### **Objective 1**

TB treatment outcomes in Madre de Dios improved

**Sub-Objective 1.1**

Review and improve pharmaceutical services standards in Madre de Dios.

**Activity 1.1a**

Present and discuss with other partners the alternative model for the provision of health services to populations living on special circumstances in MDD

**Sub-Objective 1.2**

Safety of therapeutic strategies improved

**Activity 1.2a**

Support the introduction of a TB pharmaceutical guideline for primary health facilities and assess the results of the intervention

**Activity 1.2b**

Support the implementation of ad hoc technologies for the conditioning of local medicines stores in MDD

**Goal: Quarterly Report Fields**

These are the fields that will be used to collect information for quarterly reports.

Overall Quarter Progress

Current Value: **(Sep 2012)** - SIAPS and other partners have supported the strengthening of TB control strategies in urban populations. The incidence of TB has decreased in Madre de Dios during the same period although there is no evidence that it can be attributed to these interventions. An alternative model for the provision of TB services for miners has not been implemented yet. Incidence remains high in that population.

Key challenges faced during the quarter

Current Value: **(Sep 2012)** - There few qualified personnel willing to provide health services in the harsh conditions of the mining areas. Hiring has been difficult for the local TB program.

Key activities planned for next quarter

Current Value: **(Sep 2012)** - For the next quarter, SIAPS will organize a meeting in Madre de Dios to discuss the progress in the implementation of the work plan for the alternative model of TB treatment, and provide technical assistance to specific pharmaceutical management components. SIAPS will organize a meeting in MdD to assess the progress in the implementation of SAIDI supported interventions, including the introduction of the pharmaceutical guideline. SIAPS will conduct an impact evaluation and report the results of the intervention.

Office management

Current Value: **(Sep 2012)** - All activities are supported by the MSH office in Lima.

**Quarterly Report Fields (Objective)**

Objective-level fields for collecting information for quarterly reports.

Quarterly Progress for Objective 1

Current Value: **(Sep 2012)** - SIAPS supported various components of the supply chain: warehouses conditioning, good storage practices, distribution standard operational procedures. The institutional pharmaceutical system has been improved, but the benefits have not reached underserved communities (miners) yet.

**Quarterly Report Fields (Sub-Objective)**

Fields for reporting quarterly progress at the sub-objective level.

Quarterly progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - The MoH and National TB program should be implementing the interventions, as agreed on the last joint meeting. No technical assistance activities were planned for this quarter.

Challenges in progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - No challenges this quarter.

Deliverables: Sub-Objective 1.1

Current Value: **(Sep 2012)** - No deliverables were submitted this quarter.

Quarterly progress toward sub-objective 1.2

Current Value: **(Sep 2012)** - SIAPS supported the introduction of the TB pharmaceutical guideline in Madre de Dios (MdD). Also during this quarter, SIAPS completed the conditioning of selected warehouses using affordable technology. A technical report with the results of the baseline assessment and cost of the intervention was completed and distributed.

Challenges in progress toward sub-objective 1.2

Current Value: **(Sep 2012)** - There were no challenges this quarter.

Deliverables: Sub-Objective 1.2

Current Value: **(Sep 2012)** - There was a success story edited and uploaded in the SIAPS website about the impact of low cost technology in the reduction of temperature in Madre de Dios warehouses.

## LESOTHO

Lesotho work plan details for Year 1 of the SIAPS Program

### Quarterly Report Background

AIDS constitutes an alarming threat to Lesotho and its people. Findings of the 2009 Lesotho Demographic and Health Survey, carried out by the Ministry of Health and Social Welfare (MOHSW) and the Bureau of Statistics, confirmed that Lesotho has a severe, generalized HIV epidemic. According to the DHS 2009 report, overall adult prevalence is estimated to be 23%. GOL's current HIV/AIDS National Strategic Plan (NSP) recognizes the need to provide treatment, care and support services to cater for the large number of individuals testing for HIV and AIDS. The plan makes provision for the scale-up of care and treatment by increasing access to ART services, ensuring quality and expanding capacity and efficiency of service provision in both the public and the private sectors. One of the interventions to achieve this is decentralization of services to the health center level. The government aimed to provide access for ART to more than 80% of individuals who are in need of therapy by 2010. By the end of 2009, 52% of adults and 51% of children in need of treatment were receiving antiretroviral therapy at hospitals, health centers and private practitioners' clinics across the country. The GOL and its multi-sectoral partners regard this progress as one of the most significant achievements to date within the national HIV and AIDS response.

One of the key challenges of the scale-up of HIV and AIDS prevention, care, treatment and support services is the need to ensure that adequate human, technical, infrastructural resources and effective commodity procurement and distribution systems are put in place. Inadequate information management systems to support decision making in supply chain has also been one of the critical challenges, and without reliable information, the country is unable to account for the financial resources invested in purchasing medicines and laboratory commodities. This has resulted in a condition precedent being set for Round 8, Phase 2 of the Global Fund for the fight against AIDS, Tuberculosis and Malaria (GFATM). The condition precedent requires the Principal Recipient (PR) to show in a manner acceptable to the GFATM that a robust management information system for the ART program is in place.

The United States Government (USG) has been providing support to the Government of Lesotho for its HIV and AIDS prevention, care and treatment efforts through its USAID Mission in Lesotho. Since FY08, technical support has been provided to the MOHSW through the MSH Strengthening Pharmaceutical Systems (SPS) program. As a follow on to SPS, the USG will continue to support the MOHSW through the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program of MSH.

The strategic focus of SIAPS is on assuring the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. To achieve this goal, SIAPS will promote and use a systems-strengthening approach consistent with the Global Health Initiative that will result in positive and sustainable health impact.

The focus of activities will be on health system strengthening, laboratory supply chain strengthening, and policy and strategic information support. Work initiated and successes realized under SPS will be leveraged, with the approach being to move from first generation HSS to second generation approaches. The focus with SIAPS will be to adopt interventions that are more integrated, looking at the five building blocks of health systems, with medical products as an overlay. This ensures increased efficiency in implementing interventions, broader reach and a more sustainable impact. One of the critical activities of SIAPS under this work plan will be to provide technical assistance to the MOHSW towards meeting the condition precedent set by GFATM. The MOHSW has requested SIAPS to provide TA to the PR to meet this condition precedent set by the GFATM.

### Goal: Lesotho Year 1 Work Plan Goal

To assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes

**Objective 1 - MT**

Strengthen pharmaceutical sector governance

**Sub-Objective 1.1**

Improve medicines policies, legislation, regulations, norms, and standards

**Activity 1.1.1**

Provide support for the implementation of the national STGs and EML

**Activity 1.1.2**

Implement Quality Assurance mechanisms for ARVs

**Objective 2 - MT**

Increase and enhance the capacity for pharmaceutical supply management and services

**Sub-Objective 2.1**

Strengthen pharmaceutical management capacity of individuals, institutions, organizations, and networks

**Activity 2.1.1**

Provide TA for implementation of the in-service training and supportive supervision and mentoring program for pharmacists and pharmacy technicians at 6 district hospitals

**Activity 2.1.2**

Strengthen HR capacity for supply chain management

**Sub-Objective 2.2**

Adopt and implement innovative and proven approaches for human resource capacity building

**Activity 2.2.2**

Conduct a pharmaceuticals skills audit for pharmacists and pharmacy technicians

**Objective 3 - MT**

Increase utilization of information for pharmaceutical and laboratory decision-making

**Sub-Objective 3.1**

Strengthen use of pharmaceutical management information systems (PMIS) to support both inventory and patient management

**Activity 3.1.1**

Enhance implementation of the manual PMIS and RxSolution at all district hospital ART sites

**Sub-Objective 3.2**

Improve availability and use of strategic information for laboratory systems strengthening

**Activity 3.2.1**

Provide TA for implementation of LMIS

**Objective 4 - MT**

Strengthen financing strategies and mechanisms to improve access to medicines and laboratory products

**Sub-Objective 4.1**

Strengthen NDSO and public sector supply chain system in Lesotho

**Activity 4.1.1**

Assess the organizational structure, operations, financing structure and financial operations of NDSO and the entire supply chain system

**Goal: Quarterly Report Fields**

These are the fields that will be used to collect information for quarterly reports.

Overall Quarter Progress

Current Value: **(Sep 2012)** - SIAPS program goal is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. The performance measurements for this goal is through percentage prescribed medicines actually dispensed in the out-patient department and percentage of samples passing quality checks at NDSO. The medicine access survey was conducted and informed on the prescribed medicines actually dispensed.

Another key area was on the implementation of Quality Assurance mechanisms for ARVs and other HIV-related commodities. Technical Assistance was to be provided to NDSO for random testing of the quality of ARVs and other HIV-related commodities using the minilab procured under SPS. The activity was meant to offer an intervention for ensuring that the quality of ARVs, anti-TB medicines and medicines for Opportunistic Infections (OIs) circulating in the market is assured. Quality Assurance reports have been identified as the means of verification for the quality checks. The baseline and targets have not been established as yet. The minilab standards had expired and still await procurement. The operation of the minilab has been halted by these expired standards and no quality checks have been made as yet. Therefore, there are no quality assurance reports made by NDSO to inform on the project level result.

Key challenges faced during the quarter

Current Value: **(Sep 2012)** - There have been competing priorities at the Ministry of Health that hindered progress in the implementation of certain activities. This has resulted in delays in holding

the national stakeholder validation meeting for finalizing the STGs and EML. SIAPS will continue to provide support to the MOH in this activity upon request from the MOH. Implementation of the minilab activity has been delayed by the expiry of the pharmaceutical standards for the minilab and therefore no tests were conducted. Although when the minilab was handed over to NDSO, the organization had committed to buying all the necessary requirements for its use, availability of funds was delayed. SIAPS is therefore exploring the possibility of procuring the standards for NDSO, and this process has been initiated already

On another note, there has also been a delay in disbursement of funds by GF, resulting in a funding gap within the laboratory services directorate, which crippled procurement of not only RTKs, but also other laboratory reagents such as CD4 reagents, chemistry and hematology reagents. Most reagents have been out of stock for the major part of this quarter. These items will be procured once funding is available. The SSM visits have revealed that some hospital laboratories were still using old inventory management tools (e.g. BIN cards). Some of those hospitals that are using the new BIN cards are not filling them in consistently, and this compromises the quality of the data. More SSM is planned to address this challenge.

RxSolution ceased operations in some of the sites due to refurbishment of health facilities by MCA. The affected hospitals were Berea and Ntšekhe. However, operations will continue once the refurbishments at the sites have been completed. On the other hand, piloting of Electronic Medical Records system in Motebang hospital has also halted the operations of RxSolution. Due to lack of pharmacy personnel and high work load at Butha-Buthe hospital, the staff has since ceased to utilize RxSolution because of severe workload and resorted to registering patients only in paper-based registers. It is envisaged that this challenge will be overcome once Global Fund releases funding for staff that has not been paid due to the condition precedent of GFATM. Another challenge evidenced at Paray hospital is that data has not been captured consistently and accurately. This predicament will be addressed through supportive supervision and mentoring exercises.

#### Key activities planned for next quarter

Current Value: **(Sep 2012)** - In the next quarter, SIAPS will continue to provide Technical Assistance for implementation of STGs and EML. Further support will be extended on implementation of quality assurance mechanisms for ARVs and other HIV-related commodities. SIAPS will provide technical assistance for pre and in-service training in SCM. Provide TA for the development and implementation of a procurement and supply management system at NDSO. Support implementation of ART PMIS Support implementation of Laboratory LMIS Support implementation of SSM program

#### Technical Activity Coordination

Current Value: **(Sep 2012)** - Technical activities have been implemented as per approved USAID work plan. Due to regular monitoring, the plan has been realigned through consultative meetings with USAID local mission. The initial 5 objectives have been reduced to 4. Meetings have been held with the USAID Activity manager to review program performance and monitoring of activities. Quarterly, semi-annual and annual progress reports have been prepared and shared with PEPFAR and USAID local mission. There have been monthly internal review meetings with the management team even though they have not been held regularly. The team has expanded and there will be regular planned internal review meetings conducted through monthly meetings. There has been provision of technical support and backstopping from head office by Portfolio Manager

and CPD.

#### Office management

Current Value: **(Sep 2012)** - Finance and administration manager together with administrative assistant have continuously supported the program administratively. Payments were made to the suppliers and purchase requests were prepared and vendors were paid accordingly. Staff arranged travel logistics in support of technical activities. Logistical support and arrangements for MSH staff visiting Lesotho was completed. Monthly reconciliations of gas receipts were done and inventory was updated. Logistics for trainings and workshops were done. Administration and finance department made procurement of laptops and communication devices (cell phones and modems) for field officers newly recruited.

#### Quarterly Report Fields (Objective)

Objective-level fields for collecting information for quarterly reports.

#### Quarterly Progress for Objective 1

Current Value: **(Sep 2012)** - SIAPS Lesotho supports MOH to strengthen pharmaceutical sector governance. There have been delays in finalization of STGs and EML due to competing priorities at MOH. However, SIAPS continues to provide technical support and documents have been submitted to the MOH. Stakeholder Validation workshop is yet to be approved by MOH. With regard to the Medicines Bill, the process is ongoing and additional comments have been sent to Ministry of Law and Constitutional Affairs.

#### Quarterly Progress for Objective 2

Current Value: **(Sep 2012)** - In an effort to enhance implementation of the ART PMIS at all district hospital ART sites, SIAPS has, during the reporting period, provided TA for implementation of RxSolution at all district hospital ART sites that use RxSolution. RxSolution was deployed in 11 hospitals namely, Botha Bothe Government hospital, Berea Government hospital, Mafeteng Government hospital, Ntšekhe Government hospital (Mohale's Hoek), Scott (CHAL), Maluti (CHAL), Paray (CHAL), Seboche hospital, St. James hospital, Machabeng hospital and Makoanyane Military hospital.

Other than trainings in PSM, the project held supportive supervision and mentoring(SSM) exercises with the DCD, through which 4 supportive supervision and mentoring visits were made to 4 hospitals (Maluti, Berea, Motebang and Botha Bothe hospitals). There has been additional staff recruited during the quarter. Supply Chain Advisor seconded at the Ministry of Health to coordinate pharmaceutical and laboratory supply chain nationally. Two supportive supervision and mentoring coordinators have been engaged to provide ongoing support to DHMTs and hospitals. A further recruitment of three District Logistics Officers has been done to ensure that supply chain data for all the ART related programs is collected appropriately, processed routinely and used to inform operational decisions at facility and district level. These new employees will also be instrumental in gathering baseline information and to determine the targets for the objective.

#### Quarterly Progress for Objective 3

Current Value: **(Sep 2012)** - SIAPS has continuously provided support in the management of LMIS to ensure continuous availability of essential laboratory commodities. This support has

been extended through close monitoring of the system through routine reporting and data quality assessments (timeliness, submission rates and completeness of reports). There was a significant improvement in the reporting rate for LMIS. The reporting rate improved from 44% to 76% during the quarter. The quality of the data submitted also improved significantly, with timeliness, accuracy and completeness of reporting improving by 41%, 12% and 29% respectively.

RxSolution has been implemented and installed through Strengthening Pharmaceutical Services (SPS) Project that has been succeeded by SIAPS. SIAPS has continued to provide support to the MOH in management of inventory and patient data for the ART program. Data from RxSolution is used for statistical analysis in order to monitor the supply chain system of the ART program. A lesson learnt during this training was that the pharmacy personnel from Maluti who was already using RxSolution has a thorough knowledge of the system and can perform a lot of functions in RxSolution that include modifying the regimens and protocols to suit their operating procedures. The monthly LMIS reports were used to compile quarterly reports at the central level and SIAPS has been providing assistance for the routine analysis of data.

#### Quarterly Progress for Objective 4

**Current Value: (Sep 2012)** - During the quarter technical support for the assessment of the supply chain system in the country has been provided. This assessment looked at the organizational structure, operations and financing structure of NDSO and the entire supply chain system. Information that includes products costs, mark-ups, costs of receipts and issues for medical supplies, medicines and laboratory commodities was made available for analysis. The results of the assessment, upon availability, will be used to inform the design of appropriate interventions to optimize the effectiveness and efficiency of the quantification, procurement, storage and distribution of ARVs.

#### Quarterly Report Fields (Sub-Objective)

Fields for reporting quarterly progress at the sub-objective level.

#### Quarterly progress toward sub-objective 1.1

**Current Value: (Sep 2012)** - The STGs and EML were finalized following the second stakeholder consultative meetings. The documents were handed over to the Ministry of Health (MOH) for preparation of the national stakeholder validation meeting - this is yet to be sanctioned by the MOH. Another activity under this technical area was the implementation of Quality Assurance mechanisms for ARVs and other HIV-related commodities. This activity was to be done through provision of TA to NDSO for random testing of the quality of ARVs and other HIV-related commodities using the minilab procured under SPS. The activity is meant to offer an intervention for ensuring that the quality of ARVs, anti-TB medicines and medicines for Opportunistic Infections (OIs) circulating in the market is assured.

#### Challenges in progress toward sub-objective 1.1

**Current Value: (Sep 2012)** - The minilab activities have until the reporting period been delayed. Even though SIAPS has pledged to procure the standards for NDSO, the process has not been finalized yet

Deliverables: Sub-Objective 1.1

Current Value: **(Sep 2012)** - STG piloting trip report. Draft documents submitted to MOH. MOH still to approve the conduct of a national stakeholder verification workshop.

Quarterly progress toward sub-objective 2.1

Current Value: **(Sep 2012)** - The project held supportive supervision and mentoring (SSM) exercises with the DCD, through which 4 supportive supervision and mentoring visits were made to 4 hospitals (Maluti, Berea, Motebang and Botha Bothe hospitals). This makes 67% of planned SSMs during FY. One meeting of the SCM TWG was held at the Ministry of Health during the quarter. This was the general SCM technical working group (SCM TWG) meeting which provided an update of the general performance of the SC in the country. Various programs presented an update of their program's performance, and it became clear that the stock out of laboratory commodities, particularly RTKs and CD4 reagents, had a great negative impact on most programs.

Twenty nine (29) health professionals were given an in-service training on supply chain of ART pharmaceutical services. Thirty four (34) students from the NUL underwent a pre-service training program on supply chain of ART pharmaceutical using the Pre-service training curriculum in supply chain management developed by MSH/SPS. During this last quarter a total of 63 participants were trained under objective 2 of the MSH/SIAPS work plan in order to enhance the capacity for medical products supply management and services. Just for the quarter this figure makes up over 50% of all planned trainings for FY1. Baselines will be determined to support routine PMIS reports generated

Challenges in progress toward sub-objective 2.1

Current Value: **(Sep 2012)** - Due to increased work load and other competing priorities at MOH central some SSM visits are rescheduled to new dates. This has slowed down on service delivery at the health centres. There has been a recent snow fall that presented unfavorable working and travel conditions to conduct SSM visits. Delays in engagement of DLOs and SSMCs led to delays in establishing baselines to track stock out rates.

Deliverables: Sub-Objective 2.1

Current Value: **(Sep 2012)** - SSM field trip reports

Quarterly progress toward sub-objective 2.2

Current Value: **(Sep 2012)** - Thirty four (34) final year students from National University of Lesotho were offered pre-service training in SCM. Capacity needs assessment was conducted during the quarter to inform hospitals skills plan.

Challenges in progress toward sub-objective 2.2

Current Value: **(Sep 2012)** - The capacity needs assessment was conducted late into the FY, and therefore could not inform development of the skills plans for the target facilities. The skills plan activity will therefore only be implemented during the next financial year. Results for the skills plan indicator will therefore also be measured from next FY. The National University was also in turmoil for a few months and was closed for a few weeks. This led to a delay in implementing the pre-service training, as well as an increased cost of implementation as the students no longer had accommodation at the University.

Deliverables: Sub-Objective 2.2

Current Value: **(Sep 2012)** - 1. Pre-service training trip report

Quarterly progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - Intensive SSM visits and on-going on the job training have resulted in progress through increased number of district hospitals that submit complete ART PMIS reports to HQ per quarter

Challenges in progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - Due to high workloads and shortage of staff at the hospital level, there are still some inconsistencies in the reported data. Staff at other facilities even resort to old reporting formats when overwhelmed during which time they do not utilize RxSolution

Deliverables: Sub-Objective 3.1

Current Value: **(Sep 2012)** - SSM visits trip reports and PMIS reports

Quarterly progress toward sub-objective 3.2

Current Value: **(Sep 2012)** - SIAPS has continuously provided support in the management of LMIS to ensure continuous availability of essential laboratory commodities. This support has been extended through close monitoring of the system through routine reporting and data quality assessments (timeliness, submission rates and completeness of reports). There was a significant improvement in the reporting rate for LMIS. The reporting rate improved from 44% to 76% during the quarter. The quality of the data submitted also improved significantly, with timeliness, accuracy and completeness of reporting improving by 41%, 12% and 29% respectively.

Challenges in progress toward sub-objective 3.2

Current Value: **(Sep 2012)** - There has also been a delay in disbursement of funds by GF, resulting in a funding gap within the laboratory services directorate, which crippled procurement of not only RTKs, but also other laboratory reagents such as CD4 reagents, chemistry and hematology reagents. Most reagents have been out of stock for the major part of this quarter. These items will be procured once funding is available.

Deliverables: Sub-Objective 3.2

Current Value: **(Sep 2012)** - 1. LMIS reports 2. LMIS SSM reports 3. Funding gap report

Quarterly progress toward sub-objective 4.1

Current Value: **(Sep 2012)** - In order to improve efficiency in the supply chain system and use of existing financial resources, SIAPS has, through STTA, conducted a baseline assessment of the supply chain system in Lesotho. Three phases of the assessment have been completed during the quarter and the last phase will be implemented in the next quarter.

Challenges in progress toward sub-objective 4.1

Current Value: **(Sep 2012)** - The report is yet to be presented and the set of recommendations put forth.

Deliverables: Sub-Objective 4.1

Current Value: (**Sep 2012**) - Draft NDSO costing analysis report

## **LIBERIA**

Liberia work plan details for Year 1 of the SIAPS Program

### **Quarterly Report Background**

Liberia launched Presidents Malaria Initiative (PMI)-supported activities in 2007, through different mechanisms including the Strengthening Pharmaceutical System (SPS) Program, predecessor to the Systems for Improved Access to Pharmaceuticals and Services (SIAPS). In 2008, PMI supported an assessment of the pharmaceutical management supply system in which major problems were identified including lack of skills and capacities to manage (ordering, quantification, storage, inventory management and use) including antimalarials. To address these challenges, SPS has been providing support to strengthen the pharmaceutical management system focusing on capacity and skills building for staff of the Ministry of Health and Social Welfare (MOHSW).

SPS collaborated with the MOHSW to conduct a quantification workshop for MOHSW /NMCP personnel responsible for malaria commodities quantification. SPS also conducted pharmaceutical management training of trainers (TOT) to build pharmaceutical management capacities of county pharmacists. These trainers have trained over 400 service delivery point health workers in their counties. SPS collaborated with training institutions; in this domain SPS supported the development of a new curriculum for the University of Liberia, School of Pharmacy.

SPS technically assisted MOHSW to review the outdated policy documents -the National Therapeutic Guidelines (NTG), National Formulary (NF), and the Essential Medicine List (EML) through consultation and feedback by various in-country stakeholders groups.

The Liberia National Malaria Control Program (NMCP) is trying to improve access to appropriate case management to 80% of the population. To support the NMCP, SPS in 2010, conducted an assessment of private sector capacities in the pilot site Montserrado County. The assessment consisted of mapping pharmacies and medicine stores, determining availability of antimalarials, assessing the drug supply, determining accessibility, case management practices, and supply and drug management issues. Assessment results were discussed in a stakeholders meeting and implementation of activities began.

These activities have resulted in a solid foundation upon which SIAPS can further strengthen pharmaceutical management systems at the central and county levels. SIAPS will build on SPS's achievements to support Liberia in areas of strengthening pharmaceutical supply management system for malaria commodities at the county level, improving access to ACTs through the private sector, monitoring and supervision system for malaria commodities and rational use.

### **Goal: Liberia Year 1 Work Plan Goal**

Improve the supply, quality and use of malaria commodities and other key pharmaceuticals

#### **Objective 1**

Strengthen pharmaceutical sector governance

#### **Sub-Objective 1.1**

Improve medicines policies and regulations

#### **Activity 1.1a**

Disseminate the three policy document the NTG, EML and NF: • Develop a dissemination plan • Launch

the three policy documents • Distribute the documents to the counties Conduct orientation/dissemination meetings in 15 counties

**Activity 1.1b**

Collaborate with the LMHRA to set up product registration system

**Objective 2**

Increase capacity for Pharmaceutical Supply Management and Services in 3 counties (Lofa, Nimba and Bong)

**Sub-Objective 2.1**

Strengthen pharmaceutical management capacity of health care providers

**Activity 2.1a**

Conduct pharmaceutical management training for OIC in 2 counties and dispensers In one county

**Activity 2.1b**

Collaborate with county pharmacists to conduct supportive supervision visits

**Activity 2.1c**

Nimba County depot renovation

**Sub-Objective 2.2**

Strengthen the capacity of county pharmacist to manage pharmaceutical systems in their counties

**Activity 2.2a**

Develop and implement job aids for county pharmacists • Finalize the development of job aids • Validate the job aids in 2 days workshop • Print 50 copies of job aids • Launch and disseminate the job aids in a one day meeting Follow up implementation through supervision visits

**Objective 3**

Monitor the use and availability of malaria commodities for decision making

**Sub-Objective 3.1**

Strengthen the use of End use verification (EUV) tool

**Activity 3.1a**

Implement EUV tool on a quarterly basis

**Objective 4**

Improve pharmaceutical services

### **Sub-Objective 4.1**

Increase access to ACTs through the private sector

#### **Activity 4.1a**

Program implementation • Design and disseminate labeling stickers for private sector commodities • Train dispensers from medicine stores and pharmacies • Support the NMCP to establish supply chain channels by signing MOU with select wholesalers • Support the NMCP to develop and disseminate IEC strategy towards general public Program launch

#### **Activity 4.1b**

-Conduct regular monitoring and supervision visits in close collaboration with NMCP and Pharmacy Board -Evaluate the project

#### **Goal: Quarterly Report Fields**

These are the fields that will be used to collect information for quarterly reports.

#### Overall Quarter Progress

Current Value: **(Sep 2012)** - In quarter four, SIAPS/Liberia, based on USAID request, focused its work primarily in two areas-Monitoring the use and availability of malaria commodities and providing support to improve pharmaceutical services (in the private sector). Despite several incountry challenges, SIAPS worked closely with the NMCP and in country stakeholders to re-craft the private sector strategy for Liberia. In collaboration with the MOHSW, the NMCP and the private sector ACT Technical Working Group produced a new national private sector ACT roll out strategy which identified partner roles. As a result the new geographic focus of the SIAPS ACT and RDT roll out was confirmed to be the two (2) districts of St Paul and Paynesville in the Montserrado county of Liberia.

During this period SIAPS responded to the USAID request to undertake a feasibility study on the use of ACTs and RDTs in the private sector. Following a joint review work with the NMCP of feasibility study protocol, Ethical clearance was granted by the Institutional Review Board (IRB) and the study initiated at the end of September 2012 after a 2 month delay. The outstanding work on the renovations of the Nimba County Drug Depot progressed remarkably with the development and finalization of the Bill of Quantities and Scope of work. The bidding process was completed, contract awarded and the renovation started in a timely manner. To facilitate program implementation in the coming year, SIAPS developed the strategic work plan for 2012-1013 and identified activities to be implemented in order to achieve set goals, budgeting and timelines. This document was shared with USAID.

#### Key challenges faced during the quarter

Current Value: **(Sep 2012)** - SIAPS followed up on key objective areas as agreed in the workplan. However, there were a number of challenges during this quarter namely; • The un-timely resignation of Mr David Sumo, the Country Project Director • The announcement by USAID to cut SIAPS funding for the 2013 from \$663,500 to \$363,500 necessitating a re-think of the broad SIAPS Liberia strategy in terms of Human Resources, and activity re-prioritization in the present and coming year • Request from the Mission to drop the support to Liberia Medicines and Health products Regulatory Authority (LMHRA) and focus all activities on the private sector and the EUV work only.

Another critical challenge which has not been resolved till date and which is hampering progress of the private sector work is the finalization of the mechanism to physically distribute the ACTs and RDTs. In March 2012, SIAPS drafted an MoU for the MoHSW to appoint a private wholesaler to undertake the distribution of ACTS in the private sector. There has been a delay in this process and till date the MOU has not been signed. In July 2012, the MOHSW in anticipation of funding from the Global fund issued a new advertisement in the national newspaper to appoint another private wholesaler to do national distribution of ACTs and RDTs beyond the pilot being planned by SIAPS. In several meetings with the PSACTTWG and the Deputy Minister of Health it was agreed that the National Distributor be appointed by the MOHSW to initiate the distribution of the PMI procured ACTS and RDTs in the pilot districts of Paynesville and St Paul whilst awaiting the Global Fund stocks of ACTS for national distribution. Unfortunately, till date this has not materialized.

SIAPS recommended the use of the National Drug Services (NDS) as an alternate distributor, this proposal was accompanied by a need for the NDS to dedicate a separate account under the MoHSW to track funding accrued from the sales of the ACTS. This has since been done but there are still delays in using this alternate mechanism at the national level. SIAPS is working with the MOHSW to move this process forward and will need USAID support to ensure that this challenge is overcome especially to help ensure that the PMI procured products do not expire during the period the MOHSW waits to finalize the operations of the national distributor who has given a number of power point presentations to the PSACT TWG expressing its readiness to start working. The need to finalize the distribution entity's contracting mechanism is critical since further delays in contracting this entity places the PMI stocks at a higher risk of expiring.

#### Key activities planned for next quarter

Current Value: **(Sep 2012)** - 1. Implement Q1, 2012-2013 EUV data collection activity in collaboration with the NMCP and County Health Teams 2. Award contract and complete Nimba County Depot Renovation 3. Train 120 dispensers from medicine stores and pharmacies for ACT distribution 4. Finalize and publish reports for feasibility study that was conducted for introducing ACT and RDT in Private Sector Pharmaceutical Medicines shops and Pharmacies. 5. Start the distribution of ACTS and mRDT in Paynesville and St. Paul Districts to Pharmacies and Medicines stores that were trained by SIAPS for malaria Case management using ACT and RDT in private pharmaceutical Sector

#### Technical Activity Coordination

Current Value: **(Sep 2012)** - 1. Follow up with USAID Health Team and the PMI activity lead on approval for 2012-2013 SIAPS work plan. 2. Prepare and present SIAPS Quarterly Progress Report for July-Sept012 at PMI/USAID Liberia Mission partners quarterly review meeting. 4. Participation in Private Sector ACT Technical Working Group weekly meeting. 5. Schedule STTA for SIAPS Liberia for the 2012-2013 workplan 5. Participation in Weekly Supply Chain Technical Working Group Meeting 6. Participation in one day review and validation Meeting for the National Medicines Policy of Liberia –organized by the Pharmacy Division MOHSW 7. Participation in three day conference to develop the Strategic Guideline for Operational Research Study in Liberia-National Malaria Control Program, MOHSW. 8. Participation in three day meeting to develop the Strategic Approach for National Malaria Control Program in Liberia, MOHSW

#### Office management

Current Value: **(Sep 2012)** - Finance and administrative support for local and international staff including security, travels, communication, water and electrical bills etc. were all appropriately handled and reported in a timely manner. SIAPS went ahead to renew the lease for the 2012-2013 workplan. Due to funding cuts a new CPD was not recruited. Mr Dunah the Senior Program associate served as and will the interim CPD.

### **Quarterly Report Fields (Objective)**

Objective-level fields for collecting information for quarterly reports.

#### Quarterly Progress for Objective 1

Current Value: **(Sep 2012)** - SIAPS had successfully achieved the agreed on sub objective of disseminating the developed National Treatment Guidelines (NTGs) and LMIS tools in the three (3) USAID focus counties of Bong, Nimba and Lofa. SIAPS supported JSI and the Montserrado County Health Team to undertake dissemination of NTGs and LMIS tools in the Montserrado County. SIAPS undertook initial planning meetings with the EU consultant helping the LMHRA on the activities relating to developing the LMHRA SOPS. SIAPS support to this activity was to include the development of a national medical products registration system. The RFCC to send a Technical Assistant in country to support this activity was not approved by the USAID following the decision to cut SIAPS funding and focus current work on EUVs and the private sector.

#### Quarterly Progress for Objective 2

Current Value: **(Sep 2012)** - Following the capacity building activities focused on trainings of 115 health workers (87 OICs and 28 clinical and district supervisors) from 95 functional health facilities (56 in Lofa and 39 in Bong) on pharmaceutical management principles in quarter two (2). SIAPS undertook one supportive supervisory visit to the Bong county. To ensure sustainability this supportive visit was done in collaboration with the SMU and MoHSW staff.

#### Quarterly Progress for Objective 3

Current Value: **(Sep 2012)** - To monitor the use and availability of malaria commodities for decision making purposes, SIAPS in collaboration with NMCP, SMU and County Health Teams conducted EUV assessments in two counties Sinoe and Gbarpolu. The sample frame for the selection of counties and facilities was in line with the PMI recommendations. In all seventeen (17) health facilities were visited and EUV tools applied. The final report was compiled and shared with NMCP and all partners.

#### Quarterly Progress for Objective 4

Current Value: **(Sep 2012)** - SIAPS attended 10 weekly Private sector ACT TWG meetings which were focused primarily on standardizing and finalizing the training manuals for the private sector capacity building, reviewing IEC materials and conducting joint TOTs. SIAPS worked with NMCP to develop the national private sector strategy and agreed to stakeholders on the geographic focus of each partners work. SIAPS ACTs and RDT distribution is to be focused in two districts of Montserrado county- Paynesville and St Pauls. SIAPS presently has liaised with the NDS and has received stocks of mRDTs and Gloves for distribution through the approved distributor to the private sector medicines shops. SIAPS in collaboration with NMCP has received approval from the IRB to conduct the feasibility study.

### **Quarterly Report Fields (Sub-Objective)**

Fields for reporting quarterly progress at the sub-objective level.

Quarterly progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - SIAPS had successfully achieved the agreed of sub objective of disseminating the developed National Treatment Guidelines in the three (3) USAID focus counties of Bong, Nimba and Lofa. SIAPS supported JSI and the Montserrdao county health team to undertake similar activities in the Montserrado County. SIAPS undertook initial planning meetings with the EU consultant helping the LMHRA on the activities relating to developing the LMHRA SOPs. SIAPS support to this activity was to include the development of a national medical products registration system. The RFCC to send a Technical Assistant in country to support this activity was not approved by the USAID following the decision to cut SIAPS funding and focus current work on EUVs and the private sector.

Challenges in progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - SIAPS support to the LMHRA will ultimately enhance the quality of pharmaceuticals including antimalarials which become available to the people of Liberia. Due to funding cuts and mission redirection on the focus of the SIAPS Liberia work away from this task to focus work on the private sector and EUVs the current work with LMHRA was curtailed

Quarterly progress toward sub-objective 2.1

Current Value: **(Sep 2012)** - Supervision visit was done to 21 health facilities in Bong County. 54% of facilities supervised and tended to submit reports regularly: data show 100% availability of LMIS, 90% proper utilization of LMIS, 95% staff trained in LMIS. Most of the facility not accessible now, due to bad road conditions. Plan for phase two of the exercise to be done in quarter 1 of 2012-2013. - The SOW and Bill of quantities for the renovation of the Nimba County Depot was designed, and bidding process completed, contracted awarded.

Challenges in progress toward sub-objective 2.1

Current Value: **(Sep 2012)** - Only one supportive supervisory activity was undertaken due to inaccessibility of facilities because of bad road terrains during caused by rains during the quarter.

Deliverables: Sub-Objective 2.1

Current Value: **(Sep 2012)** - Supervision reports.

Partner Contributions: Sub-Objective 2.1

Current Value: **(Sep 2012)** - The SMU and the NMCP staff were very cooperative and actually undertook 50% of the supportive supervisory work in the Bong county on their own.

Quarterly progress toward sub-objective 2.2

Challenges in progress toward sub-objective 2.2

Current Value: **(Sep 2012)** - Acute shortage of data management tool (LMIS tool) poor data quality at health facility.

Quarterly progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - SIAPS worked with the NMCP and the SMU to sample the counties to be surveyed using the EUV tools. The two counties Sinoe and Gbarpolu were selected and seventeen (17) health facilities were visited. Reports submitted and Findings use to do emergency supply of ACTs to Gbarpolu County.

Challenges in progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - Lack of a platform to share the previous findings of the EUV with both USAID and NMCP gave the wrong perceptions of the value of the EUV. SIAPS presented the findings of the quarters EUV at the NMCP in the presence of stakeholders and partners. key gaps and observed were addressed.

Deliverables: Sub-Objective 3.1

Current Value: **(Sep 2012)** - EUV report.

Quarterly progress toward sub-objective 4.1

Current Value: **(Sep 2012)** - For Activities 4:1:1 and 4:2:1 were scheduled for quarter 4. Due to changes in the focus of the SIAPS activities No activity was undertaken in this quarter. Activity 4:3:1 There was a lot of progress toward the increase of access to ACTs in the private sector. First, the PSACT TWG in collaboration with all partners developed the Liberia National Private Sector Strategy. SIAPS activities in this area were re focused to 2 counties Paynesville and St Paul. Based on work done in collaboration with the Sustainable Drug Sellers Initiative (SDSI) SIAPS selected and trained 120 dispensers from 120 medicine stores and pharmacies for Malaria Case management using ACT and RDT in Private Pharmaceutical sector in Paynesville District, Monrovia.

Challenges in progress toward sub-objective 4.1

Current Value: **(Sep 2012)** - The Private sector ACT roll out remains a key activity for the MOHSW, NMCP and the USAID. Presently the key challenge facing SIAPS is the appoint through the MOHSW of a private sector wholesaler to physically distribute the PMI ACTS and continue with the Global Fund procured ACTS once they arrive. A critical challenge which has not been resolved till date and which is hampering progress of the private sector work is the finalization of the mechanism to physically distribute the ACTs and RDTs in the private sector.

In March 2012, SIAPS drafted an MoU for the MoHSW to appoint a private wholesaler to undertake the distribution of ACTS in the private sector, there has been a delay in this process and till date the MOU has not been signed. In July 2012, the MOHSW in anticipation of funding from the Global fund issued a new advert in the dailies to appoint another private wholesaler to do national distribution of ACTs and RDTs beyond the pilot being planned by SIAPS. In several meetings with the PSACTTWG and the Deputy Minister of Health it was agreed that the National Distributor be appointed by the MOHSW to initiate the distribution of the PMI procured ACTS and RDTs in the pilot districts of Paynesville and St Paul whilst awaiting the Global Fund stocks of ACTS for national distribution. Unfortunately, till date this has not materialized.

SIAPS recommended the use of the National Drug Services (NDS) as an alternate distributor, this proposal was accompanied by a need for the NDS dedicate a separate account under the MoHSW to track funding accrued from the sales of the ACTS. This has since been done but there are still delays in using this alternate mechanism at the national level. SIAPS is working with the MOHSW to move this process forward and will need USAID support to ensure that this challenge is overcome especially to help ensure that the PMI procured products do not expire during the period the MOHSW waits to finalize the operations of the national distributor who has given a number of power point presentations to the PSACT TWG expressing its readiness to start working. The need to finalize the distribution entity's contracting mechanism is critical since further delays in contracting this entity places the PMI stocks at a higher risk of expiring.

## **MALI**

Mali work plan details for Year 1 of the SIAPS Program

### **Quarterly Report Background**

SIAPS has been provided with a total of \$950,000 in funds from the USAID/Mali mission to implement activities to improve functioning of the pharmaceutical system over a one-year period. It should be noted that \$100,000 of this was provided to the Strengthening Pharmaceutical Systems program (SPS) to allow program operations to continue while the start of SIAPS got underway. SIAPS will build on the work conducted by the SPS program to address the following key weaknesses in the pharmaceutical sector:

- Availability of regular, reliable pharmaceutical management information for decision-making
- Inadequate capacity and organization within key institutions responsible for developing, overseeing and regulating the pharmaceutical sector.
- Inadequate collaboration and communication among key actors in the pharmaceutical sector

As one of the countries participating in the US President's Malaria Initiative (PMI), and now the Global Health Initiative (GHI), Mali has the opportunity to accelerate its progress toward achieving the Millennium Development Goals (MDGs).

SIAPS will use resources being made available through the US government whose priorities include significantly improving health-related Millennium Development Goals (MDGs) 4, 5 and 6 which focus on reduction of child mortality, reduction of maternal mortality and prevention and treatment of malaria, HIV and other diseases including NTDs) in Mali through integrated programmatic interventions. The funding breakdown for Year 1 of SIAPS activity is as follows:

- \$500,000 PMI funds
- \$300,000 POP funds
- \$50,000 MCH funds

In Mali, key health commodities such as antimalarials, family planning commodities, and other essential pharmaceuticals are frequently unavailable at various different levels of the health system when they are needed by patients and information on pharmaceuticals that are needed for planning by the government, donors and technical partners are not readily available when required. Additionally, imbalances in stock levels of key commodities are a challenge to address rapidly because of poor coordination and information sharing among various actors in Mali's public health system that manage pharmaceuticals. Lastly, the key institution with responsibility for overseeing the pharmaceutical sector, the Direction de la Pharmacie et du médicament, is unable to full carry out the functions conferred through its mandate.

### **Goal: Mali Year 1 Work Plan Goal**

Improved Access to pharmaceuticals and services

#### **Objective 1**

Pharmaceutical sector governance strengthened

#### **Sub-Objective 1.1**

Improved capacity of the DPM to promote and instill good governance in the Malian pharmaceutical sector

#### **Activity 1.1.1**

Contribute to the revision process for the national health strategic plan PDDSS/PRODESS

**Activity 1.1.2**

Support the validation and the dissemination of the PPN 2010 version and the revised Schema Directeur

**Sub-Objective 1.2**

Mechanisms for national forecasting, quantification and supply planning of key pharmaceuticals are consolidated and made more efficient

**Activity 1.2.1**

Support the national stakeholders to activate and strengthen the technical Committee for quantification, forecasting and supply planning for key commodities

**Activity 1.2.2**

Develop and update national supply plans for key commodities and update them on a quarterly basis

**Activity 1.2.3**

Support national stakeholders to develop distribution plans for key commodities

**Objective: Objective 2**

Capacity for pharmaceutical supply management and services increased and enhanced

**Sub-Objective 2.1**

Mechanisms for distributing commodities improved

**Activity 2.1.1**

Monitor the distribution of malaria commodities purchased by PMI through JSI/DELIVER

**Objective: Objective 3**

Pharmaceutical management information is available and used for decision-making

**Sub-Objective 3.1**

Pharmaceutical management systems support both patients and products

**Activity 3.1.1**

Advocate for the revision of the existing LMIS

**Activity 3.1.2**

Assess the existing logistics management information system from central to community levels, with a view to redesigning the system

**Activity 3.1.3**

Monitor and report on availability of malaria stocks through the PPMRm reporting mechanism

**Activity 3.1.4**

Implement two End User Verification Surveys

**Objective: Objective 4**

Pharmaceutical services improved to achieve desired health outcomes

**Sub-Objective 4.1**

Stock outs of tracer pharmaceuticals are reduced

**Activity 4.1.1**

Stimulate corrective actions based on pharmaceutical management data received to reduce stock outs of tracer commodities

**Goal: Quarterly Report Fields**

These are the fields that will be used to collect information for quarterly reports.

Overall Quarter Progress

Current Value: (**Sep 2012**) - During Q4, SIAPS/Mali progressed on all 4 objectives as follows. Under IR 1, SIAPS progressed on standardizing approaches to pharmaceutical management by making key governance documents available to the health system. This was done by helping the Directorate of Pharmacy and Medicines (DPM) to prepare for the dissemination of the Schéma Directeur d'Approvisionnement et de Distribution des Médicaments Essentiels (SDADME) to central and regional levels of Mali's health system. The SDADME is a key document that guides the functioning of Mali's pharmaceutical sector. Additionally, SIAPS contributed to strengthening the governance of the pharmaceutical sector through its technical assistance to the national malaria control program (NMCP)'s mechanism for coordinating to strengthen the coordination of all partners involving in quantification and supply planning for malaria commodities by assisting the NMCP in holding coordination meetings for conducting the quantifying, forecasting and planning procurement of malaria commodities, and providing technical assistance to actually conduct a quantification exercise. In the future, SIAPS will focus on ensuring that all the elements necessary for this malaria commodity committee to function are in place, including updated terms of reference, developing an annual calendar of key activities, and establishing a mechanism for receiving, analyzing and using historical information for conducting consumption-based quantification.

Progress on IR 2 (Capacity for pharmaceutical supply management and services increased and enhanced the only one sub-objective approved) was also made, with respect to improving the capacity to distribute malaria commodities. SIAPS provided support to John Snow, Inc. (JSI)/DELVER to monitor the distribution of malaria commodities from the central level to the district level of the health system to ensure that commodities are correctly and effectively distributed.

Under IR 3 (Pharmaceutical management information available and used for decision making at different levels of the Malian health system), the foundation was laid for fundamentally transforming the existing system for collection and transmission of data by beginning an assessment of the logistics management information system that was completed in October. During Q4, SIAPS presented and discussed with the DPM, PPM, the national malaria control program (PNLP) and key USAID implementing partners (MCHIP, ATN+, MEASURE) a plan for the logistics management information system assessment whose output will be the redesign of the existing information system of pharmaceuticals. This assessment was then conducted using the Logistics System Assessment Tool and the Logistic Indicator Assessment Tool.

In Q4, SIAPS ensured that active data collection took place to provide data needed for monitoring the needs of the health system. This was done by supporting the NMCP and the DPM within to collect, analyze, and use data from different levels of the health system for decision-making. SIAPS produced a procurement Planning and Monitoring Reports for malaria (PPMRm), which provides information from the central level of the health system on stock levels of tracer products. SIAPS obtained data from lower levels of the health system through the End User Verification Survey, which provided information which was used for decision making such as procurement decisions and corrective actions to address imbalances in availability of stocks. But the ultimate goal for SIAPS/Mali is to collect logistic data in routine for decision making.

Progress on IR 4 (improving pharmaceutical services to achieve desired health outcomes) was made by avoiding stock outs by following up to ensure that recommendations made by SIAPS through the PPMRm were implemented, resulting in JSI/PMI procuring commodities for delivery to the PPM to avoid stock outs and maintain adequate stock levels for Malaria commodities.

#### Key challenges faced during the quarter

**Current Value: (30 Sep 2012)** - In March 2012, a military overthrow of the government created a situation of extended political unrest in the country. Immediately following this ‘coup d’état’, the United States Agency for International Development (USAID) suspended its assistance to the Malian government. Consequently, all USAID-funded activities ceased and USAID implementing partners were prohibited from implementing technical activities during the third quarter of FY12. SIAPS/Mali was unable to implement work plan activities from the end of March to mid-July 2012, when SIAPS became one of the first implementing partners to be allowed to resume activities. The resumption of activities has come with specific guidance, including ensuring that the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) activities target the community level of the health system for strengthening as much as possible.

SIAPS is permitted to implement certain activities in collaboration with Government of Mali counterparts. However, SIAPS is prohibited from implementing any family planning-related activities with Government of Mali counterparts, and can therefore only conduct activities related to family planning with non-governmental counterparts, and those activities must be focused at the community level.

During Q4, SIAPS submitted a revised work plan to USAID/Mali that took these

restrictions into account. The work plan was approved with the following exceptions:

- IR1.1 - The proposed activity "strengthening existing technical committees for contraceptives" is NOT approved due to US legal restrictions related to the coup d'état.
- IR1.2.1 – The proposed activity “Mechanisms for national forecasting, quantification and supply planning of key pharmaceuticals are consolidated and made more efficient and transparent”; This work may NOT include work on family planning.

The small number of technical staff on the Mali SIAPS team (5) also continued to present a challenge to the simultaneous execution of various activities in the Mali SIAPS Y1 work plan. However, this situation will soon be alleviated through the hiring of additional technical staff (1 M&E Advisor and 2 additional Regional Technical Advisors), which is currently underway.

#### Key activities planned for next quarter

Current Value: (**30 Sep 2012**) - SIAPS plans to implement the following activities during the next quarter:

- Obtain final approval of the SIAPS Y2 work plan from the USAID Health Team.
- Proceed with the following work plan activities to contribute to the corresponding intermediate results:
  - IR 1: Pharmaceutical sector governance strengthened
    - o Support the DPM in the printing and dissemination of the SDADME to all levels of the health system.
    - o Improve the existing mechanisms for coordinating quantification, forecasting, distribution and corrective actions for the supply of health commodities.
  - IR 2: Capacity for pharmaceutical supply management and services increased and enhanced
    - o Support quantification exercises.
  - IR 3: Pharmaceutical management information available and used for decision making at different levels of the Malian health system
    - o Disseminate the results of the LMIS assessment (LIAT and LSAT).
    - o Prepare and submit the PPMRm (collection and organization of data, preparation and submission of reports in country, validation of reports with the MoH prior to report submission to USAID Washington).
    - o Update ACT and RDT WHO needs estimation report.
    - o Disseminate the results of the 2nd EUV conducted during Q4.

#### Technical Activity Coordination

Current Value: (**30 Sep 2012**) - Work Planning During the second semester of activities of SIAPS in Mali, SIAPS submitted a revised work plan for year 1 based on the new guidance provided by USAID after the coup d'état. This revised work plan was approved. SIAPS also submitted a draft work plan for FY13 and budget; Reporting Health Partners Meeting (September): meeting organized by the Mission with all USAID implemented partners to discuss FY13 work plan and coordinate activities. Country Open Meeting (Monthly) with the Mission Cluster Santé Meetings Organized by WHO. The SIAPS/Mali team participated in the 'cluster santé' meeting organized by WHO. These meetings occurred every

Thursday and all partners (national and international) attended them. During these meetings SIAPS contributed to preparation of a contingency plan for selecting and distributing donations of health commodities to address situation in Mali following the coup d'état.

#### Office management

Current Value: **(30 Sep 2012)** - There were no major developments on office management between July 1st 2012 and September 2012

#### Quarterly Report Fields (Objective)

Objective-level fields for collecting information for quarterly reports.

##### Quarterly Progress for Objective 1

Current Value: **(Sep 2012)** - During Q4 of SIAPS's first year of operation in Mali, SIAPS contributed to the objective of improved governance in the pharmaceutical sector through its technical assistance to the national malaria control program (NMCP) to support the operationalization of the quantification mechanism for malaria commodities. As part of this technical assistance, SIAPS helped the NMCP to conduct the quantification of national needs in artemisinin combination therapy (ACT). Additional, SIAPS assisted the NMCP to develop distributions plans for ACTs, rapid diagnostic tests (RDTs), and microscopy kits for malaria case management. SIAPS also contributed to meeting this objective by helping the Directorate of Pharmacy and Medicines (DPM) to plan the distribution of copies its key document defining the standards, policies and procedures to be followed in the pharmaceutical sector. This document is known as the Schéma Directeur d'Approvisionnement et de Distribution des Médicaments Essentiels (SDADME). The SDADME will be distributed at the central and regional levels of the health system. Actual distribution of this document will take place during the 1st quarter of FY13.

##### Quarterly Progress for Objective 2

Current Value: **(Sep 2012)** - The only progress made toward reaching this objective focused on building the capacity of the pharmaceutical system to effectively delivery products and services, was the resumption of technical assistance provided by SIAPS to improve distribution planning for malaria commodities whilst ensuring that malaria commodities arriving in Bamako reach at least the district level of the health system. SIAPS provided support to John Snow, Inc. (JSI)/DELVER during Q4 to monitor the distribution of malaria commodities to the district level of the health system. On July 23rd, SIAPS provided JSI with an updated report on malaria commodities distribution from the central level to regional and district level. The End User Verification Survey (EUVS) conducted in November 2011 showed that 50% to 65% of facilities surveyed were out of stock of key Malaria commodities. The second EUVS conducted in August and September 2012, showed that 40% of the community health centers (CsComs, district and community level) and 17. 6% of the district warehouses (DRCs) were out of stock of key malaria commodities, showing a slight improvement in distribution capacity and practice within a 9 month period.

##### Quarterly Progress for Objective 3

Current Value: (**Sep 2012**) - During Q4, SIAPS progressed toward reaching the Objective of improving the quality and quantity of pharmaceutical data needed for decision-making. This was done by continuing to assist the NMCP and the DPM within Mali's Ministry of Health (MoH) with active collection, analysis and use of pharmaceutical data. Additionally, SIAPS began the process of strengthening of the national logistics management information system. Active data collection was done at different levels of the health system, using two different mechanisms: Procurement Planning and Monitoring Reports for malaria (PPMRm) submitted in July 2012, and through the implementation of an End User Verification Survey in September 2012. PPMRm reports provide information from the central level of the health system on stock levels of tracer products, was submitted in July 2012 and the recommendations made in these reports are aimed at taking actions aimed at averting stock outs of pharmaceuticals.

#### Quarterly Progress for Objective 4

Current Value: (**Sep 2012**) - SIAPS contributed to Objective 4 of the SIAPS/Mali workplan (Ensuring availability of quality pharmaceutical products and services) by taking concrete actions to both avert and mitigate stock outs. In accordance with recommendations from the July 2012 PPMRm submitted by SIAPS, JSI/PMI procured commodities for delivery to the PPM to avoid stock outs and maintain adequate stock levels for the following products: AL 20mg/120mg (Blisters of 6X1), AL 20mg/120mg, (Blisters of 6X2 tablets); AL 20mg/120mg, (Blisters of 6X3 tablets); AL 20mg/120mg, (Blisters of 6X4 tablets); RDTs (Boxes of 25 tests). Furthermore, EUV data collectors took the initiative to move medicines from district pharmaceutical warehouses to CsCOMs in certain areas that were found to be out of stock.

#### Quarterly Report Fields (Sub-Objective)

Fields for reporting quarterly progress at the sub-objective level.

##### Quarterly progress toward sub-objective 1.1

Current Value: (**30 Sep 2012**) - Activities to be implemented under this IR included the contribution of SIAPS to the revision of the national health strategic plan. Several members of the SIAPS team collaborated with the MoH to achieve this during Q1 and Q2. A second activity planned under this intermediate result was to support the validation and dissemination of the 2010 version of the National Pharmaceutical Policy (NPP) and the revised Schéma Directeur. The Schéma Directeur is a comprehensive document that describes the functioning of the pharmaceutical sector and therefore serves as a guide to persons working in this sector. During Q3, it was not possible to implement the validation and dissemination of the NPP and the Schéma Directeur because of the US government's temporary suspension of aid to Mali. After resuming activities in Q4, SIAPS met the DPM to plan these remaining activities. Terms of reference and a budget were developed for the activity, which will now be held in November 2012.

##### Quarterly progress toward sub-objective 1.2

Current Value: (**30 Sep 2012**) - The activities planned under this sub-IR were to support national stakeholders to activate and strengthen the technical committee for quantification,

forecasting, and supply planning for key commodities and to develop national supply plans for key commodities and to update them on a quarterly basis. Additionally, SIAPS had planned to support national stakeholders to develop distribution plans for key commodities. Supply chain coordination in Mali is done through thematic groups whose members include the MoH and various implementing partners for key MoH national programs.

During Q4, several meetings and discussions occurred with the DPM, the PPM, and the PNLP and agreement was reached to have only one committee with subcommittees coordinated by the DPM. This type of structure was also recommended by the Global Fund to Fight Tuberculosis, AIDS and Malaria (GF). Work remains to be done to make this coordination mechanism function more systematically by holding regular coordination meetings. Additionally the coordination mechanism needs to establish and respect a regular schedule for conducting quantification, forecasting and updating supply plans being implemented that does not revolve around a single donor. The suspension of US government aid to Mali made it impossible for SIAPS to implement this activity on time. Therefore, SIAPS will give this activity priority during its second year of operation. However, SIAPS will not be able to support the Government of Mali on the coordination of family planning commodities for the moment, as SIAPS is still prohibited from working on family planning-related activities with the Government of Mali for now.

With respect to distribution planning, SIAPS assisted the PNLP and the PPM during Q4 with the technical reception of malaria commodities received on September 2012. After that, SIAPS provided technical assistance to the PNLP to develop distribution plans for the products that had been received (ACT, RDT, and microscopy kits) The distribution plans were based on the burden of malaria in each region and district using data from the 2011 Statistical Yearbook 2011. Additional data were also considered in the distribution planning. Data on populations displaced following the March 2012 coup d'état was also taken into consideration. Further adjustments were made based on data collected in the field during the EUVS conducted from September 22 to October 9, 2012 and during the Logistics Indicator Assessment Tool assessment also conducted in Q4. The decision was made to keep a buffer stock from this shipment at the Central Medical Stores Central Warehouse in Bamako. In case where district pharmaceutical warehouses had specifically sent orders to the NMCP for the commodities in this shipment, the quantities sent to the districts equaled the quantities that were ordered.

#### Challenges in progress toward sub-objective 1.2

Current Value: **(30 Sep 2012)** - The suspension of US government aid to Mali made it impossible for SIAPS to implement this activity on time. SIAPS will make the completion of this activity a priority during Y2 of project implementation.

#### Deliverables: Sub-Objective 1.2

Current Value: **(30 Sep 2012)** - Deliverables completed for this sub-IR: distribution plan for Malaria commodities (ACT/ RDT and lab commodities).

#### Quarterly progress toward sub-objective 2.1

Current Value: **(30 Sep 2012)** - Minimum progress was made on this sub-objective, which focuses on improving mechanisms for distributing commodities. This was because the key activity contributing to this objective because the work plan was not approved and

because the US government's suspension of aid to Mali 2012 was lifted during the quarter. Still, SIAPS/Mali did provide technical assistance to ensure that adequate distributing planning was conducted to organize delivery of PMI-purchased health products from the Central Medical Stores to the district pharmaceutical warehouses.

Deliverables: Sub-Objective 2.1

Current Value: (**30 Sep 2012**) - Deliverable: Report on stock status and on distribution submitted to JSI.

Quarterly progress toward sub-objective 3.1

Current Value: (**30 Sep 2012**) - Progress toward this sub-objective occurred through beginning the process of strengthening the pharmaceutical management information system whilst actively collecting logistics management information data necessary for decision-making. PPMRm submission • Submitted 1 PPMRm report to USAID/Washington during Q4 • These data make it possible recommend whether orders should be placed for specific commodities. EUVS • Conducted in 75 sites in August/September 2012 • Data collected data from five regions in the South of Mali Major findings: • Malaria standard treatment guidelines are available in 76.81% of health facilities. • Still, number of health workers is failing to adhere to the national treatment protocol of uncomplicated malaria. 14% percent of uncomplicated malaria cases were treated with monotherapy instead of ACTs. • 49.27% (34/69) of health facilities reported receiving supervision on Malaria Case Management during the last 6 months. • 44.1% of the facilities are out of stocked for artemether lumefantrine (AL)/24 on the day of the visit; • More than 50% of the facilities did not have the tools to report logistic data. • CsComs frequently fail to collect their allocated commodities. SIAPS proposes to collaborate with USAID implementing partners to strengthen the distribution and transportation of donations from the district level to community health facilities, under its Y2 work plan to address this.

LMIS Assessment: During Q4, SIAPS began strengthening the logistics management information system for medicines in Mali by first implementing a two-part assessment of Mali's LMIS in collaboration with the DPM, the PPM and the PNLP. The objectives were to identify strengths and weaknesses of the existing system and to propose corrective measures in order to define standard operational procedures for stock management.

SIAPS collaborated with the DPM, the PPM and the PNLP to form a technical working group to plan and conduct this two part assessment using both qualitative and quantitative assessment tools. A total of 43 sites were selected for evaluation in the quantitative assessment. Preliminary results of the quantitative phase:

Recording and Transmission of Data • LMIS data is collected by 65% of facilities visited. However, 93% of these facilities do not transmit this data. • 30% of the community health workers collect the required LMIS data. • 50% of community health workers submit reports on health commodities managed to CsComs, but these reports do not always contain the required LMIS data.

Order Placement and Fulfillment • When health facilities order health commodities from higher levels of the national supply chain, they only receive 26.6% of the requested order, on average. • In general, orders are delivered rapidly (average is 5 days after placing the order). • Emergency orders are frequent (51%).

Availability of Health Commodities • 65% of the facilities had at least one stock out occurred during the last six months and 76.7% at the time of the visit at the CsCom level. • Stock-outs lasted as few as 4 days and as long as 97 days for products examined. • Some products had been repeatedly out of stock during the past 6 months at the time of the assessment- e.g. AL 24 (26 times), quinine (23 times) and AL6 (22 times).

Inventory Management • Only 3% of the health facilities had inventory levels between the maximum and minimum. • Storage instructions are rarely observed (available in only 18.6% of facilities) • On average, 3.40% of the stock is unusable due to expiry. • 100% of the community health workers interviewed obtain the commodities they manage their drugs at the CsCom. Recommendations from this Phase of the Assessment will be validated by authorities and included in work plans to be implemented.

Deliverables: Sub-Objective 3.1

Current Value: **(30 Sep 2012)** - - 1 PPMRm - 1 EUV report - 1 Draft report of the LMIS assessment

Quarterly progress toward sub-objective 4.1

Current Value: **(30 Sep 2012)** - This sub-IR focuses on reducing or avoiding stock outs of pharmaceuticals by taking corrective actions once analysis of pharmaceutical management data shows that stock outs are imminent or that stock outs currently exists. SIAPS does not take corrective actions unilaterally, but rather, coordinates with partners such as national programs (such as the NMCP for malaria commodities or the DPM to organize responses to stock outs.

When stock imbalances are found during field data collection (which is always conducted in coordination with government counterparts), SIAPS follows up to ensure that their government counterparts at lower levels of the health system (e.g. Regional Health Office) issues the appropriate communications to allow for redistribution of stocks within a region, for example.

The following are examples of corrective actions taken by various actors in Mali's health system following the receipt of recommendations from mechanisms such as PPMRm, and EUVS reports.

- In accordance with recommendations from the July's PPMRm, JSI/PMI procured commodities for delivery to the PPM to avoid stock outs and maintain adequate stock levels for the following products: AL 20mg/120mg, tablets 6X1 Blister 464,160 AL 20mg/120mg, tablets 6X2 Blister 38,4060 AL 20mg/120mg, tablets 6X3 Blister 199,960 AL 20mg/120mg, tablets 6X4 Blister 148,890 RDT Pf, bte de 25 tests 14,000 RDT/Pan, bte de 25 tests 2,000 Kit GE/FM 65

- Some corrective actions were taken during the EUVS, for example the EUV team assisted some CsComs by providing transportation means to obtain malaria commodities from district pharmaceutical warehouses. For example one EUV data collection team transported malaria drugs from Kignan district to Doumanaba CsCom) to avoid stock out.

- At the encouragement of SIAPS, the MoH is preparing a letter to send to pharmaceutical warehouse managers to report on LMIS data.

## **MOZAMBIQUE**

Mozambique work plan details for Year 1 of the SIAPS Program

### **Quarterly Report Background**

Significant gaps exist in pharmaceutical policies and the delivery of pharmaceutical services in Mozambique. They have received limited technical support and need to be addressed through strengthening the pharmaceutical sector of the Ministry of Health to ensure the quality, safety and efficacy of medicines, particularly for priority health program like HIV/AIDS. The Mozambique pharmaceutical sector has been undergoing substantial reform in recent years. Establishing an effective and sustainable regulatory system is a high priority for the pharmaceutical sector as well as improving the quality and effectiveness of pharmaceutical services.

In recognition of the importance of the pharmaceutical sector to the overall functioning of an integrated health system and the quality of services-- in particular, for priority health conditions, such as HIV/AIDS-- USAID/Mozambique has enlisted SIAPS to strengthen the sector's institutional and technical capacity with PEPFAR funds for FY11. Based on the gaps that have been identified in the pharmaceutical system, SIAPS will focus on supporting the Mozambique pharmaceutical sector in the areas of policy, regulation, pharmacovigilance, rational use and the overall delivery of pharmaceutical services.

### **Goal: Mozambique Year 1 Work Plan Goal**

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

#### **Objective 1**

Governance in the pharmaceutical sector strengthened

##### **Sub-Objective 1.1**

Improved medicines policies, legislations, regulations, norms and standards

##### **Activity 1.1b**

Provide technical support for the development and institutionalization of processes, procedures and criteria for the registration of pharmaceutical products

##### **Sub-Objective 1.2**

Transparent and accountable pharmaceutical management systems

##### **Activity 1.2a**

Conduct a stakeholder meeting to build consensus on the framework for the national pharmacovigilance system and agree on roles and responsibilities

##### **Activity 1.2b**

Assist the Pharmacy Department with the development of a monitoring and evaluation (M&E) plan

##### **Sub-Objective 1.3**

National pharmaceutical sector development plans are strategic and evidence-based

**Activity 1.3a**

Conduct a baseline assessment of the regulatory system using the Regulatory System Assessment Tool (RSAT)

**Activity 1.3b**

Assist with the development and adoption of a strategic plan for the pharmaceutical sector

**Objective 2**

Capacity in pharmaceutical management increased and enhanced

**Sub-Objective 2.1**

Pharmaceutical management capacity of individuals, institutions, organizations and networks strengthened

**Activity 2.1a**

Conduct training in the evaluation of medicine dossiers for product registration

**Activity 2.1b**

Assist the Pharmacy Department with a pharmacovigilance training for provincial level staff

**Objective 3**

Utilization of strategic information for decision-making increased

**Sub-Objective 3.1**

Pharmaceutical Management Information Systems (PMIS) support both products and patients

**Activity 3.1a**

Conduct an options analysis to identify an appropriate information system in support of the regulatory system for pharmaceuticals (and initiate implementation)

**Sub-Objective 3.2**

Innovative and proven tools broadly available and used

**Sub-Objective 3.3**

Strategic information on pharmaceutical systems strengthening available and used

**Objective 4**

Pharmaceutical services to achieve desired health outcomes improved

## Sub-Objective 4.2

Patient safety and therapeutic effectiveness assured

### Activity 4.2a

Provide technical support to the Pharmacy Department and priority health programs to pilot active surveillance activities

### Goal: Quarterly Report Fields

These are the fields that will be used to collect information for quarterly reports.

### Overall Quarter Progress

Current Value: **(Sep 2012)** - Highlights of the SIAPS program's work in Mozambique in FY12 include:

- The installation of a full-time, in-house Senior Technical Advisor for regulatory systems at the Pharmacy Department.
- Harmonized work plans with the Pharmacy Department and SIAPS.
- The provision of technical assistance to the registration team at the Pharmacy Department in the development of essential tools to guide the evaluation of products for registration.
- The provision of training to the registration staff in the evaluation of medicine dossiers and the appropriate use of registration tools.
- The provision of a three-day training as a short introduction to pharmacovigilance systems which contributed to further strengthening of Mozambique's efforts. This training began with a sharing of a common understanding of basic concepts about medicines and patient safety and laid the foundation for increased national stakeholder involvement and support towards the eventual establishment of a strong system that effectively ensures the safe use of medicines, vaccines and other health technologies.
- In this context, a key step for the engagement of stakeholders and the mobilization and organization of resources was to hold a meeting with health professionals in October 2012. At this meeting, in order to achieve a common understanding there was an agreement on the structural components to create functioning pharmacovigilance systems in Mozambique. Attendants also worked to get a consensus on the prospects of a National System of pharmacovigilance to help ensure the safety of medicines and vaccines.

### Key challenges faced during the quarter

Current Value: **(Sep 2012)** - There is only one technical adviser for the Pharmacy Department currently. MSH has had difficulties with registering the organization and this had led to delays and challenges in posting positions, hiring local staff, and establishing the project as was planned for the first year of implementation. These issues are being corrected and MSH does not foresee these delays carrying forward through Year 2.

### Quarterly Report Fields (Sub-Objective)

Fields for reporting quarterly progress at the sub-objective level.

### Quarterly progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - SIAPS has provided on-going technical support to the registration team at the Pharmacy Department to develop new guidelines and tools based on the initial training they received in the evaluation of medicine dossiers under SPS. SIAPS provided

follow-up training in the correct application of some of the new tools for the evaluation of medicine dossiers in February 2012 and outlined next steps for the development/revision/completion of a complete set of tools. The resident technical advisor worked closely with the registration department staff in developing the job description, SOPs and flow chart of process needed for reception and evaluations of the registration applications. In September, 2012 SIAPS conducted another training session with the registration team, which led to the revision and finalization of the following products: • Receiving /Screening Checklist for dossier submission (Protocol of Reception and Validation of complete registration forms and attachments). • Evaluation Report Template for evaluation of quality data submitted for registration of medicines. • Evaluation of the registration procedures list. • Guidelines for applicants and registration staff. • Job descriptions (JDs) for the registration staff. • Standard Operating Procedures (SOPs) needed for the registration receiving/screening checklist and evaluation report.

Challenges in progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - Competing priorities and a heavy workload have made it difficult for the registration team to be able to participate in the training sessions. The guidelines for applicants and registration staff need to be reviewed by the head of registration department and translated to Portuguese in order to be finalized and implemented.

Deliverables: Sub-Objective 1.1

Current Value: **(Sep 2012)** - • Receiving /Screening Checklist for dossier submission (Protocol of Reception and Validation of complete registration forms and attachments). • Evaluation Report Template for evaluation of quality data submitted for registration of medicines. • Evaluation of the registration procedures list. • Guidelines for applicants and registration staff. • Job descriptions (JDs) for the registration staff. • Standard Operating Procedures (SOPs) needed for the registration receiving/screening checklist and evaluation report.

Partner Contributions: Sub-Objective 1.1

Current Value: **(Sep 2012)** - The Pharmacy Department is taking the lead on producing the guidelines and tools for product registration with technical input from SIAPS. The product registration team has been very receptive to technical assistance and has demonstrated a strong commitment to improving the system by making its staff available for training and the development of key products.

Quarterly progress toward sub-objective 1.2

Current Value: **(Sep 2012)** - SIAPS worked with the pharmacovigilance unit at the Pharmacy Department to prepare an agenda, a participant list, presentations and other materials for the stakeholder meeting conducted in October. SIAPS also reviewed the national framework with the PV unit again to ensure a full understanding of it and its underlying concepts to ensure their preparedness to present it at the meeting. The one day workshop was attended by representatives from MISAU priority programs, DINAM, academic and training institutions, CIMed, CoPI, professional association and director of health services from the ten provinces and ended with concluding remarks from the Minister of Health.

Challenges in progress toward sub-objective 1.2

Current Value: **(Sep 2012)** - The Pharmacy Department did not efficiently manage administrative preparations and communication about the meeting, namely the distribution of

invitations to attendants, to ensure sufficient advance notice and planning. As a result, some of the key stakeholders were not able to attend.

Deliverables: Sub-Objective 1.2

Current Value: **(Sep 2012)** - Technical report under development and finalization.

Partner Contributions: Sub-Objective 1.2

Current Value: **(Sep 2012)** - The pharmacovigilance team at the Pharmacy Department does not demonstrate sufficient initiative and appears to be understaffed given the scope of its current and intended functions. They struggle to complete agreed upon tasks and products and require constant direction. SIAPS is working on strengthening their effectiveness and will work in the next quarter on more one on one follow-up.

Quarterly progress toward sub-objective 1.3

Current Value: **(Sep 2012)** - The Pharmacy Department has been operating without a strategic plan in place to guide its work. As a result, the department's annual work plan activities are not developed with a clear and consistent vision of its immediate and long-term goals and objectives. SIAPS will provide technical support to the PD to use existing information—including the RSAT, previous SPS assessments and other strategic information—to develop a 5-year strategic plan with input from other key stakeholders. The SIAPS work plans will be harmonized with the Pharmacy Department's plans to ensure they are congruent.

Challenges in progress toward sub-objective 1.3

Current Value: **(Sep 2012)** - The Strategic work plan development went under the process guidelines established by MOH. The vision, goal, and objectives were developed in coordination with the MOH strategic plan development committee. The development of sub-objectives and activities will be carried out with the Pharmacy Department planning officer and various head of departments. The challenges that it is time consuming and it will take several months until the final version of the PD strategic plan finalized

Deliverables: Sub-Objective 1.3

Current Value: **(Sep 2012)** - Only main objectives are developed, the sub-objectives and activities will be finalized in Jan-Feb, 2013.

Partner Contributions: Sub-Objective 1.3

Current Value: **(Sep 2012)** - The Pharmacy Department staff were cooperative to a certain extent. They need capacity building in the concept of strategic planning especially in defining and classifications of activities according to related objectives and sub-objectives.

## **NAMIBIA**

Namibia work plan details for Year 1 of the SIAPS Program

### **Quarterly Report Background**

Namibia is one of the countries that have seriously been impacted by the HIV/AIDS epidemic. The Government of the Republic Namibia with support from PEPEPFAR and other agencies started the treatment program in 3 sites in 2003 and rapidly scaled it up to all the key health facilities in the country. The rapid scale up and the increasing numbers of the patients have brought a strain on pharmaceutical systems and threaten sustainable provision of quality ART services. The SIAPS program with support from USAID, builds the capacity of the Ministry of Health and Social Services (MOHSS) of the Government of Namibia (GRN) and other local institutions to manage pharmaceutical systems and service delivery of HIV/AIDS commodities in all regions of Namibia. The project contributes to three strategic areas of the Partnership Framework (PF) in all regions of the country: governance, systems strengthening, and care and treatment, specifically addressing antimicrobial resistance, access to medicines, and the appropriate use of medicines.

In Namibia, SIAPS focuses on achieving the following objectives:

1. Enhancing access to pharmaceutical products and services through improved medicine policies, regulation, quality assurance and governance.
2. Strengthen human resources capacity for pharmaceutical management functions and services; increasing the capacity of local institutions and networks to provide pharmaceutical management technical assistance.
3. Strengthen pharmaceutical services to enhance achievement of planned TB and HIV program goals and objectives for both adults and pediatrics. This will include strengthened financing strategies and mechanisms for improving access to medicines.
4. Strengthened strategic information systems to ensure availability of reliable information for effective decision making in the pharmaceutical sector.

In FY2012, SIAPS will advocate for the absorption of technical staff seconded to MoHSS to reduce costs. In addition, the project will share operational costs, leverage synergies of other mechanisms managed by MSH in Namibia, and encourage MoHSS to co-fund selected interventions to be more cost-effective. SIAPS will strengthen institutional leadership to strengthen local ownership and mentor relevant staff. These steps will be key strategies for transitioning the activities to MoHSS and other in-country partners.

In order to strengthen monitoring and evaluation systems SIAPS has developed measurable indicators which have been used to track the progress of the project. SIAPS will monitor data quality assurance and outcomes and document case studies and success stories which will be disseminated. An end-of-project evaluation will also be conducted.

### **Goal: Namibia Year 1 Work Plan Goal**

To develop sustainable capacity for assuring the long-term availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes in public and private sectors in Namibia

#### **Objective 1**

To enhance access to pharmaceutical products and services through improved medicine policies, regulation, quality assurance and governance

#### **Sub-Objective 1.1**

Strengthen medicines regulation

**Activity 1.1.1**

Support implementation of strategies and best practices to improve regulatory capacity and processes for a sustainable NMRC.

**Sub-Objective 1.2**

Disseminate and implement the national medicines policy and its implementation plan

**Activity 1.2.1**

Support monitoring of implementation of the National Pharmaceutical Master Plan (NPMP)

**Objective 2**

To strengthen human resources capacity for pharmaceutical management functions and services and increase the capacity of local institutions and networks to provide pharmaceutical management technical assistance and pharmaceutical management services

**Sub-Objective 2.1**

Support to the University of Namibia for the Pharmacy Program

**Activity 2.1.1**

Provide technical support UNAM pharmacy program

**Sub-Objective 2.2**

Strengthen the institutional capacity of NHTC

**Activity 2.2.1**

Provide support for 3 staff at National Health Training Center (NHTC) for the training of Pharmacist Assistants.

**Sub-Objective 2.3**

Support Human Resources for health (Seconded staff)

**Activity 2.3.1**

Support seven technical staff seconded to support program interventions in MoHSS departments like the Therapeutics Information and Pharmacovigilance Centre (TIPC), the NMRC, the National Medicines Policy Coordination (NMPC) and in two hospitals (Usakos and Katutura Hospitals) and building their capacity in order to ensure sustainable delivery pharmaceutical services.

**Objective 3**

To Support and strengthen financing strategies and mechanisms that will enhance public private partnership in improving access to medicines

**Sub-Objective 3.1**

Technical support to strengthen the public-private partnership

**Activity 3.1.1**

Enhance public-private partnership to increase access to ART information and services.

**Objective 4**

Strengthen pharmaceutical services to enhance achievement of planned TB and HIV program goals and objectives for both adults and pediatrics

**Sub-Objective 4.1**

Technical support to strengthen the public-private partnership

**Activity 4.1.1**

Provide support to the subdivision of national medicines policy coordination to support the implementation and monitoring of standard treatment guidelines and guideline technical committees

**Sub-Objective 4.2**

Provide TA and support for AMR/HIVDR through EWIs, eTB Manager and Adherence interventions

**Activity 4.2.1**

Support monitoring of Antimicrobial Resistance (AMR) and strengthening the monitoring and interventions for HIV Drug Resistance (HIVDR) including analysis and use of Early Warning Indicators (EWI).

**Activity 4.2.2**

Strengthening human resource capacity and systems for the delivery of sustainable pharmaceutical services to support ART service delivery

**Activity 4.2.3**

Strengthen environmentally safe disposal of pharmaceutical waste in the private sector (assessment of the current waste management, implement key findings, training of pharmacists and health inspectors)

**Activity 4.2.4**

Support sites in scaling up pediatric ART coverage (technical assistance, training, equipment, EDT support)

**Activity 4.2.5**

Supporting implementation of adherence interventions in children

**Activity 4.2.6**

Strengthen national capacity for delivery and monitoring of pediatric ART services (Technical assistance, training, data analysis)

### **Sub-Objective 4.3**

Improve treatment outcomes by use of evidence from pharmacovigilance and treatment literacy

#### **Activity 4.3.1**

Support the development and implementation of adherence interventions (treatment literacy materials, routine adherence monitoring tools)

### **Objective 5**

Strengthen pharmaceutical information systems to provide evidence based analyses that enhance evidence based decision making in the pharmaceutical sector in Namibia

#### **Sub-Objective 5.1**

Support the PMIS Taskforce to finalize the PMIS review process and roll out PMIS

##### **Activity 5.1.1**

Support the pharmacy management information system (PMIS) upgrade and review; training of staff

#### **Sub-Objective 5.2**

Strengthen the quality and use of EDT ART and HIV/AIDS related Data

##### **Activity 5.2.1**

Strengthening data quality and use of data from the Electronic Dispensing Tool (EDT) at treatment facilities and NDB at the National Level (training, dissemination, data review); Support program monitoring and data quality. This will include support for data triangulation and strengthen quarterly data audits.

#### **Goal: Quarterly Report Fields**

These are the fields that will be used to collect information for quarterly reports.

##### **Overall Quarter Progress**

Current Value: **(Sep 2012)** - During the quarter, SIAPS made considerable progress towards the portfolio's overall goal of assuring the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes in Namibia. Under objective 1, the activities supported by SIAPS have contributed towards strengthening of the regulation of pharmaceutical products in Namibia by the Namibia Medicines Regulatory Council. In addition, the activities have contributed to a better coordination and technical oversight of pharmaceutical services delivery, particularly in the public sector facilities in Namibia, by the National Medicines Policy Coordination sub-Division of the Ministry of Health and Social Services. Cumulatively, 156/428(36%) of application dossiers for registration of medicines were registered; and 223/309 (73%) of medicine samples were tested for quality. The 2012 Pharmaceutical Services Support Supervision report was finalized, printed and disseminated to all 13 regions of Namibia.

In objective 2, SIAPS made progress towards strengthening of Namibia's long-term human resources capacity for the delivery of pharmaceutical management functions and services, and increasing the capacity of local institutions and networks to provide pharmaceutical management technical assistance. SIAPS continued supporting the University of Namibia in developing course modules for the pre-service teaching of supply-chain related topics for the Bachelor of pharmacy students at UNAM, including providing technical advice for the long-term planning of the School of Pharmacy. SIAPS also provided technical assistance to the Ministry's National Health Training Center towards strengthening NHTC's capacity for training of pharmacy assistants.

SIAPS activities implemented under objectives 3 and 4 have continued to strengthen the capacity of the MoHSS Division of Pharmaceutical Services to improve its information systems and tools for patient management and for the capture of essential pharmaceutical management data, as well as enhancing the Ministry's pharmaceutical data reporting processes to improve the availability of data for making evidence-based management and strategic decisions in ART and other pharmaceutical service delivery. In addition, SIAPS continued to provide TA for the implementation of Data Quality Assurance activities as well as strengthening collection and use of pharmacovigilance data.

The activities implemented under objective 5 have contributed towards enhancing the quality and delivery of ART and other pharmaceutical services in the country's public health facilities, including supporting the dissemination of the updated Namibia essential medicines list (Nemlist), evaluating the impact of the new comprehensive standard treatment guidelines (STGs), and supporting utilization of data from the EDT for the HIV Early Warning Indicators (EWIs).

#### Key challenges faced during the quarter

Current Value: (**Sep 2012**) - PMIS review: as the PMIS manual was being finalized there was a need for more consultation of Therapeutics Information and Pharmacovigilance Center (TIPC) team regarding the pharmacovigilance indicators. This review is pending and has held back the entire PMIS review process. ART Data Quality Assessment: the scheduled quarterly meeting between the HIV Response Monitoring and Evaluation (RM&E) sub-Division, National Medicines Policy Coordination and SIAPS, as well as proposed site visits to facilities with high discrepancies of their EDT & ePMS data, was cancelled due to unavailability of key RM&E staff. This has delayed the DQA exercise. Efforts continue to ensure that at least two DQAs are accomplished annually.

#### Key activities planned for next quarter

Current Value: (**Sep 2012**) - Dissemination of findings of the ART baseline adherence report. Finalization of PMIS review and development of supporting tools in preparation for roll-out in Q2 of FY13. Support the review and comparison of ART data for the period July -September 2012 from the two main ART sub-systems at health facilities- the EDT and the ePMS. Community based pharmacovigilance with Project Hope: Facilitate a TIPC training for the Project Hope-supported TB Field-based promoters in November 2012. This is aimed at improving the detection and reporting of adverse reactions to antiretroviral and anti-TB medicines; and supporting adherence to treatment especially among TB/HIV co-infected patients. Analysis of antimicrobial resistance patterns based on data from NIP: SIAPS will provide TA to the TIPC in the analysis and reporting of data from the Namibia Institute of Pathology (NIP) on the antimicrobial culture and sensitivity patterns of various pathogens. Information from this exercise will be used to guide informed decisions and will lead to targeted interventions to encourage the

appropriate use of antimicrobials and prevention of antimicrobial resistance.

#### Technical Activity Coordination

**Current Value: (Sep 2012)** - Project Management The SIAPS/SCMS Namibia management team was headed by Dr. David Mbirizi, the Country Program Director (CPD) for SIAPS/SCMS and deputized by Mr. Evans Sagwa. However, in the fourth quarter of FY12, Dr. David Mbirizi began the process of handing over the management of the SIAPS project to Mr. Evans Sagwa as the Acting CPD after Dr. Mbirizi assumed a new role at SIAPS Head Office. This was a transitional arrangement pending the appointment of the substantive CPD, who is expected to assume duty in January 2013. Dr. Mbirizi will then orient the new CPD and handover. SIAPS activities are directly supported by Senior Technical Advisors who are supported by the Deputy Country Program Director. The monitoring and evaluation of program activities is supported by the Senior M&E Advisor. This position is currently vacant and will be filled in November/December 2012. Technical activities are implemented using the proposed workplan submitted to USAID for approval, and closely monitored for budget, indicators, products and communications with partners and collaborators. Home Office Support SIAPS work in Namibia was supported by the Portfolio Manager (Dinah Tjipura) at MSH headquarters in Arlington, VA who provides financial and technical oversight. Work plan and budgeting for FY13: During this quarter, considerable progress was made in finalizing the work plan and budget for the FY13, due for submission to USAID in October 2012.

#### Office management

**Current Value: (Sep 2012)** - Financial and administrative support for both projects was provided through the team headed by the Operations Manager – Ms. Ruusa Iita. The Finance and Administration Unit comprises staff members who focus on administration and operations issues. These are supported by administrative staff from the home office. The administrative, financial and HR staff supported the four projects that are currently operating in country, i.e. SIAPS, SCMS, BLC, AIDSTAR II. The finance and office operations unit ensured that shared services such as rent, utilities, and office supplies are charged according to the correct prorata, based on the number of staff by project. SIAPS will be hiring an Accounting Manager in the first quarter of FY13, to strengthen the accounting and budget monitoring function of the team.

#### **Quarterly Report Fields (Objective)**

Objective-level fields for collecting information for quarterly reports.

#### Quarterly Progress for Objective 1

**Current Value: (Sep 2012)** - SIAPS provided technical assistance in the finalization of the draft post-marketing surveillance framework that was developed over the previous three quarters. The Pharmadex User Requirements Document (URD) was compiled, which will guide the further development of the Functional Specifications Document (FSD), upon which the enhanced web-based Pharmadex application will be developed in FY13. SIAPS provided TA for the electronic capture of data on revenues generated by NMRC product registration and facility inspection activities. This data is being collected for the options analysis for the autonomy of the NMRC. Cumulatively, 156/428(36%) of application dossiers for registration of medicines were registered; and 223/309 (73%) of medicine samples were tested for quality. Of the 223 samples, 103(46%) were tested within 2 weeks. The 2012 Pharmaceutical Services Support Supervision report was finalized, printed and disseminated to all 13 regions of Namibia. Overall, the results of the

activities supported under this objective are contributing to the stronger regulation of pharmaceutical products in Namibia and to a better coordination and technical oversight of pharmaceutical services delivery, particularly in the public sector facilities, in Namibia

#### Quarterly Progress for Objective 2

Current Value: **(Sep 2012)** - During the fourth quarter, SIAPS made progress towards long-term strengthening of the human resources capacity for the delivery of pharmaceutical management functions and services; increasing the capacity of local institutions and networks to provide pharmaceutical management technical assistance. SIAPS continued supporting the University of Namibia in developing course modules for the pre-service teaching of supply-chain related topics to the Bachelor of pharmacy students at UNAM, including providing technical advice for the long-term planning of the School of Pharmacy. SIAPS also provided technical assistance to the Ministry's National Health Training Center towards strengthening NHTC's capacity for training of pharmacy assistants. In addition, during Q4, SIAPS worked with the MoHSS HRH TWG to facilitate the transitioning of four of the 8 seconded staff positions to the MoHSS budget. The 2 SIAPS-supported UNAM lecturers were absorbed into UNAM's payroll in May 2012.

#### Quarterly Progress for Objective 3

Current Value: **(Sep 2012)** - Under this objective, SIAPS continued to support the MoHSS Division of Pharmaceutical Services to strengthen patient management and pharmaceutical data capture tools, the pharmaceutical management information system and basic skills in data manipulation, analysis and reporting to improve the availability of data for making evidence-based management and strategic decisions in pharmaceutical service delivery. In Q4, the support included implementation of the EDT Reporting Module that was finalized in Q3 and commencement of the use of the updated ART Monthly Report template, to facilitate more accurate and complete reporting of ART pharmaceutical data. Further technical assistance was provided to finalize the ART baseline adherence report and to finalize the approach for the evaluation of the eTB manager. In addition, SIAPS continued to provide TA for the implementation of Data Quality Assurance activities as well as strengthening collection and use of pharmacovigilance data

#### Quarterly Progress for Objective 4

Current Value: **(Sep 2012)** - Activities implemented under this objective, like Objective 3, also contribute towards improving the availability and use of data on the delivery and utilization of ART and other pharmaceutical services. In Q4, SIAPS continued to support the MoHSS Division of Pharmaceutical Services to enhance its pharmaceutical management information system, including conducting of data verification between EDT and ePMS system.

#### Quarterly Progress for Objective 5

Current Value: **(Sep 2012)** - In this quarter, SIAPS provided technical support to the MoHSS for the finalization of the 5th edition of the Namibia essential medicines list (Nemlist), the STG pre-implementation report and abstraction of data from the EDT for the HIV Early Warning Indicators (EWIs). These activities will enhance the quality and delivery of ART and other pharmaceutical services in the country's public health facilities.

#### Quarterly Report Fields (Sub-Objective)

Fields for reporting quarterly progress at the sub-objective level.

Quarterly progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - Development of a framework for the post marketing surveillance of antiretroviral and other essential medicines: With SIAPS support, the MoHSS sub-division of Pharmaceutical Control & Inspection (PC&I), which is also the secretariat of the Namibia Medicines Regulatory Council developed a final draft post-marketing framework (PMS) for monitoring the quality of pharmaceutical products. It provides the general framework in which the post-marketing surveillance of the quality of pharmaceutical products available in the Namibian territory will be conducted and also a sampling and testing protocol to guide the quality control assessments. This framework will guide key Inspection and Quality Control/Assurance activities of the PC&I.

Pharmadex processes and user requirements documentation: SIAPS provided technical assistance to the NMRC for the systematic summarization and documentation of the previously gathered information on:-1) medicines registration, 2) inspection and licensing, 3) narcotics control, 4) quality control and 5) pharmacovigilance. The draft Pharmadex User Requirements Document (URD) has been compiled, which will guide the development of the Functional Specifications Document (FSD) upon which the enhanced web- based Pharmadex application will be developed in FY13. Pharmadex is a SIAPS-supported electronic tool that is currently being used by the NMRC for registration of pharmaceutical products in Namibia.

Options analysis for NMRC Autonomy: SIAPS technical advisor assisted the NMRC to electronically capture data on revenues generated from product registration and pharmaceutical facility inspection activities. This data was collected to enable a detailed financial and options analysis for the autonomy of the NMRC. All the hard copy data from 2008 to date were been entered in a MS Access database, and this is being updated by the registration pharmacist on a regular basis as payments come in. A financial analysis of the data gathered for the previous three consecutive financial years of NMRC operation can now be performed to inform modeling and scenario analyses of the potential for NMRC autonomy.

Pharmaceutical products registered with SIAPS support: In FY 12, a total of 428 dossiers for application of medicines were received and 156 were evaluated (36.4%). This is because SIAPS-seconded registration pharmacist resigned and another MoHSS-funded pharmacist was redeployed, leaving only one pharmacist available in the Medicine Registration Unit to perform dossier evaluation and other medicines registration related duties and he could not cope with the workload. There was also a surge in the number of veterinary medicine dossiers submitted because the regulation of these products was transferred to NMRC.

Quality testing of products: Through SIAPS support, the pharmaceutical Quality Surveillance Laboratory (QSL) was able to test 223 out of the 309 (73%) samples received for testing. Technical assistance for the regulation of complementary medicines: Through SIAPS support, 4,000 complementary medicine products were entered into a simple MS Access electronic database that was developed with technical support from SIAPS, which will be used by NMRC to regulate complementary medicine products in the country in line with relevant Namibian laws.

Namibia Medicines Regulatory Council (NMRC) Standard Operating Procedures (SOPs): Compilation of NMRC SOPs, a process that has been ongoing since 2008, was finally

completed and all the SOPs were signed and approved by the Registrar of Medicines. In total, 50 SOPs were compiled and signed and are currently being prepared for binding and filing and will be handed over to the NMRC by the end of October 2012.

#### Challenges in progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - The position of the SIAPS-seconded registration pharmacist, which fell vacant upon the resignation of the incumbent in Quarter 1, has not yet been filled, due to the current USG moratorium on back-filling of donor supported positions. This Ministry cannot process a replacement because the position is not yet established in the public service staffing structure. The SIAPS software developer of the new Pharmadex tool resigned in August 2012, thus retarding progress towards the finalization of the tool. Lastly, the recent Ministry's transfer of staff from the Pharmaceutical Control and Inspection sub-division requires a renewed focus and strategy for building the capacity of the sub-division in performing its regulatory functions. Steps to address challenges for sub-objective 1.1 Through USAID, SIAPS will continue advocating for the establishment of a post additional to the establishment so that a registration pharmacist could be hired by the Ministry for the position. Additionally, SIAPS will continue advising the MoHSS on other potential options for resolving this challenge

#### Deliverables: Sub-Objective 1.1

Current Value: **(Sep 2012)** - • Draft Post Marketing Surveillance Framework • Draft Pharmadex User Requirements Document (URD) • MS Access electronic database for listing of complementary medicines • 50 pharmaceutical regulatory SOPs were compiled and signed

#### Quarterly progress toward sub-objective 1.2

Current Value: **(Sep 2012)** - SIAPS supported the Ministry of Health and Social Services (MoHSS) to carry-out the 2012 annual pharmaceutical national support supervision visits to the public sector health facilities, including ART sites; and provided further technical assistance in the finalization of the support supervision visit report, which was later printed and disseminated to all regions by MoHSS. (Feedback Report for National Pharmaceutical Services Supervisory Support Visits held in February 2012). In this SS visits, all 34 public hospitals were visited as well as 15 primary health care facilities (12 health centers and 3 clinics) in the 13 regions of the country. A scored checklist was used during the assessment. This enabled comparison of performance across facilities as well as with the previous visits of 2011.

Nine main areas were scored and the total score was aggregated for each facility. Facilities were then ranked in descending order based on their total score. The nine areas scored were as follows: (i) Resolution of issues identified in previous visits; (ii) storage practices; (iii) stock cards use; (iv) cold chain management; quantification for main orders; (v) Therapeutics Committees (TCs); (vi) Pharmacy Management Information System (PMIS) implementation; (vii) use of the Electronic Dispensing Tool (EDT) for stock management, (viii) use of EDT for patient management and (ix) management of data for outreach and IMAI sites.

#### Challenges in progress toward sub-objective 1.2

Current Value: **(Sep 2012)** - There have been resignations and transfers of donor-funded pharmaceutical staff in the country (they are the majority), due to uncertainty of funding. This has been especially true to those funded by the Global Fund and the CDC.

These changes and transitions have contributed to the reduced follow-up on the resolution of issues that were identified in the previous support supervision visits. Steps to address challenges for sub-objective 1.2 MSH is a member of the MoHSS “HRH Technical Working Group” (HRH TWG) that was established in November 2010 to advise the Ministry's management on matters related to the transition of donor-funded staff to the MoHSS budget. SIAPS utilized MSH's membership in this forum to advocate for the transition of 2 SIAPS-funded pharmaceutical staff to the Ministry's budget in Quarter 4.

Deliverables: Sub-Objective 1.2

Current Value: **(Sep 2012)** - Feedback Report for National Pharmaceutical Services Supervisory Support Visits held in February 2012

Quarterly progress toward sub-objective 2.1

Current Value: **(Sep 2012)** - SIAPS supported a total of 8 human resource positions at the Ministry of Health and Social Services (NHTC = 2, TIPC = 2, NMPC = 2, and health facilities = 2). SIAPS contributed to the HRH TWG meetings and consultations. Four of the 8 SIAPS-seconded staff who applied for absorption were considered for transitioning into the MoHSS budget. The two SIAPS-supported UNAM lecturers were successfully transitioned to UNAM budget earlier in May 2012.

Challenges in progress toward sub-objective 2.1

Current Value: **(Sep 2012)** - The slow pace of transitioning of seconded staff into the MoHSS budget. Steps to address challenges for sub-objective 2.1 MSH is a member of the MoHSS “HRH Technical Working Group” (HRH TWG) that was established in November 2010, with representatives from MoHSS, Global Fund, USAID, CDC, UNAIDS, WHO, and Intrahealth, to advise the Ministry Senior Management of matters related to the absorption of donor-supported staff. Following the absorption of medical officers to the MoHSS, the HRH TWG decided to initiate the transitioning of donor-funded pharmacy staff to the MoHSS in May 2012. In this quarter, SIAPS utilized this platform to continue engaging with the HRH TWG to speed-up the process of absorption of pharmacy staff.

Deliverables: Sub-Objective 2.1

Current Value: **(Sep 2012)** - Report of SIAPS-seconded staff that were absorbed by the MoHSS

Quarterly progress toward sub-objective 2.2

Current Value: **(Sep 2012)** - SIAPS continued supporting two (2) tutor positions for the NHTC pharmacy assistants (PA) program. As reported in the previous quarter, 25 PAs who successfully completed their studies in 2011 graduated from the NHTC program in May 2012, 22 (88%) of whom were already employed as at the time of their graduation. This output is in line with the projected levels.

Challenges in progress toward sub-objective 2.2

Current Value: **(Sep 2012)** - The employment contract of one of the SIAPS-seconded tutor for the NHTC pharmacy assistant's program was terminated due to absenteeism. The staff lodged a complaint of unfair dismissal with the Labor SIAPS subsequently contested this decision with the Magistrate's court and a decision is being waited. This slightly affected the teaching of some of the curriculum modules, which may have contributed

to the slightly less than targeted number. Steps to address challenges for sub-objective 2.2 Follow-up with the MSH lawyer so that the case is concluded within next quarter.

Deliverables: Sub-Objective 2.2

Current Value: **(Sep 2012)** - Report on SIAPS support to NHTC.

Quarterly progress toward sub-objective 2.3

Current Value: **(Sep 2012)** - Supply chain management teaching materials for UNAM B. Pharm course: - SIAPS initiated the process of developing supply chain management teaching materials (Lecturer guides, student workbook and slides) for pre-service training for the B. Pharmacy course. This commenced with the development of the lecturer guide (draft 0) on supply chain management for pre-service training for the B. Pharmacy course. The draft teaching guide was the basis of crucial curriculum discussions during the UNAM Pharmacy symposium held on the 9th of July 2012. UNAM Pharmaceutical Lab and Manufacturing Plant: SIAPS provided technical assistance to UNAM Department of Pharmacy in the drafting of specifications for the equipment that are required for the pharmaceuticals research lab and the quality control laboratory.

Technical assistance was also provided in the drafting of a concept paper for the development of a pharmaceutical manufacturing plant for the University. These two facilities will be used for the practical teaching of the B. Pharm students on pharmaceutical product quality control and manufacturing, respectively. Orientation of UNAM B. Pharm second year students for rural placements: SCMS and SIAPS provided an overview of pharmaceutical supply chain in Namibia to the UNAM's second year Bachelor of Pharmacy students prior to them going for rural placements. This was in line with the learning outcomes for Pharmacy Rural Placements program whereby students are expected to be able to manage medicine supply systems at public health facilities in Namibia. The presentation pivoted on the current Namibia public health pharmaceutical supply chain, the purpose of logistics systems, inventory management, introduction to tools used for stock-keeping in Namibia and expected supply chain role of students at the health facilities. Through SIAPS support, a total of 49 students (First year=35 and Second year=14) are currently enrolled on the UNAM Bachelor of Pharmacy program.

Challenges in progress toward sub-objective 2.3

Current Value: **(Sep 2012)** - Finding suitable sites by the UNAM Department of Pharmacy for the pharmacy students to do the practical sections of the course. Steps to address challenges for sub-objective 2.3 Continue providing technical assistance and advise to the UNAM Department of Pharmacy on finding feasible ways engaging the private community pharmacists and wholesalers and how to persuade them to consider taking up students for practical assignments.

Deliverables: Sub-Objective 2.3

Current Value: **(Sep 2012)** - • Draft Supply chain management teaching materials for UNAM pharmacy course. • Draft concept paper for the development of a pharmaceutical manufacturing plant for the university.

Quarterly progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - In the third quarter, SIAPS disseminated key findings and recommendations of the report "Comparison of Public and Private Sector Wholesale

Cost of Antiretroviral Medicines in Namibia” to private sector pharmacists. A meeting was recommended for further discussions between the MoHSS, MSH and the Pharmaceutical Society of Namibia to come up with a model of a public-private partnership that would work for Namibia. Although SIAPS continued following up with the Division: Pharmaceutical Services regarding the way forward for this activity, little progress was made.

Challenges in progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - Lack of clear guidance by the Division: Pharmaceutical Services regarding the way forward on the development of a model of a public-private partnership that would work for Namibia. Steps to address challenges for sub-objective 3.1 Reconsider the feasibility of this activity and discuss the way forward with the Division: Pharmaceutical Services.

Deliverables: Sub-Objective 3.1

Current Value: **(Sep 2012)** - Activity report

Quarterly progress toward sub-objective 4.1

Current Value: **(Sep 2012)** - PMIS Review: SIAPS provided technical support to the Division: Pharmaceutical Services in the finalization of the PMIS review which entailed expansion of the system to include indicators for monitoring provision of services at national and regional level. An integrated PMIS manual which includes NMPC, CMS, RMS and PC&I indicators was compiled.

Challenges in progress toward sub-objective 4.1

Current Value: (Sep 2012) - none

Deliverables: Sub-Objective 4.1

Current Value: **(Sep 2012)** - PMIS report

Quarterly progress toward sub-objective 4.2

Current Value: **(Sep 2012)** - SIAPS provided technical support in the analysis and comparison of EDT and ePMS summary patient data and participated in the DSP/PhSs quarterly data verification meetings.

Challenges in progress toward sub-objective 4.2

Current Value: **(Sep 2012)** - ART Data Quality Assessment: the scheduled quarterly meeting between RM&E, NMPC and SIAPS as well as proposed site visits to facilities with high discrepancies of their EDT & ePMS data was cancelled due to unavailability of key RM&E staff.

Deliverables: Sub-Objective 4.2

Current Value: **(Sep 2012)** - DQA report

Quarterly progress toward sub-objective 5.1

Current Value: **(Sep 2012)** - Nemlist 5th Edition: Technical assistance was provided by SIAPS in the design, typesetting and printing of the 5th edition of the Namibia Essential Medicine List (Nemlist). The Nemlist 5th Edition will be launched and distributed to facilities in the first quarter of FY 13. Since the Nemlist guides procurement of essential medicines in the Public Sector, changes made to the document will be incorporated in the next tender by the Central Medical Stores.

STG Pre-implementation Report: the draft version of the report was compiled and forwarded to the Chief Pharmacist, sub-division: National Medicines Policy Coordination (NMPC) for final review before printing and dissemination. The STG pre-implementation report provides baseline data on the prescribing practices before the introduction of the comprehensive STGs and will be used as a reference document to assess the effectiveness of interventions aimed at improving compliance to STGs.

Therapeutics Committees (TCs): In Q3, the annual Therapeutics Committees activity report for FY 2010/11 (National Therapeutic Committee Activities Feedback Report FY 2010/11) was finalized with technical assistance from SIAPS. The report was disseminated to health facilities and regional directorates by the Division: Pharmaceutical Services, MoHSS. In Q4, SIAPS continued providing technical support to specific TCs to facilitate implementation of some of the recommendations of the TC feedback report.

#### Challenges in progress toward sub-objective 5.1

Current Value: **(Sep 2012)** - Delays by the sub-Division: National Medicines Policy Coordination in finalizing the draft STGs Pre-implementation Report so that it could be implemented. Attrition of trained TC members due to staff transfers and resignations. Steps to address challenges for sub-objective 5.1 SIAPS will continue engaging the Chief Pharmacist, NMPC to ensure that the report is finalized and disseminated in the first quarter of FY 13. On staff attrition, SIAPS will discuss modalities of re-training of new TC staff so that they can be more competent in conducting TC activities

#### Deliverables: Sub-Objective 5.1

Current Value: **(Sep 2012)** - Nemlist 5th edition STG pre-implementation report Therapeutics Committees feedback report

#### Quarterly progress toward sub-objective 5.2

Current Value: **(Sep 2012)** - HIVDR EWI Data Abstraction: SIAPS staff supported RM&E and DSP teams to prepare for the annual HIVDR EWI data abstraction by extracting patient statistics from the national ART dispensing database (NDB) to help determine the appropriate sample sizes per facility. Further support was provided to extract the actual patient samples from the NDB and to validate the data using the ePMS at national level and at facilities. Additionally SIAPS supported RM&E & DSP with tailor-made queries for extracting ART patient cohorts for the HIVDR Surveillance study

#### Challenges in progress toward sub-objective 5.2

Current Value: **(Sep 2012)** - HIVDR EWI data abstraction: Site visits schedules for September 2012 were postponed, awaiting completion of the central validation of EWI data from the EDT with the ePMS by the RM&E team. The central validation process was delayed because most RM&E staff were involved in the preparations for the Global Fund grant. Steps to address challenges for sub-objective 5.2 This challenge will be brought to the

attention of the Head of RM&E for resolution.

Deliverables: Sub-Objective 5.2

Current Value: **(Sep 2012)** - Activity report on SIAPS support for HIVDR EWI data abstraction

Quarterly progress toward sub-objective 3.2

Current Value: **(Sep 2012)** - EDT Reporting Module: The EDT Reporting Module was finalized and the ART Monthly Report template updated to facilitate more accurate and complete reporting, commencing in July 2012. The updated reporting module and template were uploaded remotely by the Systems Administrator at Division: Pharmaceutical Services in Windhoek to all EDT sites through the remote desktop system that was previously developed with SIAPS support. Adherence Survey Report: SIAPS continued working with the consultant leading this activity to compile the ART baseline adherence survey report. The report will be finalized in the first quarter of FY 13. EDT Training: SIAPS supported Division: Pharmaceutical Services to conduct a 3-day EDT training between 14th and 16th August 2012. Ten pharmacists, 25 pharmacist's assistants and one nurse drawn from 32 health facilities representing 28 of the 34 health districts and 11 of the 13 regional directorates in the country were trained on the use of the EDT for dispensing, patient management, adherence monitoring and reporting and stock management. As part of preparations for this training, a Quick Reference EDT Processes Document was developed to assist facility staff to standardize practices at their facilities including dispensing, adherence monitoring and quantification. Evaluation of eTB manager pilot: The pilot phase of the e-TB manager came to an end in June 2012 and arrangements were made to evaluate the pilot using an existing tool. The evaluation will guide MoHSS (NTLP) on the way forward regarding the deployment of the eTB manager. A meeting was held with the NTLP to discuss the evaluation tool and methodology, which was finalized in July 2012. The evaluation will be conducted and report compiled in Quarter 1 of FY 13.

Deliverables: Sub-Objective 3.2

Current Value: **(Sep 2012)** - ART Baseline Adherence Report (Draft 2) EDT Training Report eTB manager evaluation tool

Quarterly progress toward sub-objective 3.3

Current Value: **(Sep 2012)** - Therapeutics Information and Pharmacovigilance Center (TIPC). SIAPS continued supporting the TIPC advisor and TIPC coordinator positions and through this support, a total of 249 adverse reports and 39 TI requests were received and responded to by the TIPC in FY 12. As reported in Q3, SIAPS provided technical assistance for the analysis and drafting of a technical report on the signal of skin and liver reactions associated with nevirapine use. In collaboration with the University of Washington, SIAPS supported the TIPC to initiate active surveillance of safety of first-line ARVs in Namibia. By end of September 2012, 168 patients had been recruited into the active surveillance activity over a period of two months at the two sentinel sites (Windhoek Central Hospital and Katutura State Hospital).

Community based pharmacovigilance with Project Hope: SIAPS facilitated discussions between TIPC and Project Hope aimed at improving the detection and reporting of adverse reactions to antiretroviral and anti-TB medicines; and supporting adherence to treatment especially among TB/HIV co-infected patients. In line with this, two trainings for the Field based promoters under project Hope in Oshana, Oshikoto and Kavango,

have been scheduled for November 2012 and February 2013.

Namibia Medicines Watch Vol 3 (2) 2012: Through technical assistance from SIAPS, the design of this bulletin was completed and submitted for editorial and peer review.

Comments will be collated and incorporated and the final version printed by the end of October 2012. Most importantly, SIAPS successfully advocated for the absorption of the TIPC Advisor into the Ministry payroll, for sustainability.

#### Challenges in progress toward sub-objective 3.3

**Current Value: (Sep 2012)** - Initiation of active ARV safety surveillance: There are challenges in getting staff to routinely and completely fill in the required forms TIPC has been receiving ADR reports via the faxmail. However, there was a loss of TIPC's internet connectivity for more than two months, which negatively impacted the amount of reports reaching the center. Steps to address challenges for sub-objective 3.3 Advise the TIPC to follow-up on a twice weekly basis (Wednesday and Friday) to ensure completeness of the forms Efforts are being made to restore and stabilize the SIAPS-supported TIPC internet connectivity and then hand it over to the MoHSS.

#### Deliverables: Sub-Objective 3.3

**Current Value: (Sep 2012)** - TIPC activity report TIPC active surveillance report TIPC pharmacovigilance technical report

## **RWANDA**

Rwanda work plan details for Year 1 of the SIAPS Program

### **Quarterly Report Background**

While Rwanda, like most developing countries, benefits from increased accessibility of new medicines and fix-dosed combination formulations to treat HIV/AIDS and malaria, the country's lack of experience with these products creates concerns about medicine safety and highlights the need to identify and evaluate Adverse Drug Reactions (ADR) to better understand possible risks and improve treatment protocols. Rwanda can address these issues through a pharmacovigilance—or medicine safety—system.

In many countries, the national drug authority is responsible for ensuring the quality, safety, and efficacy of the medicines available in the country through activities such as medicine registration, quality control testing, and pharmacovigilance. In Rwanda, regulatory functions are administered by the Ministry of Health (MoH). Over the last few years, the Pharmacy Task Force (PTF) has increased its presence as the authority to regulate pharmaceutical management in both public and private sectors. However, the decisions related to medicines are quite fragmented. Long-term sustainability of PEPFAR and PMI interventions requires that the political and legal frameworks of the pharmaceutical system become better coordinated, and cover all aspects of the pharmaceutical sector, including rational medicine use, drug quality and pharmacovigilance. In line with the Government of Rwanda's (GOR) objectives, several assessments have confirmed the need for Rwanda to work towards establishing a national medicine regulatory authority to enforce laws and build capacity in core functions of medicines regulation.

The SIAPS Program has developed a one-year plan to provide technical assistance to improve health system development in Rwanda and contribute to USAID/Rwanda's strategic objective of a better educated and healthier population. This program is designed to improve governance, build capacity for pharmaceutical management and services, and improve pharmaceutical services to achieve desired health outcomes in the pharmaceutical sector. SIAPS Rwanda FY11 work plan will build on the SPS work in fiscal year (FY) 09 and FY 10, particularly in improving pharmaceutical, policies, laws, and regulations, as well as in establishing an ADR reporting system.

### **Goal: Rwanda Year 1 Work Plan Goal**

Assure availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes

#### **Objective 1**

Improved Patient Access

#### **Sub-Objective 1.1**

Pharmaceutical regulatory systems improved

#### **Activity 1.1.1**

Assist the MOH/ PTF to review, update, and develop medicine policies, legislation, regulations, norms, and standards as needed through a consensus building process

#### **Activity 1.1.2**

In collaboration with the MOH PTF and WHO, plan and implement an option analysis as a precursor to the establishment of the RFMA

**Activity 1.1.3**

Assist MOH PTF to strengthen and improve pharmaceuticals registration

**Sub-Objective 1.2**

Transparent and accountable pharmaceutical management systems are created

**Activity 1.2.1**

Assist the MPPD by conducting a functional analysis and develop a strategic plan of action to guide its work

**Sub-Objective 1.3**

Strategic and evidence-based national pharmaceutical sector development plans are utilized

**Activity 1.3.1**

Assist MOH PTF to improve its planning and management process by reviewing its past performance and developing a strategic plan

**Objective 2**

Increased availability of CCM commodities at the community level

**Sub-Objective 2.1**

Pharmaceutical management capacity of individuals, institutions, organizations and networks strengthened

**Activity 2.1.1**

Increase the capacity of CHD staff to effectively carry out supply chain management of CCM commodities

**Objective 3**

Patient safety and therapeutic effectiveness increased.

**Sub-Objective 3.1**

Pharmacovigilance and ADR reporting system

**Activity 3.1.1**

Strengthen pharmacovigilance and ADR reporting system

**Sub-Objective 3.2**

Medication use improved

**Activity 3.2.1**

Support MoH/PTF to streamline the process needed to strengthen and supervise Drug Therapeutics Committees in the management of ADR reports and the improvement of medication use

### Activity 3.2.2

Support the development, dissemination and implementation of STGs for primary health care facilities.

### Goal: Quarterly Report Fields

These are the fields that will be used to collect information for quarterly reports.

#### Overall Quarter Progress

Current Value: (**Sep 2012**) - During this quarter, SIAPS focused on finalizing all planned activities to ensure proper transfer of capacity to the Ministry of Health for the close out of the SIAPS project. In line with strengthening Pharmaceutical sector governance, during the quarter of FY11, SIAPS continued to support the Ministry of Health to improve patient access by working closely with the Ministry of Health/Pharmacy Task Force (MOH/PTF) in planning for the establishment of the Rwanda Food and Medicine Authority (RFMA); in line with the proposed Road Map for the establishment of the Rwanda Food and Medicine Authority which had been approved by the Ministry of Health. The road map shows the proposed structure and functions of the RFMA, the implementation of core regulatory functions and implementation of road map.

SIAPS also assisted MOH/PTF during discussions with the social commission of the Rwanda Parliament on the draft law of the Pharmacy Council and on the Pharmacy Act this one was recently approved during the plenary sessions of the Parliament. During the same reporting period, SIAPS supported the Ministry of Health/Pharmacy Task Force in the evaluation of its Strategic plan 2009-2012 and its development of the new strategic plan 2012-2017.

The Rwanda Bomedical Center request to develop a strategic plan was initiated with the development of a functional analysis for all the various divisions by a Joint IHSSP and SIAPS consultancy team the final report was shared with RBC authorities. In relation to strengthening supply chain management of community case management, during the reporting period, SIAPS focused on transferring capacity to the Community Health Desk (CHD). SIAPS in collaboration with CHD developed a practice manual for community health commodity management. The manual will help the health community logistics team to monitor and evaluate their procurement supply chain plans. The practice manual was submitted to CHD for approval.

In Quarter 3, SIAPS in collaboration with the ministry of health conducted a Rapid assessment of pharmaceutical management of medicines and supplies for preventing and managing emergency obstetrics. As a follow on SIAPS organized a workshop to disseminate findings of this assessment, which attracted over thirty-one persons who made, agreed and finalized recommendations to improve the prevention of postpartum hemorrhage through improved pharmaceutical management.

To improve Pharmaceutical services to achieve desired health outcomes, during this quarter, SIAPS continued to transfer capacity to the Ministry of Health/PTF as part of the closing of SIAPS project. SIAPS supported PTF to train 23 health professionals of the newly formed National Medicine safety committee. During the same reporting period, SIAPS worked closely with the MSH Integrated Health System Strengthening Project (IHSSP) and the MOH Clinical Services to finalize the Clinical Protocols/Treatment Guidelines (CPs/TGs). Those CPs/TGs were approved by the Ministry of Health. SIAPS assisted also in the development of strategic

document on the approach to be used during Clinical Protocol and treatment guidelines updates (from the revision to the implementation of the revised CPs/TGs). The strategic document was finalized and shared with MoH.

Key challenges faced during the quarter

Current Value: **(Sep 2012)** - 1. Delay in parliamentary approval of laws and key pharmaceutical sector governance documents 2. Uncertainty on the official nominations for the members of national medicines safety committee leading to delayed training.

### Quarterly Report Fields (Objective)

Objective-level fields for collecting information for quarterly reports.

Quarterly Progress for Objective 1

Current Value: **(Sep 2012)** - Continuous support in strengthening Pharmaceutical sector governance, during the last quarter, SIAPS in collaboration with stakeholders continued to support MOH/PTF to plan for the establishment of the Rwanda Food and Medicine Authority (RFMA), and the development of its implementation plan. During this quarter, SIAPS supported the MOH/PTF to evaluate the MoH/PTF 2009-2012 strategic plan and the development of the new one for 2013-2017 which is of great importance in strengthening pharmaceutical regulatory systems for improved access. Finally, during the reporting period, SIAPS worked with the RBC/MPPD to develop the functional analysis according to the new development occurred within RBC.

Quarterly Progress for Objective 2

Current Value: **(Sep 2012)** - SIAPS focused on the continuous transfer of capacity to the Community Health Desk (CHD). SIAPS in collaboration with CHD developed a practice manual for community health commodity management. The manual will help the community health workers to monitor and evaluate their procurement and supply chain plans. In quarter 3, SIAPS conducted a Rapid assessment of pharmaceutical management of medicines and supplies for preventing and managing emergency obstetrics and new born conditions following that a workshop organized by SIAPS in this quarter attracted over thirty participants finalized and agreed on the pharmaceutical management recommendations necessary to prevent and management obstetric emergencies and complications.

Quarterly Progress for Objective 3

Current Value: **(Sep 2012)** - To improve Pharmaceutical services to achieve desired health outcomes, during this quarter, SIAPS continued to transfer capacity to the Ministry of Health/PTF as part of the closing of SIAPS project. SIAPS supported PTF to train 23 health professionals of the newly formed National Medicine safety committee. The training took place from the 23rd to 28 September 2012. As a deliverable of the training the committee developed an action plan. The training report is available. During the same reporting period, SIAPS worked closely with the MSH Integrated Health System Strengthening Project (IHSSP) and the MOH Clinical Services to finalize the Clinical Protocols/Treatment Guidelines (CPs/TGs). Those CPs/TGs was approved by

Ministry of Health SIAPS assisted also in the development of strategic document on the approach to be used during Clinical Protocol and treatment guidelines updates (from the revision to the implementation of the revised CPs/TGs).The strategic document was finalized and shared with MoH.

### Quarterly Report Fields (Sub-Objective)

Fields for reporting quarterly progress at the sub-objective level.

Quarterly progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - During this quarter, the draft law of the Pharmacy council law was finalized and discussed with the social commission of the Parliament.

Challenges in progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - Pace of work at the at the parliamentary level lead in some instance to delays

Quarterly progress toward sub-objective 1.2

Current Value: **(Sep 2012)** - During the reporting period, SIAPS has undertook a joint IHSSP and SIAPS functional analysis of the Rwandan Biomedical Center and produce the report which will be feeding the RBC's strategic plan. SIAPS focus during this exercise was on the MPPD, MPDD divisions of the RBC Challenges in progress toward sub-objective 1.2

Current Value: **(Sep 2012)** - Delays in structuring the joint consultancy team

Deliverables: Sub-Objective 1.2

Current Value: **(Sep 2012)** - MPPD functional analysis.

Quarterly progress toward sub-objective 1.3

Current Value: **(Sep 2012)** - As continuous support in strengthening Pharmaceutical sector governance, during the previous quarter, SIAPS supported the MOH/PTF to evaluate the MoH/PTF 2009-2012 Pharmaceutical Sector strategic plan and to start the process of the development of the new one for 2012-2017. This strategic plan shall be aligned with the Health Sector Strategic Plan (HSSP) III, which states that health service delivery depends on a reliable supply of medicines, vaccines and contraceptives supported by accurate and timely information on consumption and stock management. During this reporting period, SIAPS supported the Ministry of Health/Pharmacy Task Force to finalize the development of the Pharmaceutical Sector strategic plan 2012-2017.

Challenges in progress toward sub-objective 1.3

Current Value: **(Sep 2012)** - Costing of the Pharmaceutical Sector strategic plan 2012-2017.

Deliverables: Sub-Objective 1.3

Current Value: **(Sep 2012)** - The Pharmaceutical Sector strategic plan 2012-2017.

Quarterly progress toward sub-objective 3.2

Current Value: (**Sep 2012**) - During this reporting period, SIAPS has continued to assist PTF to ensure that hospitals are consistently reporting all Adverse Drug Reactions (ADR) and Medicine with Poor Quality (MPQ) reports. SIAPS assisted also in the finalization of the strategic document on the approach to be used during Clinical Protocol and treatment guidelines updates.

Challenges in progress toward sub-objective 3.2

Current Value: (**Sep 2012**) - The culture of spontaneous reporting is not yet established. Further support is needed when the new RFMA is formed

## **SOUTH AFRICA**

South Africa work plan details for Year 1 of the of the SIAPS Program

### **Quarterly Report Background**

The goal of the SIAPS program in South Africa (SA) is to “Strengthen the Capacity of Pharmaceutical Systems at all levels to support the South African Government (SAG) priority health programs and initiatives to improve health outcomes”. Six overall objectives will be addressed.

The first objective is to strengthen Pharmaceutical Sector Governance Strengthened (IR 1). This objective will contribute to the improvement of key elements to guide access to medical products and the provision of pharmaceutical services. This includes development and implementation of policies, laws, regulations, rules and guidelines to support good governance in the pharmaceutical sector. This work will be done in close collaboration with the SAG and relevant statutory and regulatory bodies.

The second objective aims to enhance capacity for Pharmaceutical Supply Management and Services (IR 2). Availability of sufficient numbers of human resources (HR) with the appropriate knowledge and skills has been identified as one of the key challenges facing provision of pharmaceutical services in SA. This objective focuses on developing and implementing strategies to ensure that qualified pharmacists and pharmacy support personnel are available according to approved HR norms and standards and that the right tool(s) to monitor progress are in place.

The third objective is to improve the use of information for decision making for pharmaceutical services (IR 3). Data is generally available at various levels. It is, however, not always transformed into information that can be used to support decision-making. This objective will support the strengthening of the production of timely and accurate routine information at the national and provincial levels by developing and/or implementing systems and building capacity in their use. It will also contribute to the monitoring and evaluation frameworks under development.

The fourth objective is to improve access to medicine by implementing new strategies (IR 4). SA is embarking on the implementation of new national strategies to improve equitable access to health products and services by streamlining procurement by the establishment of a Central Procurement Authority at a national level, providing universal coverage by the introduction of National Health Insurance and improving disease prevention and management at the lowest level the re-engineering of PHC services. SIAPS will collaborate with the SAG and other stakeholders to support this objective.

The fifth objective is to improve availability of medical products (IR 5). Availability of medical products is one the key component of the access framework to strengthen service delivery. SIAPS will improve quantification practices, strengthen provincial pharmaceutical warehouses and improve medicine supply management at facility level. This will be done at the provincial and district levels in partnership with SAG personnel.

The sixth objective is to improve rational use of medicine and patient safety (IR5). This objective will address the SIAPS “Patient-Centered” approach by supporting end users, through strengthening rational medicine prescribing and dispensing practices of health care providers, enhancing systems to monitor patient safety, increasing patient knowledge about rational medicine use.

### **Goal: South Africa Year 1 Work Plan Goal**

Strengthen the Capacity of Pharmaceutical Systems at All Levels to Support the SAG Priority Health Programs and Initiatives to Improve Health Outcomes

### **Objective 1**

## Pharmaceutical Sector Governance Strengthened

### **Sub-Objective 1.1**

The National Drug Policy was published in 1996. There is a need to conduct an assessment of the impact of its implementation. Results of this assessment will then inform the review of the policy. SIAPS will be part of a ministerial task team which has been identified to conduct the review. SIAPS will also assist the SAPC in reviewing and proposing amendments to the Pharmacy Act, and the regulations and rules published in terms of this Act. SIAPS will continue to provide TA to the MCC to improve the governance of pharmaceutical product registration and the review of clinical trials at various stages of product development. This TA is expected to expand as the MCC is undergoing major transformation. It is moving from a heavy reliance on external consultants to a more efficient medicines regulatory authority that will be managed by in-house experts.

#### **Activity 1.1a**

Conduct an impact assessment of the key objectives of the SA National Drug Policy (NDP) to guide its review

#### **Activity 1.1b**

Assist with Review of Pharmacy Act

#### **Activity 1.1c**

Provide TA to the Medicines Control Council (MCC)

### **Sub-Objective 1.2**

SIAPS will be represented on the National EML committee and on three technical committees (PHC, Hospital/Adult and Tertiary Hospital). The STGs are expected to be revised and published every three years. TA will also be provided by SIAPS to the provinces to support implementation of STGS. SIAPS will work with provincial PTCs to develop, publish and promote their formularies. The second step will be to support the development of institutional formularies for large hospitals. SIAPS will collaborate with the University of Washington (UW), to develop and implement a training of trainer's workshop on the application of the principles of Evidence- Based Medicine (EBM) selection.

#### **Activity 1.2a**

Review National EML

#### **Activity 1.2b**

Develop Provincial/Institutional Formularies

#### **Activity 1.2c**

Provide-Evidence Based Medicine (EBM) Selection Training

### **Sub-Objective 1.3**

SIAPS will provide support to the Pharmaceutical Evaluations Unit of the National Department of Health in the development and revision of the regulatory tools relating to the transparent pricing system

including the Single Exit Price (SEP) for medicine, the logistics dispensing fees, as well as the implementation of international benchmarking. SIAPS will provide TA in the management and evaluation of national pharmaceutical tenders to support good governance. SIAPS will also provide TA to selected provinces to develop service level agreements between the provincial depots and their clients.

**Activity 1.3a**

Provide TA to NDoH in Conducting Pharmacoeconomic Evaluations and International Benchmarking (IB)

**Activity 1.3b**

Assist with the Management and Evaluation of National Pharmaceutical Tenders

**Activity 1.3c**

Provide TA to selected Provinces to Develop Service Level Agreements (SLA)

**Sub-Objective 1.4**

SIAPS will work in collaboration with the National Office of Standards Compliance (OSC) to support the implementation, of the NCS for “Pharmaceutical Services” which is a sub-domain of Domain 3 - “Clinical Support Services”.

**Activity 1.4a**

Support the National Core Standards (NCS) implementation

**Objective 2**

Capacity for Pharmaceutical Supply Management and Services Enhanced

**Sub-Objective 2.1**

SIAPS will continue to provide assistance to the SAPC to support the development of the scopes of practice and qualifications for the Pharmacy Technician and the Pharmacy Technical Assistant and will provide assistance in the development of the qualification and curriculum for the Pharmacy General Assistant. SIAPS will also provide TA to the South African Pharmacy Council (SAPC) in the development of the qualification and curricula for 5 categories of specialist pharmacists which have already been identified, as well as the development of the curriculum for authorized pharmacist prescribers. SIAPS will work in close collaboration with the SAPC and the pharmacy schools to increase the production of pharmacists and pharmacy support personnel in SA.

**Activity 2.1a**

Support the introduction of new categories of pharmacy personnel

**Activity 2.1b**

Increase the production of pharmacists and pharmacy support personnel

**Sub-Objective 2.2**

Leadership and management practices of pharmacists improved leading to better quality pharmaceutical

services

**Activity 2.2a**

Implement Pharmaceutical Leadership Development Program (PLDP)

**Activity 2.2b**

Support the development and implementation of quality improvement plans using the challenge model

**Sub-Objective 2.3**

SIAPS will assist provincial pharmaceutical services with the development of their M&E frameworks. This will be done through an extensive consultative process that will lead to the development of results frameworks, the definition of performance indicators, identification of targets, and the development and implementation of reporting systems.

**Activity 2.3a**

Develop M&E frameworks for provincial pharmaceutical services

**Activity 2.3b**

Support M&E system(s) to monitor availability of medicines

**Objective 3**

Use of Information for Decision Making In Pharmaceutical Services Improved

**Sub-Objective 3.1**

SIAPS will set up a National pharmaceutical data warehouse at the NDoH into which selected provincial data will be uploaded at regular intervals. Once in place the data warehouse will allow for improved transparency and availability of information relating to consumption vs. estimates, depot stock levels, provincial use and expenditure. SIAPS also will work with depot (warehouse) managers to implement an off-the-shelf report generator that will be connected to the warehouse database. A set of report templates that will allow the generation of standard reports from all provinces in an electronic format, will be developed. It will also be possible to produce customized reports. SIAPS will develop and implement a provincial data warehouse for North West, Eastern Cape and Free State where selected data from all sites using RxSolution © will be uploaded regularly.

**Activity 3.1a**

Implement National pharmaceutical data warehouse

**Activity 3.1b**

Roll out provincial pharmaceutical depot (warehouse) electronic reporting system(s)

**Activity 3.1c**

Develop and implement provincial data warehouses for the provinces that are using RxSolution ©

**Sub-Objective 3.2**

The SA based SIAPS development team will develop a new version of RxSolution© using newly available technologies and development tools. SIAPS will also develop middleware to facilitate integration and/or sharing of RxSolution© data with other new or legacy systems. SIAPS will continue to deploy and maintain RxSolution © at existing and new sites. To ensure the sustainable use of RxSolution ©, SIAPS will train provincial information system managers to maintain and support the system thereby creating a pool of super users. RxSolution © will also be installed in the simulation computer laboratories of selected pharmacy schools. Pharmacy managers and other relevant personnel will be trained in the analysis and use of pharmaceutical data for decision-making.

**Activity 3.2a**

Improve RxSolution © using new development platform

**Activity 3.2b**

Develop middleware to facilitate integration and/or sharing of RxSolution data with other new or legacy systems

**Activity 3.2c**

Support RxSolution © implementation at existing sites, roll-out to new sites and increase the pool of users and super users

**Activity 3.2d**

Train pharmacy managers and other relevant personnel in the analysis and use of pharmaceutical data for decision- making

**Objective 4**

Access to Medicine Improved by Implementing New Strategies

**Sub-Objective 4.1**

SIAPS will assist the NDoH with the implementation of the Central Procurement Authority (CPA). The main objectives of the CPA are to improve the efficiency of procurement activities and to establish control mechanisms at all levels. An evaluation of the outsourcing of provincial supply chain will be conducted. The evaluation will be conducted to understand the potential strength and pitfalls of outsourcing services.

**Activity 4.1a**

Assist the NDoH with the implementation of the Central Procurement Authority (CPA)

**Activity 4.1b**

Conduct an evaluation of the outsourcing of the provincial supply chain

**Sub-Objective 4.2**

SIAPS will support the pharmacy component of the re-engineering of Primary Health Care (PHC) Services. This support will include the piloting of different chronic medicine management models, including the establishment of chronic dispensing units in at least two provinces. SIAPS will also support

the implementation of the National Health Insurance in South Africa. Once the implementation plan for the NHI is finalized, SIAPS will work with the SAG to assist in establishing dialogue between policy makers and stakeholders from the public and the private sector to define their roles and develop models for the provision of pharmaceutical services.

**Activity 4.2a**

Support the pharmacy component of the re-engineering of Primary Health Care (PHC) Services

**Activity 4.2b**

Support National Health Insurance (NHI) implementation

**Objective 5**

Improved Medicine Availability

**Sub-Objective 5.1**

Under SIAPS, new quantification models will be developed to address the SAG priorities such as non-communicable diseases (including diabetes, hypertension, etc.). In SA, quantification for national tenders is typically done at the provincial level using depot data based on the volume of medicines distributed, with the assumption that this reflects actual usage. There is a need to build capacity to allow quantification to take place at lower levels of the supply chain. SIAPS will train pharmacy managers and other relevant staff in the principles of quantification and the use of relevant tools.

**Activity 5.1a**

Develop and implement quantification models

**Activity 5.1b**

Train relevant health personnel in forecasting medicine needs

**Sub-Objective 5.2**

SIAPS will assist provincial depots to analyze their own environment and practices, and make the necessary improvements in order to be licensed by the Medicines Control Council. TA and training will be provided to depot (warehouse) personnel to strengthen compliance with good warehousing practices.

**Activity 5.2a**

Assist provincial depots in obtaining MCC licensing

**Activity 5.2b**

Provide TA and training to depot personnel to strengthen compliance with good warehousing practices

**Sub-Objective 5.3: Improved medicine supply manage**

SIAPS will conduct provincial assessments of medicine supply management practices in at least two provinces. SIAPS will also conduct MSM training workshops at district level to support compliance with NCS and PHC re-engineering. Under this activity SIAPS will also work with district pharmacists to strengthen supervision and mentorship practices.

**Activity 5.3a**

Conduct provincial assessment of medicine supply management practices

**Activity 5.3b**

Conduct medicine supply management training for facility personnel with follow-up mentorship

**Objective 6**

Improved Rational Use of Medicine and Patient Safety

**Sub-Objective 6.1**

SIAPS will support the governance and functionality of these committees by reviewing their terms of reference, building local capacity, facilitating access to data and information and providing assistance in conducting targeted interventions. SIAPS will support operational research projects to improve rational medicine use and patient safety. These projects will address potential medicine use problems identified by provincial counterparts, including medication errors and issues around reconciliation of medicines of patients admitted to hospitals with the medicine used as an out-patient. Whenever feasible, this activity will be conducted in collaboration with local pharmacy schools.

**Activity 6.1a**

Strengthen Pharmaceutical and Therapeutic Committees (PTCs)

**Activity 6.1b**

Support Medicine Use Evaluations (MUEs)

**Sub-Objective 6.2**

SIAPS will work with the NDoH and all stakeholders to review the recommendations from the IPAT assessments conducted previously and explore opportunities to provide support to both private and public sectors. SIAPS will support the programmatic component of the Pharmacovigilance Unit of the NDoH. The first phase will include the training of provincial staff to promote the reporting of Adverse Medicines Events (AMEs). In the second phase, additional TA will focus on building capacity for data analysis and reporting to strengthen spontaneous reporting systems and active surveillance.

**Activity 6.2a**

Explore opportunities to support recommendations of the public and private IPAT assessments

**Activity 6.2b**

Strengthen the programmatic National Pharmacovigilance program

**Sub-Objective 6.3**

One of the criteria in the NCS includes patient knowledge on medicine. SIAPS will support the development of patient literacy, and social and behavior change and communication (SBCC) material to inform patients of their rights with regard to information about medicine including those used in the treatment of HIV/AIDS, TB and non-communicable diseases. SIAPS will also continue to support

National and Provincial efforts to promote the role of the pharmacists and pharmacy services during the National Pharmacy week campaign. This activity will be done in partnership with the statutory body, the SAPC, and the pharmacy professional organization, the Pharmaceutical Society of South Africa (PSSA).

**Activity 6.3a**

Develop a patient education and information campaign(s)

**Activity 6.3b**

Support National Pharmacy Week campaign

**Sub-Objective 6.4: Sustainable strategies in place**

SIAPS will assist the NDoH with the implementation of the National IPC Plan by disseminating the National IPC Manual, the ICAT tool, the National IPC Strategy and Policy, and supporting National Hand Hygiene campaigns. SIAPS will also provide TA to ensure that pharmaceutical waste management practices across all provinces comply with the current legislation, by facilitation of training-of-trainers (TOT) workshops and developing Standard Operating Procedures (SOPs). SIAPs will also provide support to develop adherence support measures to improve adherence to treatment.

**Activity 6.4a**

Support National Infection Prevention and Control (IPC) implementation plan

**Activity 6.4b**

Develop adherence support measures to improve adherence to treatment

**Goal: Quarterly Report Fields**

These are the fields that will be used to collect information for quarterly reports.

Overall Quarter Progress

Current Value: **(Sep 2012)** - SIAPS supported the National Essential Drug List Committee in the review of the Adult Hospital Level Essential Medicines List which was published by the National Department of Health (NDoH) during the quarter. SIAPS continued to provide support to the Pricing Committee of the NDoH. The annual Single Exit Price adjustment was finalized for the 2012 cycle. In addition, a revised logistics fee was gazetted for comment. In the Free State (FS) a draft service level agreement between the Medical Depot, Pharmaceutical Services & demanders was finalized & submitted to the provincial Legal Department for comment.

Considerable progress was made towards developing capacity for human resources. In Eastern Cape (EC), 24 pharmacy managers completed the PLDP & presented their achievements to senior management & other stakeholders in August. All 5 teams achieved their measurable result, with 3 teams addressing challenges relating to National Core Standards. The PLDP was launched in North West for 19 pharmacy managers & an introductory workshop held for facility managers & responsible pharmacists from 12 facilities in the Western Cape (WC). SIAPS provided technical assistance (TA) in identifying strategies to achieve outcomes in the results framework for pharmaceutical services in Kwazulu-Natal (KZN) & WC through workshops at annual provincial pharmacy conferences. Support was also provided support to the Gauteng (GP)

provincial conference to develop strategies & a model to ensure 98% availability of medicines at all levels of care.

RxSolution, an integrated pharmaceutical management system developed by MSH, continued to be used at 216 sites across South Africa. SIAPS continued to enhance service delivery at facility level through the introduction of electronic batch management capability linked with dispensing. The use of batch management will contribute to reduced wastage through expiry of medicines. Automated ordering processes were implemented for 13 facilities in FS with the aim of enhancing productivity. Presentations were made at the ICT4Health Conference 2012 on the introduction of stock re-order levels on stock availability & use of the batch management module.

SIAPS provided TA in the development of a policy framework for private providers providing health care services on behalf of the provincial Department of Health in the WC. During the quarter, a decision was taken by management to adopt & implement the policy. At a national level, input was provided on the new draft policy to increase access to contraceptive agents.

SIAPS continued to collaborate with other PEPFAR partners & NDoH in strengthening the pharmaceutical supply chain in Limpopo Province (LP) where the provincial Department of Health is under administration. SIAPS provided TA in the installation of Infomaker software as well as development of report templates to facilitate reporting of information from PDSX, the inventory management system used at the depot. Further support was provided in implementing a mechanism for monitoring short dated stock received by the pharmaceutical depot. A Stock Availability & Reporting Tool was developed to facilitate monitoring of tracer medicine at facilities. Stock availability at the depot, increased from 65% in June to 68% by the end of the quarter.

#### Key challenges faced during the quarter

Current Value: **(Sep 2012)** - The post of Senior Technical Advisor for Pharmacovigilance under SIAPS is still vacant despite the job being advertised. Two candidates are being pursued for the position

#### Key activities planned for next quarter

Current Value: **(Sep 2012)** - SIAPS will continue to work with other PEPFAR partners and the National Department of Health in stabilizing the pharmaceutical supply chain in Limpopo province. The request to strengthen medicine supply management within primary health care (PHC) facilities in Mangaung district, in the Free State will be addressed in the following quarter. This is an initiative to improve the quality of care at the 10 facilities which achieved the lowest scores on the National Core Standards assessment

SIAPS will continue to provide support to the NDoH in the awarding and management of tenders. Emphasis will be on the antiretroviral tender which is scheduled for award in the following quarter. In the Free State (FS) the draft service level agreement (SLA) between the Medical Depot, Pharmaceutical Services & demanders will be finalized after input from the Legal Department in the Free State has been obtained. It is anticipated that this SLA will serve as a template for other provinces and will improve governance in the procurement and distribution of medicine.

SIAPS will continue to provide support to the formulary subcommittee and rational medicine use committees of the Gauteng Pharmaceutical Therapeutics Committee (PTC). Work will also be done on developing guidelines for PTCs. Technical assistance

will continue to be provided to the National Essential Medicines List committee in finalizing the Tertiary and Quaternary Level Essential Medicines recommendations. Discussions are planned in Kwazulu-Natal as to how SIAPS can support the province to build the capacity of the district PTCs and strengthen their role in pharmacovigilance.

Workshops and coaching visits for the Pharmaceutical Leadership and Management Program will be conducted in North West, KwaZulu-Natal and Western Cape provinces. A series of follow up workshops for all teams who have completed the PLDP was scheduled for the next quarter to determine progress of teams after completion of the program. A Technical Discussion Series is planned to be held in December. Support will continue to be provided to facilities currently using RxSolution®. Roll out of RxSolution in one district in Kwazulu-Natal will commence. Development of report templates and training for Infomaker® will continue to be conducted at the depots where the software is installed.

#### Technical Activity Coordination

**Current Value: (Sep 2012)** - Meetings were held with representatives of Pharmaceutical Services Departments in the Northern Cape (NC), North West (NW) and Mpumalanga (MP) provinces to present the draft SIAPS Memorandum of Understanding (MOUs) as well as to discuss province specific workplans. Work on preparing the provincial MOUs for SIAPS is on-going. SIAPS held a strategic planning meeting on 19 and 20 July in Johannesburg which was facilitated by Sylvia Vriesendorp for the Centre for Leadership and Management. South Africa's Portfolio Manager Ian Sliney and Michael Cohen, Director of M&E for the Centre for Pharmaceutical Management (CPM) were part of the strategic planning meeting. They also worked with the South African team which was preparing the workplan for year two. The workplan for year two was drafted and has undergone two rounds of review. The plan will be finalized in the following quarter.

The Vice President for CPM joined South Africa's Country Representative in presenting the recently launched Strategic Road Map 2017 (SRM) to the MSH team on 18 July. The presentation highlighted the key principles of the SRM and how they relate to the team's work going forward. The SIAPS Country Director and the COMU director attended a Business and Resource Development workshop in Cambridge in September 2012. Recruitment for the Cluster Manager for Medicine Selection and Use was completed. The new Cluster Manager is expected to start work on 1 October 2012.

#### **Quarterly Report Fields (Objective)**

Objective-level fields for collecting information for quarterly reports.

#### Quarterly Progress for Objective 1

**Current Value: (Sep 2012)** - During the quarter progress was made in strengthening pharmaceutical governance at national, provincial as well as facility level. The Adult Hospital Level Essential Medicines List (EML) was published by the National Department of Health (NDoH). SIAPS supported the National Essential Drug List Committee in the development of the EML. Draft Standard Treatment Guidelines (STGs) for ARVs were concluded & utilized in the preparation of the upcoming tender for ARVs. The guidelines will be finalized once the prices of treatment options have been revealed by the tender process. SIAPS provided TA in terms of pharmacoeconomics, governance, evidence based medicine & pharmacovigilance in the preparation of the STGs.

SIAPS continued to provide support to the Pricing Committee of the NDoH. The annual

Single Exit Price (SEP) adjustment was finalized for 2012. In addition, a revised logistics fee was gazetted for comment. TA was provided in the review of comments received from stakeholders on the national pharmacoeconomic guidelines. During this period, the guidelines were finalized in preparation for presentation to the Pricing Committee prior to recommendation to the Minister for implementation.

In the Free State (FS) a draft service level agreement (SLA) between the Medical Depot, Pharmaceutical Services & demanders was finalized after input from stakeholders was incorporated and submitted to the Legal Department of the province for comment. In the Western Cape (WC) a workshop on the National Core Standards (NCS) was facilitated at the annual conference held for pharmacist's assistants. Participants identified interventions that they could undertake to improve compliance of their facilities with the NCS.

Suggested amendments as well as a guidance document that had been developed in collaboration with the Directorate: Affordable Medicines of the NDoH was provided to the NDoH task team reviewing the NCS & developing a dictionary of terms. Through the Pharmaceutical Leadership Development Program (PLDP) in the Eastern Cape (EC), three teams addressed challenges relating to the NCS with all three teams improving compliance with aspects of the NCS in the facilities where projects were implemented.

#### Quarterly Progress for Objective 2

Current Value: (**Sep 2012**) - During the quarter, considerable progress was made towards developing capacity for pharmaceutical human resources. In the EC, 24 pharmacy managers completed the PLDP and presented their achievements to senior management & other stakeholders in August. All five teams achieved their measurable result. The PLDP was launched in the North West (NW) for 19 pharmacy managers. In the WC an introductory PLDP workshop was held for facility managers & pharmacy managers from 12 facilities. SIAPS will conduct a condensed version of the PLDP for these facilities commencing in November. A cost-sharing agreement was reached with the counterpart.

Support was provided in September for a workshop on pharmacy human resources organized by the South African Pharmacy Council (SAPC). Stakeholders including the provinces, pharmacy schools, NDoH, & the Department of Trade and Industry provided input on strategies to increase the production of pharmacy personnel in SA. SIAPS provided support for Pharmacy Law & Ethics and medicine supply management (MSM) lectures at Nelson Mandela Metropolitan University in EC, as well as Financial Management for Pharmaceutical Services at the University of Limpopo.

SIAPS provided technical assistance in identifying strategies to achieve outcomes in the results frameworks for pharmaceutical services in Kwazulu-Natal (KZN) and WC through workshops at the annual provincial pharmaceutical services conferences. Support was also provided to the Gauteng (GP) provincial conference to develop strategies & a model to ensure 98% availability of medicines at all levels of care within the province.

#### Quarterly Progress for Objective 3

Current Value: (**Sep 2012**) - RxSolution, an integrated pharmaceutical management system developed by MSH, continued to be used at 216 sites across SA. SIAPS continued to enhance service delivery at facility level through the introduction of electronic batch management capability linked with dispensing. The use of batch management will contribute to reduction of wastage through expiry of medicine. In addition automated ordering

processes were implemented in 13 facilities in the FS with the aim of saving time & enhancing productivity. Two presentations were made at the ICT4Health Conference 2012 in Cape Town on the introduction of stock re-order levels on stock availability & use of the RxSolution batch management module to reduce wastage due to expiry of medicine at facilities in EC. A weekly “Tip of the week” mailing list was established to support pharmacy personnel using RxSolution across the country.

#### Quarterly Progress for Objective 4

Current Value: **(Sep 2012)** - SIAPS made progress in supporting the development of the policy framework for private providers providing health care services on behalf of the provincial Department of Health in the WC. After input was provided by stakeholders, a decision was taken by management to adopt and implement the policy. As an initial step, private providers will be contracted to provide immunization and family planning services. At a national level, input was provided on the new draft policy to increase access to contraceptive agents by making them available at schools and places of work.

#### Quarterly Progress for Objective 5

Current Value: **(Sep 2012)** - SIAPS continued to collaborate with other PEPFAR partners and the NDoH in strengthening the pharmaceutical supply chain in Limpopo Province (LP) where the provincial Department of Health is under administration. SIAPS provided technical assistance in the installation of Infomaker software at the provincial pharmaceutical depot to facilitate reporting of information from PDSX (inventory management system). Report templates for extracting information were developed. SIAPS provided support in implementing a mechanism for monitoring short dated stock received by the pharmaceutical depot, in order to reduce the value of stock that expires at the depot prior to distribution.

A Stock Availability & Reporting Tool was developed to facilitate monitoring of availability of tracer medicine at facilities serviced by the pharmaceutical depot. Stock availability at the depot increased from 65% in June to 68% by the end of the quarter. A consultant was contracted to conduct Pharmaceutical Management of Tuberculosis (PMTB) assessments in selected National Health Insurance (NHI) pilot sites in six provinces - EC, FS, LP, Mpumalanga (MP), NW & WC. The sampling methodology & sites to be assessed were finalized and MSH PMTB assessment tools adapted to suit the South African context. Interview templates were developed for the strategic elements. These tools were tested in a regional hospital, district hospital & two Primary Health Care clinics. Data collection will commence in the next quarter.

#### Quarterly Progress for Objective 6

Current Value: **(Sep 2012)** - In GP, the protocol entitled: ‘What are the reasons for switching ART patients (adults & adolescents) to 2nd line regimens in public health settings in GP?’, was granted ethical approval. Training of district pharmacists who will collect data for the study will be conducted in October. SIAPS worked in partnership with the SAPC, the Pharmaceutical Society of South Africa (PSSA) and the NDoH to develop communication material for the Pharmacy Week campaign 2012. SIAPS also provided financial support for printing communication material. The campaign which was conducted in September aimed to encourage people to know and understand their medicine in accordance with the requirements for quality pharmaceutical services in the National Core Standards.

#### Quarterly Report Fields (Sub-Objective)

Fields for reporting quarterly progress at the sub-objective level.

Quarterly progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - SIAPS provided technical assistance to the Clinical Trials Committee (CTC) of the Medicine Control Council (MCC) for the review of three clinical trials in Tuberculosis. SIAPS also provided support to MCC staff in the application of Good Clinical Practice (GCP) for the review and verification of clinical data submitted in support of a clinical claim or medicines safety.

Challenges in progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - Delays in the finalization of the contract with the external consultant who will be supporting the drafting of amendments to the Pharmacy Act

Quarterly progress toward sub-objective 1.2

Current Value: **(Sep 2012)** - SIAPS continued to provide technical assistance to the National Essential Drug List Committee (NEDLC) in the review of the Primary Health Care (PHC) Essential Medicines List (EML) and Standard Treatment Guidelines (STGs). The NEDLC approved the circulation of three chapters of the PHC EDL (viz. Chapter 1: Dental and Oral Conditions, Chapter 5: Skin conditions and Chapter 18: Eye conditions) for consultation with external stake holders. Draft STGs for antiretrovirals (ARVs) were concluded and utilized in the preparation of the upcoming tender. The guidelines will be finalized once the prices of some of the treatment options have been revealed by the tender process.

SIAPS provided TA in terms of pharmacoeconomics, governance, evidence based medicine and pharmacovigilance in the preparation of these STGs. TA was provided in an initiative to consolidate four essential medicines lists into a single national essential medicines list that is currently being reviewed by the National Department of Health (NDoH). It is envisaged that this list will assist in the alignment of procurement with selection and facilitate the compilation of formularies at a provincial and institutional level. TA was provided in the review of comments received from stakeholders on the national pharmacoeconomic guidelines.

The pharmacoeconomics task team of NDoH finalized the guidelines to be presented to the Pricing Committee for recommendation to the Minister for implementation. SIAPS mentored NDoH staff on the application of the pharmacoeconomic principles to assist decision making in both the PHC and tertiary level EML. This was a follow up to the pharmacoeconomic training hosted by SIAPS in collaboration with the University of Washington in April 2012. A lecture was presented to 4th year pharmacy at the University of Limpopo, Medunsa Campus on the application of evidence based medicine and pharmacoeconomics principles in the Essential Medicine List program.

Challenges in progress toward sub-objective 1.2

Current Value: **(Sep 2012)** - The tender process is not yet well aligned with the EML and STGs. Steps being taken to address challenges: A detailed analysis of the tablet tender is being prepared and will be presented to the NEDLC and Pricing Committee. It is hoped that this will form the impetus for policy change. Proposals have been made for tendering per class and only awarding the most economically advantageous example. The principles have been applied in the 2012 ARV tender.

Deliverables: Sub-Objective 1.2

Current Value: **(Sep 2012)** - 1. The Adult Hospital Level EML in print format was distributed to Universities and depots for circulation. 2. Tertiary EML published on the 23rd August 2012.

Quarterly progress toward sub-objective 1.3

Current Value: **(Sep 2012)** - SIAPS continued to provide support to the Pricing Committee of the National Department of Health (NDOH). TA was provided in the review of the formula for the annual Single Exit Price (SEP) adjustment. It was identified that the British pound has a significant impact on the price of medicines & should be added to the basket of currencies applied. Current data is being modeled to arrive at appropriate weights. The annual SEP adjustment was finalized for the 2012 cycle. The revised logistics fee was gazetted for comment. The comment period was later extended based on requests from the public. Training was provided to principal officers of medical schemes who are members of Board of Health Funders (BHF) on the dispensing fee, annual SEP adjustment and temporary price reductions. Consultation with the pharmaceutical industry on international benchmarking for pharmaceutical pricing is ongoing. In the Free State (FS) the draft service level agreement (SLA) between the Medical Depot, Pharmaceutical Services & demanders was finalized after input from stakeholders was incorporated and the annexures finalized. The document was submitted to the Legal Department of the province for comment. During this quarter work commenced on a similar SLA between the Port Elizabeth Pharmaceutical Depot in the Eastern Cape (EC) & demanders served by this Depot. It is anticipated that the implementation of these SLAs will contribute to improving medicine supply management (MSM) & subsequently medicine availability in both provinces.

Quarterly progress toward sub-objective 1.4:

Current Value: **(Sep 2012)** - In the Western Cape, a workshop on the National Core Standards (NCS) was facilitated at the annual conference held for pharmacist's assistants. Background was provided on the NCS, the tools were shared & participants identified interventions that they could undertake to improve compliance of their facilities with the NCS. Suggested amendments as well as a guidance document that had been developed in collaboration with the Directorate: Affordable Medicines of the National Department of Health (NDoH) was provided to the NDOH task team reviewing the NCS & developing a dictionary of terms. A request was received to provide support for strengthening pharmaceutical services within primary healthcare facilities in Mangaung, in the Free State (FS). Support is expected to be part of a PHC re-engineering initiative in the district. The request was received following low scores achieved on a National Core Standards baseline assessment. This activity will be pursued in the next quarter. Three of the teams who completed the Pharmaceutical Leadership Development Program (PLDP) in Eastern Cape addressed challenges relating to the NCS and presented their achievements to senior management & other stakeholders in August. All three teams achieved their measurable result

Quarterly progress toward sub-objective 2.1

Current Value: **(Sep 2012)** - Support was provided in September for a workshop on pharmacy human resources organized by the South African Pharmacy Council (SAPC). Stakeholders including the provinces, pharmacy schools, NDoH, & the Department of Trade and Industry provided input on strategies to increase the production of pharmacy personnel in

SA. At Nelson Mandela Metropolitan University in the Eastern Cape support was provided in the lectures for final year BPharm students on Pharmacy Law & Ethics as part of the undergraduate curriculum. The semester test & final assessments were prepared. Training on Financial Management for Pharmaceutical Services was conducted for 16 postgraduate students registered for the Hospital Pharmacy Management Diploma at the University of Limpopo.

Deliverables: Sub-Objective 2.1

Current Value: **(Sep 2012)** - 1. Training material for Financial management workshop

Quarterly progress toward sub-objective 2.2

Current Value: **(Sep 2012)** - The 24 pharmacy managers who completed the Pharmaceutical Leadership Development Program (PLDP) in EC presented their achievements to senior management & other stakeholders in August. All five teams achieved their measurable result. In the North West (NW), SIAPS launched a PLDP with 19 pharmacy managers on 9 July. The first 2 workshops were conducted in July & August. Coaching visits took place in August & September. Teams are working on the following challenges – 1) Dr Kenneth Kaunda - Increase availability of indicator medicines in identified pharmacies & clinics in the district 2) Dr Ruth S. Mompoti - Increase the number of eligible patients enrolled on Isoniazid Preventative Therapy at Vryburg Hospital 3) Ngaka Modiri Molema - Improve compliance with NCS relating to provision of pharmaceutical services in 10 PHC clinics in the district 4) Bojanala - Improve identifying & reporting of ADRs and 5) NW Provincial Team - Shorten the time taken to pay suppliers by the provincial depot. In September an introductory PLDP workshop was held for facility managers & pharmacy managers from 12 facilities in the Western Cape (WC). SIAPS will conduct a condensed version of the PLDP for these facilities commencing in November. A cost-sharing agreement has been reached with the counterpart. A series of follow up workshops for all teams who have completed the PLDP was scheduled for the next quarter to determine progress of teams after completion of the program. SIAPS is investigating an alliance with Regional Training Centres for accreditation & wider dissemination of the PLDP.

Challenges in progress toward sub-objective 2.2

Current Value: **(Sep 2012)** - How to ensure sustainability of the improvements implemented by the teams as well as sustainability of the program itself post SIAPS Steps to address challenges: 1. SIAPS is investigating an alliance with Regional Training Centres for the accreditation and wider dissemination of the program. 2. A series of follow up workshops for all the teams who have completed the PLDP has been scheduled for the last week of November. The purpose of the workshops is to determine the progress made by teams after completion of the PLDP. 3. Tools to assess the sustainability of the difference that the program is making in the facilities are being investigated.

Deliverables: Sub-Objective 2.2

Current Value: **(Sep 2012)** - 1. Presentations and posters developed by 5 teams in the EC 2. 5 Success stories submitted to the local mission:

Quarterly progress toward sub-objective 2.3

Current Value: **(Sep 2012)** - SIAPS provided technical assistance to the Kwazulu-Natal Pharmacy Conference where strategies to achieve outcomes in the provincial results framework

were identified. A report on the routine monitoring system implemented was presented by a representative of the province. In the Western Cape (WC) a workshop was facilitated at the annual pharmacists conference on the results framework developed for Pharmacy Services in the province. Participants identified strategies to achieve the outcomes in the framework. Work was done on the indicators for routine monitoring of pharmaceutical services in the WC. SIAPS provided support for the annual Gauteng (GP) Pharmacy Conference where 4 working groups were formed to address specific issues in the province. SIAPS provided TA to the working group tasked to develop strategies & a model to ensure 98% availability of medicines at all level of care within the province. A draft operational plan was submitted to the Pharmaceutical Services Directorate.

#### Challenges in progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - No activities took place under SIAPS during this quarter. Work was ongoing under the Strengthening Pharmaceutical Systems program.

#### Quarterly progress toward sub-objective 3.2

Current Value: **(Sep 2012)** - RxSolution continued to be used at sites across SA. There are currently 216 active sites distributed as follows: • Currently 100 facilities using RxSolution in the Eastern Cape (EC). • Currently 43 facilities using RxSolution in the Free State (FS). • Currently 38 facilities using RxSolution in the North West (NW). • Currently 35 facilities using RxSolution in Tshwane Metro and City of Johannesburg. In Limpopo (LP), assessments were conducted to determine the feasibility of implementing RxSolution at Pietersburg and Mankweng Hospital ARV sites in Polokwane, Limpopo. These facilities would serve as pilot sites for RxSolution within the province.

In Gauteng (GP) SIAPS held meetings with the Tshwane Metro (TM) pharmaceutical services unit to discuss the implementation of the dispensing module in all facilities currently using RxStore. Work is underway to customize dispensing module features to meet the needs of TM. The dispensing module will initially be piloted in two sites. The use of electronic batch management capability linked with dispensing was implemented at Du Preez Street Clinic in EC, which is the first PHC facility using electronic batch management.

In FS, ordering of medication from the pharmaceutical depot was enhanced by the introduction of automated ordering at 13 facilities. Automated ordering is based on calculation of stock levels & historic product consumption. Four facilities were converted from stand-alone to server based functionality for RxSolution. This will enable more people to work on the system simultaneously, thus saving time & enhancing productivity.

A weekly “Tip of the week” mailing list was established, where a brief description of common challenges that users encounter will be sent to all registered users. Formal training was conducted in FS & EC (50 people trained). Two presentations were made at the ICT4Health Conference 2012 in Cape Town on the introduction of stock re-order levels on stock availability & use of the RxSolution batch management module to reduce wastage due to expiry of medicine at facilities in EC.

#### Challenges in progress toward sub-objective 3.2

Current Value: **(Sep 2012)** - Availability of suitable information technology infrastructure, as well as limited computer literacy amongst provincial and Metro staff hamper the successful implementation of RxSolution in many facilities.

Deliverables: Sub-Objective 3.2

Current Value: **(Sep 2012)** - 1. Abstracts and presentations made at the ICT4 Health Conference 2012  
2. Two success stories submitted to the local mission

Quarterly progress toward sub-objective 4.1

Current Value: **(Sep 2012)** - No activities took place under SIAPS during this quarter. Work was ongoing under the Strengthening Pharmaceutical Systems program.

Quarterly progress toward sub-objective 4.2

Current Value: **(Sep 2012)** - In the Western Cape (WC), TA was provided on the policy framework for private providers, outlining guidelines governing the provision of medicines to private, non-governmental & other organizations providing health care services on behalf of the provincial Department of Health. After input was provided by stakeholders, a decision was taken by management to adopt and implement the policy. As an initial step private providers will be contracted to provide immunization and family planning services. TA was provided in the drafting of an information document, application forms and the request for service to be published in the local press and placed on the provincial website. At a national level, input was provided on the new draft policy to increase access to contraceptive agents by making them available at schools and places of work. SIAPS attended a forum of pharmacists entitled, "Pharmacists for National Health Insurance (NHI)", in Johannesburg during August. The aim of the forum was to explore the roles for the pharmacist under NHI. SIAPS was identified as a potential partner that could provide valuable guidance in this. In the Northern Cape (NC) a draft organizational structure and job descriptions for the provincial pharmaceutical services unit were developed and submitted to the province for comment.

Quarterly progress toward sub-objective 5.1

Current Value: **(Sep 2012)** - No activities took place under SIAPS during this quarter. Work was ongoing under the Strengthening Pharmaceutical Systems program.

Quarterly progress toward sub-objective 5.2

Current Value: **(Sep 2012)** - SIAPS continued to collaborate with other PEPFAR partners and the National Department of Health (NDOH) in strengthening the pharmaceutical supply chain in Limpopo Province (LP) where the provincial Department of Health is under administration. During the reporting period, TA was provided at the pharmaceutical depot in LP as follows: 1) Infomaker software was installed at the depot to facilitate reporting of information from PDSX (inventory management system). Templates to be extracted from PDSX have been identified and will be developed by SIAPS. 2) A mechanism was established for monitoring products that are received at the depot with an expiry date of less than 18 months. 3) A Stock Availability & Reporting Tool was developed for use at facilities and the depot. This spread sheet will be completed on a weekly basis at facility level to monitor availability of tracer medicines. TA was also provided in the preparation of management reports on usage, expenditure, backorders, invoice/returns value reports, order reports, for ARVs and other products as requested by management. Support was provided to the office of the Acting Senior Manager in the development of reports & SOPs for depot functions. At the Depot, stock availability increased from 65% in June to 68% by the end of the quarter. Support was also provided in the creation of a database of suppliers to be used by the depot's procurement section to

source quotations.

Deliverables: Sub-Objective 5.2

Current Value: **(Sep 2012)** - 1. Stock Availability & Reporting Tool

Quarterly progress toward sub-objective 5.3

Current Value: **(Sep 2012)** - SIAPS continued to collaborate with other PEPFAR partners & National Department of Health (NDoH) in strengthening the pharmaceutical supply chain in Limpopo (LP) where the provincial Department of Health is under administration. TA was provided in conducting medicine availability assessments at clinics and hospitals using NCS checklists. Assessments are ongoing in Vhembe, Mopani & Waterberg districts with daily/weekly feedback on stock availability to management. Information received by the end of the reporting period showed 80% stock availability within the facilities assessed. TA was provided to Waterberg & Vhembe district pharmacy managers on generating stock-on-hand reports. Similar TA was provided at Mankweng Hospital Complex & George Masebe hospital.

TA was also provided to the pharmacy manager at Voortrekker Hospital on ABC report generation & analysis. A further comparison of usage trends with current stock holding helped identify 135 items that were overstocked. A plan is being developed to re-distribute excess stock to other facilities. Formal MSM training was provided for 68 people. A consultant was contracted to conduct Pharmaceutical Management of Tuberculosis (PMTB) assessments in selected NHI pilot sites in six provinces Eastern Cape, Free State, Limpopo, Mpumalanga, North West & Western Cape. An initial research team meeting with stakeholders was held in August to finalize the consultant's scope of work. The sampling methodology and sites to be assessed were finalized. The consultant customized MSH PMTB assessment tools to suit the South African context. Interview templates were also developed for the strategic elements. These tools were tested in a regional hospital, district hospital and two primary health care clinics to check user friendliness and validity. Data collection will commence in the next quarter. MSM for TB training was conducted for 21 people in Sisonke district in KZN. An implementation plan for the conversion of MSH courses on TB & HIV to an online format was received.

Quarterly progress toward sub-objective 6.1

Current Value: **(Sep 2012)** - In Gauteng Province (GP), the protocol entitled: 'What are the reasons for switching ART patients (adults & adolescents) to 2nd line regimens in public health settings in GP?', was granted ethical clearance by Pharma-ethics and the GP Provincial Ethics Committee. The study is an observational descriptive study with an analytical component. A sample of 312 medical records within 33 facilities will be reviewed. Letters were sent to facility managers, district pharmacists and facility pharmacists introducing the study and requesting permission to collect data. District pharmacists nominated pharmacists working in local facilities to conduct data collection. Training of data capturers will be conducted in October.

Quarterly progress toward sub-objective 6.2

Current Value: **(Sep 2012)** - SIAPS attended a National Pharmacovigilance Gap Analysis and Planning Project Workshop in August. The goals of the project are to conduct a gap analysis of pharmacovigilance activities being undertaken in the public sector in SA and develop a plan of action for a robust national pharmacovigilance program. SIAPS will continue to

work with the NDoH in the implementation of the national pharmacovigilance strategy.

Challenges in progress toward sub-objective 6.2

Current Value: **(Sep 2012)** - The post of Senior Technical Advisor for Pharmacovigilance under SIAPS is still vacant despite the job being advertised. Steps taken to address challenge: Two candidates are being pursued for the position

Quarterly progress toward sub-objective 6.3

Current Value: **(Sep 2012)** - SIAPS worked in partnership with the South African Pharmacy Council (SAPC), the Pharmaceutical Society of South Africa (PSSA) and the National Department of Health (NDoH) to develop communication material for the Pharmacy Week campaign 2012. The campaign aimed to encourage people to know and understand their medicine. SIAPS also provided financial support for printing communication material. The NDoH, PSSA and SAPC facilitated distribution of the materials to public and private health facilities nationwide. A launch was held for the local MSH staff (SIAPS and Building Local Capacity for HIV/AIDS) where presentations were made on the campaign message.

Deliverables: Sub-Objective 6.3

Current Value: **(Sep 2012)** - Pharmacy Week 2012 posters, flyers and bookmarks

Quarterly progress toward sub-objective 6.4

Current Value: **(Sep 2012)** - SIAPS contracted a consultant to conduct a baseline assessment of adherence for MDR/XDR patients. The protocol for this assessment was received for review.

## **SOUTH SUDAN MAL/PHARM**

South Sudan work plan details for Year 1 of the SIAPS Program

### **Quarterly Report Background**

Under FY11, the Systems for Improved Access to Pharmaceuticals and Services (SIAPS), the follow on project to SPS will aim to consolidate the achievements made under previous years. Using a systems strengthening approach consistent with the Global Health Initiative, SIAPS will aim to assure availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes.

The SIAPS South Sudan project activities will aim to strengthen pharmaceutical sector governance; enhance capacity for pharmaceutical supply management and services; introduce rational use and quality assurance interventions; improve malaria planning and coordination; and, strengthen malaria monitoring and evaluation systems.

Activities proposed under FY2011 are consistent with the USAID Result Areas for the SIAPS program and will contribute to the achievement of the USAID Sudan Field Office multi-sectoral strategy for infectious diseases and Intermediate Result 10.1 related development of core institutional structures for an effective, transparent, and accountable Government of South Sudan.

### **Goal: South Sudan Year 1 Work Plan Goal**

To assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes

#### **Objective 1**

Pharmaceutical sector governance strengthened

##### **Sub-Objective 1.1**

Good governance principles adopted

##### **Activity 1.1a**

Develop concept paper for establishing an autonomous CMS

##### **Sub-Objective 1.2**

Improved medicine policies, legislations, regulations, norms & standards

##### **Activity 1.2a**

Finalize review of the South Sudan Food and Drug Control Authority Bill

##### **Activity 1.2b**

Review and update the STG and EML

##### **Activity 1.2c**

Review and update regulatory guidelines for licensing private sector businesses and import controls

**Activity 1.2d**

Develop policy/ guidelines for pharmaceutical waste management

**Sub-Objective 1.3**

Transparent & accountable pharmaceutical management systems in place

**Activity 1.3a**

Establish supplier performance monitoring system

**Sub-Objective 1.4**

Strategic & evidence-based national pharmaceutical sector plans developed

**Activity 1.4a**

Finalize the South Sudan Pharmaceutical Sector Strategic/ Master Plan, including elaboration of transition plan to pull system

**Objective 2**

Capacity for pharmaceutical supply management and services increased and enhanced

**Sub-Objective 2.1**

Enhanced individual, institutional and organizational capacity for pharmaceutical management

**Activity 2.1a**

Develop/ update various in-service pharmaceutical management training manual/ materials

**Activity 2.1b**

Conduct in-service pharmaceutical management trainings and workshops

**Activity 2.1c**

Develop job descriptions for pharmaceutical roles at State, County and facility level

**Activity 2.1d**

Provide TA to GFATM PRs on PSM implementation

**Sub-Objective 2.2**

Innovative & proven approaches for human resource capacity building adopted

**Activity 2.2a**

Develop/ update SOPs and job aids to support task shifting

**Objective 3**

Information for decision-making challenge in the pharmaceutical sector addressed

**Sub-Objective 3.1**

Pharmaceutical management information system (PMIS) in place to support products & patients

**Activity 3.1a**

Print and disseminate LMIS/PMIS tools

**Activity 3.1b**

Support automation of inventory management at CMS

**Sub-Objective 3.2**

Information on pharmaceutical systems strengthening available and used

**Activity 3.2a**

Set up pharmaceutical coordination & information-sharing mechanisms

**Objective 4**

Pharmaceutical services improved to achieve desired health outcomes

**Sub-Objective 4.1**

Improved availability of pharmaceuticals and medical supplies

**Activity 4.1a**

Improved availability of essential medicines through TA for product selection, quantification, procurement, receipt, storage and distribution

**Sub-Objective 4.2**

Patient safety and therapeutic effectiveness assured

**Activity 4.2a**

Startup pharmacovigilance system to promote patient medication safety

**Activity 4.2b**

Strengthen quality assurance mechanisms and enforcement of regulatory frameworks

**Sub-Objective 4.3**

Medication use improved

**Activity 4.3a**

Establish and strengthen DTCs at hospitals

**Activity 4.3b**

Develop IEC materials for promoting RDU & AMR containment

**Objective 5**

Scale up of malaria interventions better coordinated and documented

**Sub-Objective 5.1**

Malaria planning and coordination mechanisms strengthened

**Activity 5.1a**

Orient Malaria Control Program staff on malaria control policies and strategies

**Activity 5.1b**

Support development of state and county malaria action plans

**Activity 5.1c**

Support Commemoration of World Malaria Day

**Activity 5.1d**

Support actual scale up of selected malaria control interventions

**Sub-Objective 5.2**

Malaria Monitoring and Evaluation systems strengthened

**Activity 5.2a**

Support MOH to plan the 2011 Malaria Indicator Survey (MIS)

**Activity 5.2b**

Support MOH to conduct a Malaria Program Review (MPR)

**Activity 5.2c**

Support NMCP to monitor efficacy of antimalarial medicines

**Goal: Quarterly Report Fields**

These are the fields that will be used to collect information for quarterly reports.

Overall Quarter Progress

Current Value: **(Sep 2012)** - Pharmaceutical management capacity of MOH & partners was enhanced

through development of training materials, supportive supervision and private sector inspection capacity, hence contributing to improvements in quality of products and services rendered through both the public and private sectors. With PMIS tools printed in the previous quarter, SIAPS facilitated a number of initiatives to generate, analyze and make available information for decision making. More health facilities in the focus states now have the necessary tools and skills to collect and report pharmaceutical data.

Improvements in access to essential pharmaceutical products, including those for prevention of PPH, the leading cause of maternal mortality in South Sudan, through SIAPS support for MOH procurement and distribution mechanisms. Significant progress was also made towards completion of the renovation of the Central Equatoria warehouse, which will increase MOH storage capacity at the central level. In the area of quality assurance, SIAPS continued to provide TA for the Minilab sites in Juba and Kaya.

With SIAPS support, the Kaya office managed to detect illegal imports and/ or substandard medicines, hence averting exposure of patients to poor quality medicines. Under its continued support to the National Malaria Control Program, SIAPS supported NMCP to finalize preparations for the start-up of the Therapeutic Efficacy Testing (TET) sites. NMCP has also been supported/ guided to better oversee implementation of the Global Fund grant for malaria managed by PSI, the PR.

#### Key challenges faced during the quarter

Current Value: **(Sep 2012)** - There continued to be funding constraints under the FY11 work plan and budget requiring further re-prioritization of planned activities. This hampered completion of some project activities and led to the project focusing on key activities perceived to be essential for achieving the FY11 work plan objectives. Further, delays in disbursement of funds for malaria activities from the consolidated GFATM malaria grant negatively affected FY11 work plan implementation. This is more critical especially given that some SIAPS activities e.g. trainings, M&E, etc. were to leverage resources from the GFATM grant and hence could not be initiated.

#### Key activities planned for next quarter

Current Value: **(Sep 2012)** - Next quarter activities will be in line with the new SIAPS FY2012 work plan, which still awaits final approval by USAID.

#### Technical Activity Coordination

Current Value: **(Sep 2012)** - SIAPS/ South Sudan finalized its 5-years strategic plan, which aims to outline priorities over the life of the Global project (up to September 2016, subject to availability of funding). The project prepared and participated in a Data Quality Audit (DQA) conducted by USAID/ South Sudan mission. During this quarter, the project hosted a programmatic and technical oversight STTA from Gladys Tetteh, the SIAPS Deputy Director based at headquarters in Arlington, US.

During this trip, the Deputy Director helped to review the country work plan and strategic direction with the mission, and also discussed continuity of operations and finance support with closure of SHTP II. In light of pipeline challenges, the project held several meetings with USAID/ South Sudan to review work plan implementation progress. As a result, the project reviewed and prioritized remaining activities in the FY11 SIAPS work plan to match available funds. The meeting also discussed areas of future focus, which helped inform development of the F12 work plan.

The project continued to work with SMOH and UNICEF to finalize arrangements for

renovation of the Central Equatoria state medical stores. This involved building consensus between the different stakeholders including a meeting between USAID and the Minister of Health, Central Equatoria state, and several meetings with UNICEF. The contract was signed with the selected vendor and a letter of understanding outlining roles of each stakeholder was drafted to guide support to the state. SIAPS drafted job description for Malaria Technical Advisor to be recruited in FY12.

#### Office management

Current Value: **(Sep 2012)** - SIAPS continued to meet program operations for SIAPS and NMCP offices, including cost sharing arrangements with SHTP II - office utilities (internet, stationery) and other overheads. These cost sharing activities includes provisions for local office operations and all associated costs such as office supplies and stationery, internet connectivity for NMCP office and the new pharmaceutical pre-fab, vehicle maintenance and operations, as well as finance and administrative support functions.

#### **Quarterly Report Fields (Objective)**

Objective-level fields for collecting information for quarterly reports.

#### Quarterly Progress for Objective 1

Current Value: **(Sep 2012)** - Following achievement of the key milestones under this objective in previous quarters, no objective-specific activities were conducted during this quarter.

#### Quarterly Progress for Objective 2

Current Value: **(Sep 2012)** - SIAPS supported MOH to adapt training material on rational drug use, identify topics to be covered and developed detail programs for training health workers in the three teaching hospitals with funds from MOH. In EES, SIAPS assisted the SMOH to plan, conduct and report on inspection of the private sector outlets and clinics.

#### Quarterly Progress for Objective 3

Current Value: **(Sep 2012)** - SIAPS facilitated a number of initiatives to generate, analyze and make available information for decision making. These included: dissemination of PMIS tools in CES and WES; guiding M&E team at PSI to adapt existing Continuous Results Monitoring System (CRMS) tools for purposes of collecting data on malaria-related services and commodities in selected health facilities; collection, analyzing and providing feedback on CRMS data from health facilities. SIAPS also organized the first state pharmaceutical coordination meeting for partners in WES, and supported MOH to revitalize the pharmaceutical technical work group (TWG) meetings.

#### Quarterly Progress for Objective 4

Current Value: **(Sep 2012)** - SIAPS provided TA to MOH, USAID and other donors to expedite product selection and emergency procurement for essential medicines and medical supplies so as to avoid potential stock out in 2013. Guidance was also provided to ensure appropriate quality assurance mechanisms are built into the entire procurement process.

SIAPS also facilitated preparation for the routine CMS distribution by providing TA for updating the distribution plan. SIAPS supported county medical stores and health facilities to

distribute/ re-distribute medicines and medical supplies. SIAPS coordinated the product supply chain management aspects of the ongoing USAID-funded prevention of post-partum hemorrhage (PPH) program in Mvolo and Mundri East. This included facilitating custom clearance, receipt and storage at CMS, distribution to the counties, and pre-packaging for dispensing of the Misoprostol to be used for the program.

SIAPS continued to work on the contracting and mobilization of funding for completion of the renovation of the Central Equatoria warehouse to increase storage space and conditions. To strengthen pharmaceutical management practices, SIAPS conducted several supportive supervisory visits to health facilities during the quarter. These included visits to collect CRMS data, assist with improvements in storage conditions and conduct on-job training on the PMIS tools. In the area of quality assurance and pharmacovigilance, SIAPS continued to provide TA for the Minilab sites in Juba and Kaya. With SIAPS support, the Kaya office managed to detect illegal imports and/ or substandard medicines. This resulted in an official complaint being submitted by MOH to the Uganda National Drug Authority (NDA). SIAPS also initiated work on draft guidelines and tools for Adverse Drug Reaction (ADR) monitoring and reporting.

#### Quarterly Progress for Objective 5

**Current Value: (Sep 2012)** - As part of its continued support to the National Malaria Control Program, SIAPS supported NMCP to finalize preparations for the start-up of the Therapeutic Efficacy Testing (TET) sites, although the start of study awaits delivery of study items to study sites. SIAPS also supported NMCP to plan and train health workers in Wau in malaria sentinel surveillance. SIAPS supported MOH/ NMCP to exercise its oversight and coordination role in implementation of the malaria Global Fund grant managed by PSI the PR. NMCP was also supported to follow up on progress on activities as well as address issues/bottlenecks hindering implementation. SIAPS also drafted a concept paper (malaria control-a focus on prevention) that contains basic information regarding Malaria transmission, the basis for setting up the malaria control strategies.

#### **Quarterly Report Fields (Sub-Objective)**

Fields for reporting quarterly progress at the sub-objective level.

#### Quarterly progress toward sub-objective 1.2

**Current Value: (Sep 2012)** - SIAPS supported the Department of Pharmaceuticals and Equipment, EES, MOH to draft a proposal for inspection of private health facilities in the state. SIAPS also participated in the inspection activities and attended the presentation and deliberation of the report on inspection of private sector health facilities in the Eastern Equatoria State Legislative Assembly. SIAPS provided TA for writing this report.

#### Challenges in progress toward sub-objective 1.2

**Current Value: (Sep 2012)** - Appointment of Board members and key staff of the South Sudan Drug and Food Control Authority did not take place during the quarter. This hampered initiation or conduct of some quality assurance and regulatory activities

#### Deliverables: Sub-Objective 1.2

**Current Value: (Sep 2012)** - Draft proposal for inspection of private health facilities in the Eastern Equatoria state. Report on inspection of private sector health facilities presented to the Eastern Equatoria State Legislative Assembly.

Quarterly progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - SIAPS distributed various PMIS tools (stock card=101, dispensing registers Hospital (general) =15, dispensing registers hospital (units) =78, dispensing registers (PHCU) =92 to health facilities in CE and WES to help improve pharmaceutical management such as reporting of commodity use and stock status. SIAPS supported the M&E team at PSI to adapt existing CRMS tools for purposes of collecting data on malaria-related services and commodities in selected health facilities. This is aimed at informing designing the distribution strategy for Global Fund antimalarial commodities. SIAPS continued to collect CRMS data from health facilities in Terekeka, Lainya and Juba Counties. Data cleaning and entry in a spreadsheet program was also initiated. SIAPS worked with SHTP-II to quantify needs for PMIS tools in WES and CES. This was to inform procurement decisions related to usage of fund balance from the SHTP-II project for printing additional tools for these USAID-supported states. SIAPS collected and analyzed consumption data for June and July from Nyong PHCC and Torit State Hospital.

Challenges in progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - Due to funding constraints, it was not possible to carry out extensive field-based on-job trainings and follow up on usage of the PMIS tools during the quarter.

Deliverables: Sub-Objective 3.1

Current Value: **(Sep 2012)** - Distribution list/ report for PMIS tools CRMS tools adapted for M&E team at PSI for malaria-related services and commodities CRMS reports (WES & CES) Quantification of PMIS tools for WES and CES for funding with SHTP-II fund balance Consumption data reports from Nyong PHCC and Torit State Hospital for June/ July

Quarterly progress toward sub-objective 3.2

Current Value: **(Sep 2012)** - SIAPS organized the first state pharmaceutical coordination meeting that brought together pharmaceutical stakeholders from all the 10 counties of Western Equatoria State. SIAPS supported the DP&E to revive the pharmaceutical technical work group (TWG) meetings. Support included coordination of preparations with MOH and UNFPA, preparing the Agenda and inviting key stakeholders participants, and technical facilitation of the discussions. SIAPS was seconded as the secretariat for the TWG.

Challenges in progress toward sub-objective 3.2

Current Value: **(Sep 2012)** - Due to competing priorities at MOH, it took long to schedule the first pharmaceutical management TWG. Interest from partners and collaboration with UNFPA helped to raise the profile and need for the TWG.

Deliverables: Sub-Objective 3.2

Current Value: **(Sep 2012)** - WES pharmaceutical coordination meeting report Pharmaceutical technical work group (TWG) meeting minutes Updated pharmaceutical management TWG terms of reference (TOR)

Quarterly progress toward sub-objective 4.1

Current Value: **(Sep 2012)** - SIAPS supported MOH to select essential medicines and medical supplies for primary health care in line with the basic package of health services. Inputs were sought from stakeholders before finalizing the list, which was adapted by donors (USAID, DFID, and NORAD) to come up with the minimum requirements for effective primary health care. SIAPS supported MOH to quantify the needs for the minimum list of pharmaceutical products and medical supplies agreed upon by MOH and the donors. SIAPS also drafted CPIR forms for these procurements, and participated in a quality assurance teleconference call with USAID, DELIVER & FHI360 to review the QA SOP for the procurement to be done by DELIVER/PROJECT.

In preparation for the next round of distribution of kits, SIAPS supported the Central Medical Stores to review options for allocation of kits for next regular of distribution. Rather than have two separate cycles, each with complex and lengthy procurement process for transporters, SIAPS recommended consolidating the two cycles (of 4-5 months' supply for health facilities) into one distribution partly also to create more space for incoming supplies. SIAPS took part in meetings with DFID (Jay), UNICEF and NMCP to discussion arrangements for importation and use of a donation of 150,000 doses of artemether/lumefantrine combination, the 2nd line for treatment of uncomplicated malaria. SIAPS facilitated UNICEF to obtain the necessary import verification certificate for this consignment. SIAPS finalized selection and contracting of a vendor to undertake renovation of Central Equatoria state medical stores (funded through SPS). Additional funds (about \$45,000) were also leveraged from UNICEF to supplement SPS funds and ensure a whole block is covered.

SIAPS handled the product supply chain management aspects of the ongoing prevention of post-partum hemorrhage (PPH) program. These support included: a) participating in TWG meetings on the introduction of misoprostol in two counties (Mvolo and Mundri East); developing roles & responsibility matrix for partners at all levels; coordinating with VSI to obtain import verification certificate, clear the misoprostol through customs and linking up with CMS to receive and store; organizing for delivery of the first consignment of misoprostol to Mvolo and Mundri East counties, timed to coincide with the start of roll out of training for the home health promoters (HHPs) by MCHIP; supporting CHD to re-package and label appropriately doses of misoprostol ready for dispensing by the HHPs; participating in the first training in Mvolo County; conducting supportive supervision to ten (10) health facilities in Mundri East and Mvolo to orient staff on supply chain management and reporting for misoprostol SIAPS conducted several supportive supervisory visits during the quarter.

These included visits to: Yambio Civil Hospital; 9 facilities in the five eastern counties of Western Equatoria state (i.e. Mundri East, Mvolo, Mundri West and Maridi) to complete CRMS checklists; Mvolo County to review implementation of PMIS; Mundri East health facilities, including: Mideh PHCC, Kediba PHCC, Mariba PHCU, Dosho PHCU and Wandu PHCU; seven (7) facilities in 3 counties in the western part of WES (Ezo, Tambura and Nagero). SIAPS supported county medical stores health facilities to distribute/ re-distribute medicines and medical supplies. These included: working with Torit County Health Department in sorting and distributing the last CMS consignment to Osito PHCU, Mutaram PHCU, Ohila PHCU, Ohiri PHCU, Imurok PHCU, Khormus PHCU, Mokoru PHCU and Moti PHCU; and coordinating redistribution of ACTs from Nyakuron PHCC to Kator PHCC and Lalogo PHCC SIAPS supported the EES, MOH to allocate and distribute medicines and medical supplies donated to the health facilities in the state by NPA

Current Value: **(Sep 2012)** - Funding constraints required further prioritization of planned activities, hence field-based activities were curtailed. This affected the roll out of PMIS tools and supervisory visits meant for on-job training and providing hands-on support for improvement in storage and dispensing practices.

Deliverables: Sub-Objective 4.1

Current Value: **(Sep 2012)** - Minimum list of essential medicines and medical supplies vital for primary health care Minutes of meetings with MOH & donors on the minimum list of essential medicines & medical supplies Quantified list of the minimum list of pharmaceutical products and medical supplies agreed upon by MOH and the donors Draft DELIVER/CPIR forms for these procurements Reviewed QA SOP for the procurement to be done by DELIVER PROJECT with SIAPS comments MOH technical specifications shared with USAID, DELIVER & FHI Distribution option analysis for Central Medical Stores for allocation of MDTF kits in stock Roles and responsibilities matrix for of partners involved in pharmaceutical management of misoprostol Flow chart illustrating the supply chain for misoprostol Supportive supervision trip reports to Mundri East & Mvolo to oversee re-packaging and labeling misoprostol for dispensing by the HHPs Regular supportive supervisory visits reports in WES, CES & EES

Quarterly progress toward sub-objective 4.2

Current Value: **(Sep 2012)** - • In the area of quality assurance and pharmacovigilance, SIAPS: - Met with RSS MOH quality assurance and control team to discuss on Kaya minilab progress and CMS minilab technical and administrative issues - Continued to provide TA for the Minilab sites in Juba and Kaya. With SIAPS TA, the Kaya office detected illegal imports and/ or substandard medicines, which resulted in an official complaint being submitted by MOH to the Uganda National Drug Authority (NDA) - SIAPS also facilitated physical inspection of drug samples collected from private drug outlets at the Juba, CMS Minilab testing site. - Provided TA to MOH to review storage condition documents and stability studies data submitted to MOH QA department by Missionpharma to support claim for suitability for use of a consignment of "keep cool" products that had broken cold chain in transit. The supplier was compelled to provide additional data to facilitate verification of extent of the damage and also make a written undertaking for any liability for product defect. • SIAPS initiated work on draft guidelines and tools for Adverse Drug Reaction (ADR) monitoring and reporting

Deliverables: Sub-Objective 4.2

Current Value: **(Sep 2012)** - Minilab sites Juba and Kaya technical report Communication with Uganda National Drug Authority (NDA) on illegal exports and/ or substandard medicines caught at Kaya Draft guidelines for monitoring Adverse Drug Reaction (ADR) Draft tools for reporting ADR

Quarterly progress toward sub-objective 5.1

Current Value: **(Sep 2012)** - SIAPS worked with MOH, NMCP and partners to draft the Integrated Community Case Management (ICCM) proposal for submission to AMREF and UNICEF. The proposal is still being reviewed. SIAPS assisted NMCP in elaborating the management and coordination, the approach, and gap analysis sections of the proposal. Participated in MOH face to face interviews for selection of a vector control specialist– Dr Emmanuel Chanda was selected as the best candidate. Supported NMCP to plan for a national vector control conference, including drafting a concept paper and setting

objectives for the conference Actively participated in the mission by a WHO hired consultant to kick start the desk thematic review phase of the Malaria Program Review.

SIAPS is working with NMCP and partners to draft several malaria thematic areas Assisted the South Sudanese Military Corps with the necessary documents and information for doing a gap analysis for the army, in preparation for a gap analysis meeting Prepared a budget (in collaboration with NMCP Staff) for the proposed malaria quantification meeting Participated in NMCP weekly meetings and assisted the program in planning for the GFATM supported activities Participated in CCM meeting and contributed to discussions on implementation of GFATM malaria grants. The need to independently verify reports by the PR was emphasized. SIAPS represented the NMCP Manager and articulated key concerns including the need for improved technical and financial accountability by the PR.

Attended an NMCP Meeting with PSI to discuss NMCP activities and budgets, including pending documents which need to be provided to the GF to facilitate release of funds (e.g. MOU, document to validate use of First Response RDTs in South Sudan, updated population figure) Attended a two-day Sub-Recipient (SR) meeting organized by PSI. SIAPS made a presentation on behalf of the NMCP program manager highlighting the roles and responsibilities of the MOH and partner NGOs, and what is expected from partners. Participated in an MOH and PSI meeting to discuss and harmonize pharmaceutical management aspects under the GFATM malaria grant. It was noted that the collaboration should start early with the procurement of the antimalarial commodities. It was agreed that once renovation of the Riverside medical store is complete and certified by the LFA, antimalarial commodities procured under GFATM will be managed through the national supply system. Attended a program meeting whereby NMCP GF budgets were reviewed, including activity timelines.

Activities for remaining quarter of the year were highlighted. Attended the Directorate of Preventive Medicine and Non-communicable Diseases meeting to discuss progress on activities by the different departments/ units as well as address issues/bottlenecks hindering implementation. SIAPS also participated in Directorate meetings that discussed reporting requirements and staff appraisal plans Drafted a concept paper (malaria control-a focus on prevention) that contains basic information regarding Malaria transmission, the basis for setting up the malaria control strategies. This was requested by the MOH Health Education Program for designing BCC messages. The document was shared with the NMCP and Health Education staff for inputs and comments.

#### Challenges in progress toward sub-objective 5.1

Current Value: (**Sep 2012**) - Continued delays in disbursement of funds for malaria activities from the consolidated GFATM malaria grant negatively affected FY11 work plan implementation. This is more critical especially given that some SIAPS activities e.g. trainings, M&E, etc. were to leverage resources from the GFATM grant and hence could not be initiated. Related to delayed disbursement, activities co-funded with Global Fund and other partners could not be completed; for example, WHO provided initial funding for antimalarial efficacy studies, SIAPS worked with NMCP and WHO to train health workers from the sentinel sites, but enrollment of study subjects could not be initiated because of delayed release of Global Funds.

#### Deliverables: Sub-Objective 5.1

Current Value: (**Sep 2012**) - Draft Integrated Community Case Management (ICCM) proposal for

submission to AMREF and UNICEF Draft concept paper and objectives for the national vector control conference PowerPoint presentation at two-day Sub-Recipient (SR) meeting organized by PSI Training report, budget and timelines for the Wau training for sentinel site staff Terms of Reference (TOR) for the National Technical Advisory Group for South Sudan

Quarterly progress toward sub-objective 5.2

Current Value: **(Sep 2012)** - Supported NMCP to finalize preparations for the start-up of the Therapeutic Efficacy Testing (TET) sites. Timelines and budget were reviewed and a letter from MOH (signed by undersecretary to facilitate procurement) was sent to WHO. Terms of reference (TOR) for various stakeholders/ implementers; control sheets, screening forms and contracts for field staff were finalized. The start of study awaits delivery of study items to study sites. Reviewed budget and timelines for the Wau training for sentinel site staff, and facilitated the workshop when funds were released by WHO for the activity. In total 28 participants (4 females, 24 males) from three different states (Western Bahr el Ghazal, Northern Bahr el Ghazal and Warrap) were trained.

Challenges in progress toward sub-objective 5.2

Current Value: **(Sep 2012)** - Activities co-funded with Global Fund and other partners could not be completed e.g. WHO provided initial funding for antimalarial efficacy studies, SIAPS worked with NMCP and WHO to train health workers from the sentinel sites, but enrollment of study subjects could not be initiated because of delayed release of Global Funds.

Deliverables: Sub-Objective 5.2

Current Value: **(Sep 2012)** - Therapeutic Efficacy Testing (TET) timelines, budget and TOR

## **SOUTH SUDAN EPI**

Year 1 work plan for supporting routine immunization in Southern Sudan.

### **Goal: South Sudan EPI Year 1 Work Plan Goal**

Assure the availability of quality and effective vaccine products and their delivery services to achieve Vaccine Preventable Diseases Control in RSS.

### **Objective 1**

Vaccines and EPI services governance strengthened

#### **Sub-Objective 1.1**

EPI policies, guidelines and strategies updated and used

##### **Activity 1.1.1**

Annual EPI planning and review meeting

##### **Activity 1.1.2**

Development of an Integrated EPI work plan for South Sudan in line with cMYP

##### **Activity 1.1.3**

Support standardized national EPI reporting for international partnerships (JRF/GAPR)

##### **Activity 1.1.4**

Conduct 3 state-level EPI planning workshops

##### **Activity 1.1.5**

Support 6 of the 13 SHTP II counties in micro-planning for EPI delivery

##### **Activity 1.1.6**

Support EPI Technical coordination meetings (TWG and ICC meetings)

##### **Activity 1.1.7**

Production of the EPI Newsletter for Southern Sudan

##### **Activity 1.1.8**

Finance Implementation routine EPI sessions micro-plans in line with REC approach

### **Objective 2**

Capacity for vaccines and EPI services management enhanced

#### **Sub-Objective 1.2**

National comprehensive multi-year and annual plans of action are strategic and evidence-based

**Activity 2.1.1**

National Launching of the EPI Policy implementation guidelines

**Activity 2.1.2**

Dissemination of the EPI Policy to the 13 SHTP II Counties

**Activity 2.1.3**

Dissemination of the EPI Standards for immunization in Southern Sudan

**Activity 2.1.4**

Dissemination of the Immunization in Practice manual for Southern Sudan

**Objective 3**

Utilization of EPI M&E data for decision-making increased

**Sub-Objective 2.1**

Strengthen EPI Program management capacity of individuals, institutions, organizations, and networks

**Activity 3.1.1**

TOT on Immunization in Practice (at least 15 trainers)

**Activity 3.1.2**

Training of at least 10 tutors of pre-service training institutions in Southern Sudan

**Activity 3.1.3**

OPL training of health personnel

**Activity 3.1.4**

Support study documenting the risk of risk peri-natal transmission of Hepatitis B at JTH

**Objective 4**

Support EPI services delivery to achieve desired health outcomes

**Sub-Objective 2.2**

Innovative and proven approaches for human resource capacity building implemented.

**Activity 4.1.1**

Support supervision to 5 out of 10 states

**Activity 4.1.2**

Field testing of the adapted EPI reporting tools for county and state levels

**Activity 4.1.3**

Quarterly EPI coverage monitoring report/feedback to all the 10 states

**Activity 4.1.4**

EPI coverage Verification Survey in 1 state

**Activity 4.1.5**

Produce 500,000 child health cards

**Objective 5**

SIAPS/EPI project coordination and monitoring

**Sub-Objective 3.1**

EPI Program information systems supports both immunization outputs and vaccines utilization

**Activity 5.1.1**

Procurement of office supplies and stationary

**Activity 5.1.2**

Contribute to Internet connectivity and communications

**Activity 5.1.3**

Cost-sharing for office space

**Activity 5.1.4**

Recruitment of driver to support EPI program operations

**Sub-Objective 3.2**

Innovative and proven tools for EPI M&E broadly available and used

**Activity 5.2.1**

Draft SPS/EPI program support work plan and ensure timely reports

**Activity 5.2.2**

Support meetings and coordination of EPI implementation stakeholders

**Goal: Quarterly Report Fields**

These are the fields that will be used to collect information for quarterly reports.

#### Overall Quarter Progress

Current Value: **(Sep 2012)** - SIAPS worked with the EPI program to develop the first draft for the 2013 EPI business and operations plan for immunization services delivery in South Sudan. The program was also supported to update and cost the comprehensive multi-year plan (cMYP) for immunization systems development. The program was also supported to upload the cMYP, costing tool, coverage verification survey and the EVM improvement plan to the GAVI/Vaccine Fund application portal for new vaccines. SIAPS continued to receive and collate comments on the plan for introduction of new vaccines into South Sudan program for immunization. This was finalized and used to complete the web-based application for new and underused vaccines to the GAVI/Vaccine fund.

SIAPS supported the EPI program to forecast, cost and plan for Hepatitis B monovalent vaccine procurement for health worker protection services. SIAPS also worked with the EPI program to provide technical support to the several state EPI managers on measles outbreak investigation and response planning, and how to defining monitoring and supervision needs. EPI operations micro-plans for all 80 counties of South Sudan was costed with SIAPS TA and presented to the Ministry of Health and WHO for funding using the GAVI/ISS and USAID funding grants for routine immunization.

SIAPS provided a technical analysis of the EPI performance for the reporting period January to June 2012 and used it to advocate for financial support to 16 priority counties selected on the basis of the highest number of missed DTP-3 immunizations. The EPI program was also capacitated to provide monthly EPI performance feedback bulletin to all states. SIAPS also provided technical support to coverage survey estimates for South Sudan and used the new estimates to compile and re-submit the revised WHO/UNICEF official estimates to be updated in June 2013. In addition, SIAPS collated comments on the draft National Immunization Coverage survey estimates for South Sudan, and reviewed the concept note for dissemination of the National Immunization Coverage verification survey report. The project also guided decision-making on the timing for the November/December rounds of NIDs and provided TA for development of a media advisory and briefing memo on wild polio outbreak status for South Sudan.

#### Key challenges faced during the quarter

Current Value: **(Sep 2012)** - Understaffing of the EPI program at the national level remains a key constraint. Only 3 of the 12 approved positions are filled. With no people to mentor and transfer skills to, the technical capacities of the programs remain limited.

#### Key activities planned for next quarter

Current Value: **(Sep 2012)** - SIAPS will not be receiving additional funding for EPI support following successful development and dissemination of the critical policies & guidelines for the EPI program.

#### Technical Activity Coordination

Current Value: **(Sep 2012)** - The SIAPS EPI support came to an end during the quarter.

#### Office management

Current Value: **(Sep 2012)** - SIAPS continued to meet program operations, including contributing to cost-sharing arrangements with SHTP II - office utilities (internet, stationery) and other overheads.

**Quarterly Report Fields (Objective)**

Objective-level fields for collecting information for quarterly reports.

Quarterly Progress for Objective 1

Current Value: **(Sep 2012)** - SIAPS supported the EPI program to set up the National Technical Advisory Group for South Sudan as well as coordinate ICC meetings and functions. The EPI program now has the 2013 EPI business and operations plan for immunization services delivery in South Sudan, a comprehensive multi-year comprehensive plan and the country also poised to introduce new vaccines.

Quarterly Progress for Objective 2

Current Value: **(Sep 2012)** - SIAPS supported the EPI program to provide for health worker protection by providing TA for procurement of Hepatitis B monovalent vaccine. Capacity of EPI program staff was built through training and focused technical support at state level and to partners.

Quarterly Progress for Objective 3

Current Value: **(Sep 2012)** - SIAPS made progress towards this objective through participation in regular coordination meetings, instituting monthly EPI performance feedback bulletin to all states, providing technical analysis of the EPI performance and using this to advocate for financial support to 16 priority counties. SIAPS also provided technical support to coverage survey.

Quarterly Progress for Objective 4

Current Value: **(Sep 2012)** - SIAPS supported planning and preparations for the November/December rounds of NIDs, now confirmed for 6th - 9th November and 4th - 7th December 2012. SIAPS also costed the EPI operations micro-plans for all 80 counties of South Sudan.

**Quarterly Report Fields (Sub-Objective)**

Fields for reporting quarterly progress at the sub-objective level.

Quarterly progress toward sub-objective 2.1

Current Value: **(Sep 2012)** - SIAPS supported the EPI program to adapt Terms of Reference (TOR) for the National Technical Advisory Group for South Sudan SIAPS worked with the EPI program to develop the first draft for the 2013 EPI business and operations plan for immunization services delivery in South Sudan. The program was also supported to update and cost the comprehensive multi-year plan (cMYP) for immunization systems development. The program was also supported to upload the cMYP, costing tool, coverage verification survey and the EVM improvement plan to the GAVI/Vaccine Fund application portal for new vaccines Functioning as the secretariat, SIAPS assisted in coordinating preparations and documentation of the proceedings of the 14th ICC meeting held on August 2nd, 2012. SIAPS also presented to the meeting MOH's plan for

introduction of new and underused vaccines. Another presentation was made on the costing and financial sustainability of the comprehensive multi-year plan (cMYP) for immunization systems development Subsequent to the ICC meeting; SIAPS drafted a Briefing Memo from the Ministry of Health to the Ministry of Finance on the New Vaccines Introduction co-financing obligations and commitments for South Sudan. SIAPS continued to receive and collate comments on the plan for introduction of new vaccines into South Sudan program for immunization. This was finalized and used to complete the web-based application for new and underused vaccines to the GAVI/Vaccine fund

Quarterly progress toward sub-objective 3.1

Current Value: **(Sep 2012)** - SIAPS supported the EPI program to forecast, cost and plan for Hepatitis B monovalent vaccine procurement for health worker protection services SIAPS worked with the EPI program to provide focused technical support to the state EPI manager for Northern Bahr El Ghazal in measles outbreak investigation and response planning SIAPS made a technical and briefing presentation to the 10 state health coordinators of South Sudan Red Cross Society at a training on epidemic preparedness and response SIAPS provided technical support to the planning of the first international cross-border meeting on Polio eradication between South Sudan and Ethiopia SIAPS supported the Central Equatoria State EPI team to define monitoring and supervision needs for the greater Yei County

Quarterly progress toward sub-objective 4.1

Current Value: **(Sep 2012)** - SIAPS: - Regularly attended the weekly Epidemic Preparedness and Response coordination meetings, and shared experiences from other countries during the Ebola outbreak control - Provided a technical analysis of the EPI performance for the reporting period January to June 2012 and used it to advocate for financial support to 16 priority counties selected on the basis of the highest number of missed DTP-3 immunizations - Provided monthly EPI performance feedback bulletin to all states - Provided focuses technical support to the Central Equatoria state EPI team to develop and disseminate a quarterly feedback bulletin to the counties and respective partners - Provided focused technical support to Jonglei state on the county performance of reported immunization rates for the period January to June 2012. Special focus is motivated by the high population estimates and second lowest DTP-3 coverage reported in the first half of the year. - Provided technical support to coverage survey estimates for South Sudan and used the new estimates to compile and re-submit the revised WHO/UNICEF official estimates to be updated in June 2013 - Collated comments on the draft National Immunization Coverage survey estimates for South Sudan, and reviewed the concept note for dissemination of the National Immunization Coverage verification survey report

## **SWAZILAND**

The goal of the SIAPS program in Swaziland is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes.

### **Quarterly Report Background**

The Kingdom of Swaziland has a predominantly rural population (77%) of just over 1 million people. Women of child-bearing age (15 – 49 years) make up 26.2% of the population while all females account for 53% of the population. According to the Demographic Health Survey (2007), about 60% of the population is aged below 30 years of which 39.6% are children under the age of 15 years. The largest share of the Swazi burden of disease remains communicable diseases, with HIV/AIDS and TB rates the highest in the world. HIV has a high impact on the health of the population with 26% prevalence among the adult population (15-49 years), with higher prevalence rates among females (31%) compared to males (20%). (Demographic Health Survey, 2007).

As of June 2011, 86,356 clients had enrolled (at one time) for ART, while 67,871 were on treatment (6,448 children) a total coverage of 76.6%. It is estimated that 88,620 people are in need of ART treatment in Swaziland (National ART assessment report, 2010). There are 75 ART initiation sites and 35 combined (refill and initiation) sites. For TB, the case notification rate is at 847 cases/100,000 population. The case detection rate (78%) and the treatment success rate (68%, 2009) are both below the WHO targets, but are gradually approaching the targets set.

Medicine stock-outs are a common occurrence, in part due to the current national fiscal climate. The country relies on foreign suppliers for its essential medicines and laboratory products. The Central Medical Stores is the main point of receipt for all essential medicines to be used in the public sector. The country was maintaining a minimum national stock of 6 months for all priority health products but in the past year, this was reduced to 4 months due to financial constraints.

The health sector is faced with a severe shortage of human resources across all cadres at all levels of the health system. In terms of human capacity development for health, there are 3 local training institutions for health professionals, mainly nurses and nursing assistants. There are no training facilities for pharmacists or pharmacy technicians (National Health Sector Strategic Plan, 2008 – 2013).

It was from this background that SPS and now SIAPS technical assistance to the government of Swaziland was established. SIAPS will build on the success of its predecessor programs such as the Strengthening Pharmaceutical Systems (SPS, since 2007) and Rational Pharmaceutical Management Plus (RPM-Plus, since 2006). The mandate of the SIAPS program in Swaziland is to promote and utilize a system strengthening approach consistent with GHI principles that will result in improved and sustainable health impact. In the previous year, MSH support was mainly on improving program implementation for the scale-up of treatment and care services. The SIAPS program will ensure the health system strengthening approach is implemented to support program implementation. Under this program, country ownership, capacity building and evidence based interventions will be central in all the intervention. The SIAPS program will work through the main building blocks: service delivery, health workforce, information, health products, and governance.

With FY11 funding, SIAPS will work to support the implementation of the five year goal for care and treatment of the PEPFAR/Government of the Kingdom of Swaziland Partnership Framework: decentralize and improve the quality of HIV care and treatment services to increase access and improve outcomes for PLWHA. SIAPS will also support the following technical areas of the Swaziland Country Operational Plan: ARV Drugs, Adult Care & Support, Pediatric Care & Support, Adult Treatment, Pediatric Treatment, Laboratory Infrastructure, TB/HIV, Strategic Information and Human and Institutional Capacity Development.

**Goal: Swaziland Year 1 Work Plan Goal**

The goal of the SIAPS program in Swaziland is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes.

**Objective 1**

STRENGTHEN GOVERNANCE IN THE PHARMACEUTICAL SECTOR

**Sub Objective 1.1**

Improve medicines policies, legislation

**Activity 1.1.1**

Support the launch, implementation and training of health care workers on the STG/EML

**Activity 1.1.2**

Provide technical assistance in the review of the Pharmacy Bill and Medicines and Related Substances Control Bill, and the establishment of the MRA

**Sub-Objective 1.2**

Support the development of a strategic and evidence

**Activity 1.2.1**

Provide technical assistance in the development of a pharmaceutical strategic plan & the implementation of the National Pharmacy Policy.

**Sub-Objective 1.3**

Improve coordination of stakeholders in pharmaceutical systems

**Activity 1.3.1**

Support national coordination meetings for pharmaceutical systems strengthening

**Sub-Objective 1.4**

Support the health commodity procurement system (Pharmaceuticals, supplies and laboratory commodities) within the MOH Procurement Unit

**Activity 1.4.1**

Promote an effective procurement practice through providing technical assistance to the Procurement Unit

**Objective 2**

INCREASE CAPACITY FOR PHARMACEUTICAL SUPPLY MANAGEMENT AND SERVICES

**Sub-Objective 2.1**

Increased pharmaceutical management capacity for individuals, institutions and organizations

**Activity 2.1.1**

Provide technical assistance in reviewing the organizational structure of pharmaceutical services including the CMS

**Activity 2.1.2**

Support the training and mentorship of health workers on pharmaceutical management of HIV&AIDS, TB, and supply chain management of health commodities

**Activity 2.1.3**

Support the establishment of a pharmacy training program

**Objective 3**

Address information for decision making challenges in the pharmaceutical sector

**Sub-Objective 3.1**

Support pharmaceutical management information systems for both products and patients

**Activity 3.1.1**

Support the development of a comprehensive Pharmaceutical Management Information System

**Sub-Objective 3.2**

Support proven, innovative tools for the pharmaceutical management information system

**Activity 3.2.1**

Support the implementation of information system tools (RxPMIS, RxSolution, Quantimed, PipeLine, eTB Manager, Commodity Tracking Tool)

**Objective 4**

IMPROVE PHARMACEUTICAL SERVICES TO ACHIEVE DESIRED HEALTH OUTCOMES

**Sub-Objective 4.1**

Improved availability of pharmaceuticals

**Activity 4.1.1**

Strengthen the supply chain management including Warehousing and distribution of health products for HIV/TB, OI (medicines and laboratory)

**Sub-Objective 4.2**

Assure Patient safety and therapy effectiveness

### Activity 4.2.1

Support quality assurance of medicines, adherence and ADR monitoring at NARTIS sites

### Sub-Objective 4.3

Provide technical assistance in the decentralization of HIV, TB services to improve access to quality pharmaceutical services

### Activity 4.3.1

Support integration of TB/HIV, HIV/FP and OI management at facilities

### Goal: Quarterly Report Fields

These are the fields that will be used to collect information for quarterly reports.

#### Overall Quarter Progress

Current Value: (**Sep 2012**) - SIAPS continues to work closely with the Ministry of health in Swaziland to ensure availability and rational use of medicines for priority health programs (HIV, TB, Malaria). In this quarter, the focus has been to distribute the Essential Medicines List / Standard treatment guidelines (STG/EML) that were developed in the previous quarters. The availability of this document at all facilities will ensure the standardization of treatment protocols and also provision of quality health care to clients at the primary health care levels. The pre-implementation assessment which was conducted in quarter 3 formed the basis and a strong case for having STG/EML in the country's health sector. The launch of the STG/EML was attended by over 300 local stakeholders with official remarks from the Honorable Minister of Health. The document was well received by stakeholders and the Ministry encouraged all to use this document.

SIAPS understands that building capacity in supply chain management is not only complete without having an adequately skilled workforce. It is from this background that SIAPS worked with the Southern Africa Nazarene University (SANU) to establish the very first Pharmacy certificate program in Swaziland. A group of 19 learners have been registered for this 2 year program. The next step is to finalize the Diploma in Pharmacy program also to be offered by the same university.

The legislative environment for the pharmaceutical sector is continuing to be improved and in this quarter, the Medicines and Related Substances control bill and the Pharmacy Bill (repealing Pharmacy Act of 1929) were published in the government gazette of the Kingdom of Swaziland. This is the first step towards getting the country's legislators (parliament & Senate) to debate the bills towards enactment.

The work on supply chain management is at the core of all these activities mentioned above. The Central Medical Stores as the national warehouse for all health products is continuously being supported towards operational efficiency. This support seeks to ensure that the best practices gained in the supply management of ARVs are replicated in the essential medicines supply. The

support of procurement, quantification and forecasting ensures that the limited government resources for health products are used efficiently, availability is assured and also value for money is achieved. The Pipeline tool is used for forecasting of ARVs and medicines for opportunistic infections.

#### Key challenges faced during the quarter

Current Value: **(30 Sep 2012)** - The shortage of pharmacy trained personnel poses a challenge in various interventions aimed at ensuring availability of medicines and rational use thereof. In the past the MOH had employed 4 regional pharmacists with the responsibility to oversee the pharmacy services at each of the four regions. Since their salaries were paid through Global Fund, the MOH was meant to absorb them at the end of June 2012 - which didn't happen. This now means all the gains of the past year and a half are at risk of being reversed. Logistics information data is another challenge. Most facilities have the electronic inventory management software but they do not utilize it efficiently. Furthermore, they do not even use the manual logistics management information system tool that is meant to serve as a report & requisitioning form for all facilities. This affects the quality of the data used in forecasting and quantification. Currently there is no reliable Logistics information for TB, Malaria and Reproductive health.

#### Key activities planned for next quarter

Current Value: **(30 Sep 2012)** - Design a regional pharmacy support and mentoring system to continue on the work of regional pharmacists in supporting pharmaceutical services in the four regions - Strengthen the use of information tools (electronic and manual) for logistics information -

#### Technical Activity Coordination

Current Value: **(30 Sep 2012)** - SIAPS worked on both the Quarter 3 report to be submitted to USAID/W. The process of developing the Strategic Plan 2012 - 2016 continued with the draft plan ready and currently being reviewed. The Workplan Year 2 was developed and finalized for submission to USAID/W.

#### Office management

Current Value: **(30 Sep 2012)** - During this quarter, the office completed the internal audit with the report of the audit findings submitted to MSH audit committee and later published on the MSH intranet. Activities to address gaps from the audit finding began and the MSH Senior Officer for Project Management visited Swaziland to assist in this exercise.

### Quarterly Report Fields (Objective)

Objective-level fields for collecting information for quarterly reports.

#### Quarterly Progress for Objective 1

Current Value: **(Sep 2012)** - The Pharmacy Bill no. 7 of 2012 and the Medicines and Related Substances Control Bill no. 8 of 2012 were gazetted in preparation for tabling before both Houses of Parliament. The Certificate in Pharmacy

training program commenced at the Southern African Nazarene University (SANU) and the curriculum received Senate approval at the University of Swaziland (UNISWA).

#### Quarterly Progress for Objective 2

Current Value: (**Sep 2012**) - Coordination of technical assistance in supply chain strengthening continued this quarter with one technical working group meeting held. The task force made recommendations to support the supply chain system for health products and also to meet the conditions on PSM from the Global Fund. The Pharmacy certificate curriculum was approved by the Senate of the University of Swaziland (UNISWA) and Southern Africa Nazarene University (SANU). The first cohort of students was registered at the SANU for the 2-year certificate program.

#### Quarterly Progress for Objective 3

Current Value: (**Sep 2012**) - a total of 80, 280 patients on ARVs were registered on the electronic database (APMR / RxPMIS) at the end of June according to the national Quarterly Service Coverage Report (QSCR, June 2012). 32 ART facilities are utilizing the RxPMIS / APMR software for electronic patient medical record. The commodity tracking (lmis.org.sz) has been finalized and work is underway to capture data on ARV and Laboratory logistics information. The software will be live in the next quarter.

#### Quarterly Progress for Objective 4

Current Value: (**Sep 2012**) - during this quarter, no facility reported stock out of ARVs. The country maintained the minimum of 4 months stock for all the first line antiretrovirals. Facilities were advised on the shortage of the zidovudine + lamivudine + efavirenz co-pack which was substituted with the zidovudine + lamivudine dual pack and efavirenz single pack. Continuous support is being provided to facilities on improving the reporting on ADRs amongst patients on ARVs and TB medicines. The reporting rate is still very low with only 6 of 32 facilities submitting reports at the end of the quarter. The Pharmacy and Therapeutics Committees at the 6 health facilities are still being supported to play a significant role in rational medicines use at facilities.

### **Quarterly Report Fields (Sub-Objective)**

Fields for reporting quarterly progress at the sub-objective level.

#### Quarterly progress toward sub-objective 1.1

Current Value: (**30 Sep 2012**) - The Pharmacy Bill no. 7 of 2012 and the Medicines and Related Substances Control Bill no. 8 of 2012 were gazetted in preparation for tabling before both Houses of Parliament. The Certificate in Pharmacy training program commenced at the Southern African Nazarene University (SANU) and the curriculum received Senate approval at the University of Swaziland (UNISWA).

#### Challenges in progress toward sub-objective 1.1

Current Value: (**30 Sep 2012**) - Because the Ministry of Health launched STG/EML much

later than originally planned, trainings have been planned during the next FY.

Deliverables: Sub-Objective 1.1

Current Value: **(30 Sep 2012)** - •STG/EML pre-implementation assessment report •STG/EML dissemination report •Swaziland Government Gazette vol. XLX, no. 94 Part A; Pharmacy Bill no 7 of 2012. •Swaziland Government Gazette vol. XLX, no. 95 Part B; Medicines and Related Substances Control Bill no. 8 of 2012.

Quarterly progress toward sub-objective 1.2

Current Value: **(30 Sep 2012)** - Commenced the SPSP costing exercise and collected costing data for all SPSP activities as outlined in the 2-year action plan. A draft SPSP costing report is available. SIAPS assisted in conducting the pharmaceutical services baseline survey data collection, in support of the monitoring and evaluation of the SPSP implementation. The baseline survey has since been completed and the report is available.

Challenges in progress toward sub-objective 1.2

Current Value: **(30 Sep 2012)** - having started with the costing of the Strategic Plan, we have been having challenges in getting the list of funding sources outside government to fill the funding gap

Deliverables: Sub-Objective 1.2

Current Value: **(30 Sep 2012)** - •Pharmaceutical services baseline survey draft report. •SPSP costing report draft.

Quarterly progress toward sub-objective 1.3

Current Value: **(30 Sep 2012)** - A supply chain technical working group meeting was held in August 2012. It was in this meeting that the team resolved to develop a plan to strengthen supply management of health products in the country's health facilities. This was necessitated by the withdrawal of the regional pharmacists due to funding constraints in the ministry. SIAPS also supported the MOH to recruit a Chief Executive Officer for the Central Medical Stores. SIAPS facilitate interviews for the CEO candidates and prepared a selection report which was submitted to the MOH. This position is funded by Global Fund under the Round 10 TB grant.

Challenges in progress toward sub-objective 1.3

Current Value: **(30 Sep 2012)** - challenges with getting the full attendance in the Supply Chain TWG. The Director of Health Services (Chair of the TWG) has requested representatives from Ministry of Finance to attend and participate in this meeting.

Deliverables: Sub-Objective 1.3

Current Value: **(30 Sep 2012)** - Minutes of the 5th Supply Chain TWG meeting

Quarterly progress toward sub-objective 1.4:

Current Value: **(30 Sep 2012)** - Draft SOP manual for MOH Procurement Unit have been prepared. The MOH Procurement unit staff members have been capacitated.

Challenges in progress toward sub-objective 1.4

Current Value: **(30 Sep 2012)** - Limited storage space remains a challenge at Lab Warehouse in the procurement of pharmaceuticals and laboratory commodities, warehouse

Deliverables: Sub-Objective 1.4

Current Value: **(30 Sep 2012)** - •Trip report on Procurement Technical Assistance •Procurement SOPs •Procurement Unit capacity building report

Quarterly progress toward sub-objective 2.1

Current Value: **(30 Sep 2012)** - SIAPS conducted training for laboratory professionals on Laboratory LMIS and inventory management. A refresher training on Rx-Solution was provided to health workers using Rx-Solution at facilities including CMS. SIAPS also facilitated the commencement of the Certificate in Pharmacy training program at SANU with 25 candidates registered for study. Mentorship is becoming a more effective and efficient strategy to assisting health workers and systems to improve service delivery, a total of 22 facilities were visited in the Hhohho region during quarter 4.

Challenges in progress toward sub-objective 2.1

Current Value: **(30 Sep 2012)** - Delays in recruiting the Course Coordinator (we didn't receive qualifying applicants) - Review of the organizational structure has been put on hold subject to the MOH completing the national staffing norms assessment - weak coordination of supportive supervision activities leading to duplication of efforts. This tends to be disruptive to the facilities as they need to attend to many partners that visit them at different times/days in a week.

Deliverables: Sub-Objective 2.1

Current Value: **(30 Sep 2012)** - Training Report

Quarterly progress toward sub-objective 3.1

Current Value: **(30 Sep 2012)** - SIAPS continues to support facilities with technical assistance on hardware issues and Rx-Solution use for store & dispensing. Other facilities were visited with the intention to expand the use of Rx-Solution to all other essential medicines and sutures. SIAPS continues to support MOH-SID on implementation of the RxPMIS tool used to manage ART clients.

Challenges in progress toward sub-objective 3.1

Current Value: **(30 Sep 2012)** - Lack of Local Area Network in some facilities to support Rx-Solution expansion

Deliverables: Sub-Objective 3.1

Current Value: **(30 Sep 2012)** - •Working Rx-Solution Barcode Scanner •Fully functional HMIS electronic tool •Rx-Solution expansion technical report

Quarterly progress toward sub-objective 3.2

Current Value: **(30 Sep 2012)** - Support is continuously provided to the CMS, Laboratory warehouse and Facilities to address some hardware problems which compromise the functionality of the RxSolution system. Stock status reports are generated monthly for laboratory, TB, HIV and tracer essential medicines list. This report is discussed with MOH and disseminated to all stakeholders through the office of the Senior Pharmacist/Chief Laboratory Technologist. In order to complete the redesign of the web-based APMR/RxPMIS, SIAPS has conducted the process of selecting a sub-contractor to work on this activity. The Commodity Tracking Tool has been finalized and data is currently being captured. A data clerk is assisting with capturing historical data from Jan 2012. The phase two of the commodity tracking will include Malaria, TB and Reproductive Health commodities.

Challenges in progress toward sub-objective 3.2

Current Value: **(30 Sep 2012)** - troubleshooting support not adequate hence the tools tend to be frequently down, which compromises of data quality.

Deliverables: Sub-Objective 3.2

Current Value: **(30 Sep 2012)** - Technical Report detailing processes of implementing RxSolution at facilities Selection report for the APMR/RxPMIS redesign system.

Quarterly progress toward sub-objective 4.1

Current Value: **(30 Sep 2012)** - SIAPS engaged LMI to conduct an initial analysis of supply chain systems in the country, mainly focusing on warehousing and distribution. This technical assistance seeks to ensure that products are stored and distributed to facilities in an efficient manner. Forecasting and Quantification workshops were held to plan for the 2013/2014 financial year tenders. The ARV and opportunistic infection medicines forecast was done using the Pipeline / Quantimed tool of SIAPS.

Challenges in progress toward sub-objective 4.1

Current Value: **(30 Sep 2012)** - Fiscal challenges in the country tend to compromise the continuous availability of life saving essential medicines. This tends to affect the work done by SIAPS as there are often not adequate medicines in public facilities and subsequently this impedes accessibility of health care commodities. SIAPS will continue advocating for more financial resources from the government for health products / commodities, by demonstrating cost savings, reduced wastage with an emphasis on value for money in commodity supply management.

Deliverables: Sub-Objective 4.1

Current Value: **(30 Sep 2012)** - •Trip report on Supply Chain Option analysis assessment Supply Planning meeting report

Quarterly progress toward sub-objective 4.2

Current Value: **(30 Sep 2012)** - Advocacy to have PTCs functional in all hospitals is ongoing. The PTCs are also tasked with monitoring medicines safety and use at their respective facilities. Pharmacovigilance systems in the country are still at a formative stage and as part of establishing the system, SIAPS engaged a consultant to develop a detailed

protocol on HIV/TB active surveillance in the country. A number of consultative meetings have already taken place with SNAP, NTP, hospital administrators and MOH senior management. Several sites were visited to provide a thorough understanding for the scoping and mapping of services. SIAPS supported the development of a 3rd issue of the Swaziland Medicines Safety Watch newsletter and printed 500 copies for distribution to health practitioners in both the public and private sector.

Challenges in progress toward sub-objective 4.2

Current Value: **(30 Sep 2012)** - Low reporting rate for adverse drug reactions remains a challenge mainly because this is passive reporting. However an Active surveillance is being put in place which is aimed at improving the reporting rate.

Deliverables: Sub-Objective 4.2

Current Value: **(30 Sep 2012)** - Medicines Safety Watch newsletter.

Quarterly progress toward sub-objective 4.3

Current Value: **(30 Sep 2012)** - SIAPS continues to work closely with the National TB Program and AIDS Program in pharmaceutical management of TB and HIV. Through the routine and quarterly supportive supervisory visits facility health workers are mentored especially pharmacy staff among other things on good dispensing and stock management practice.

Challenges in progress toward sub-objective 4.3

Current Value: **(30 Sep 2012)** - Delays in finalizing the Family Planning - HIV standard operating procedure Vertical distribution system for TB medicines

Deliverables: Sub-Objective 4.3

Current Value: **(30 Sep 2012)** - Stock status report for TB medicines including Isoniazid, antiretrovirals and family planning commodities

## **VIETNAM**

Vietnam work plan details for Year 1 of the SIAPS Program

### **Quarterly Report Background**

In the recent changing environments for pharmacy practice, including the pharmaceutical management demands placed by a huge increases in the supply of essential medicines for priority public health programs such as HIV/AIDS, TB and malaria, pharmacy students are expected to acquire sound pharmaceuticals supply management (PSM) knowledge and skills by the time they graduate and join the workforce. But, more often than not, pre-service pharmacy curricula in many places do not provide adequate exposure to the theoretical and practical aspects of this important pharmacy-related task. In this context, the Hanoi University of Pharmacy (HUP) is reforming the curriculum to ensure appropriate coverage of PSM elements in their pharmacy training course. With USAID support, SIAPS is assisting HUP in this task. This curricular reform activity will help generate “local” human resources skilled in PSM, strengthen local training capacity, and support sustainability. A systematic and step-wise process will be adopted to ensure that the resulting curricula for both undergraduate and postgraduate levels are tailored to suit the specific needs of Vietnam.

SPS will work with HUP and other relevant stakeholders to:

- Map the existing gaps and the required competencies.
- Develop a draft of the curriculum, including the contents and instructional plans.
- Finalize the draft of the curriculum through a wide review and consultative process.

### **Goal: Vietnam Year 1 Work Plan Goal**

Bring positive patient and health outcomes through improved availability and use of pharmaceuticals

#### **Objective 1**

In-country human resource capacity for pharmaceutical services strengthened

#### **Sub-Objective 1.1**

Provide Technical Assistance to Hanoi University of Pharmacy to Develop Pre-Service Curriculum on Pharmaceutical Supply Management

#### **Activity 1.1a**

Map the existing gaps and the required competencies

#### **Activity 1.1b**

Develop a draft of the curriculum including the contents and instructional plans

#### **Activity 1.1c**

Finalize the draft of the curriculum through a wide review and consultative process

### **Goal: Quarterly Report Fields**

These are the fields that will be used to collect information for quarterly reports.

Overall Quarter Progress

Current Value: **(Sep 2012)** - Progress continued during this quarter toward supporting the work plan objective [in-country human resource capacity for pharmaceutical services strengthened leading to improved patient outcomes (contributes to IR2.1 and 5.1)]. Based on the planned outline and time allocations, SIAPS and HUP's Department of Pharmaceutical Management and Economics collaborated to develop detailed curriculum drafts of the 8 modules for both post-graduate and under-graduate courses. Wider consultation and feedback was obtained via a workshop attended by stakeholders representing HUP, Government and non-government entities.

Key activities planned for next quarter

Current Value: **(Sep 2012)** - Finalize the curriculum by incorporating all the relevant suggestions and feedback obtained during the Curriculum Review Workshop from the 26th September, 2012. Additionally, support HUP by providing technical assistance to develop a detailed set of teaching slides for all the 8 modules of the PSM curriculum

Technical Activity Coordination

Current Value: **(Sep 2012)** - Administrative and coordination work to keep engaging the SIAPS senior consultant hired to 1. assist with revising and finalizing the curriculum and; 2. Support the HUP with technical assistance to develop teaching slides for the PSM curriculum.

Office management

Current Value: **(Sep 2012)** - Regular local and headquarters office management support including administrative support.

Technical Assistance

Current Value: **(Sep 2012)** - Mohan Joshi - Principal Technical Advisor/SIAPS. Andy Barraclough, Senior SIAPS Consultant • Technical report for Technical Assistance visit to Vietnam in September 2012 for conducting a full-day Curriculum Review Workshop. • Obtained more than 50 comments/suggestions/feedback from the majority of the stakeholders attending the workshop. Technical assistance during the next quarter for revision and finalization of the curriculum.

### **Quarterly Report Fields (Objective)**

Objective-level fields for collecting information for quarterly reports.

Quarterly Progress for Objective 1

Current Value: **(Sep 2012)** - Detailed curriculum drafts of all 9 modules for both Postgraduate and Undergraduate courses were drafted including: aim, learning objectives, topic area, pedagogical techniques and detailed content summaries.

### **Quarterly Report Fields (Sub-Objective)**

Fields for reporting quarterly progress at the sub-objective level.

Quarterly progress toward sub-objective 1.1

Current Value: **(Sep 2012)** - Curriculum drafted for HUP postgraduate and undergraduate courses.

Workshop facilitated to obtain comments for informing the final draft