SIAPS Performance Monitoring Report

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

Project Year 2 Quarter 1

October—December 2012

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About SIAPS

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

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ACRONYMS AND ABBREVIATIONS

AAR	after action review
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
API	application programming interface
AMRH	African Medicines Regulatory Harmonization
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
CPD	country program director (SIAPS)
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
IAPH	International Association of Public Health Logisticians
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
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
PIRS	performance indicator reference sheet
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 this reporting period, 29 technical assistance visits were conducted by members of the technical team in support to 13 portfolios.

In support to the effort to finalize the monitoring and evaluation plan, the team collaborated with the M&E Specialist for the development of a set of country level indicators to complement the core indicators finalized last quarter. The indicators have been reviewed and finalized.

In response to an invitation from Duke University, SIAPS delivered a presentation on "Accredited Drug Dispensing Outlet (ADDO): An Innovative Model for Access to Antimicrobials" at the University antimicrobial resistance (AMR) meeting held at the Duke University from 6 to 8 December 2012. The meeting focused on generating ideas for innovations in support to AMR containment. Amongst the many international donors and partners that attended the meeting were WHO, USAID, Duke University, and ReAct.

Representatives from the technical team participated in the Global Health Supply Chain Summit held in Kigali. The meeting is organized by the International Association of Public Health Logisticians (IAPH). The forum was a rich opportunity to exchange on innovations and on best practices in the area of supply chain. Also the technical team was represented at the African TB conference held in December in Zanzibar delivering presentations and facilitating work sessions on TB supply chain management improvement and on TB commodity quantification.

SIAPS published a new document on infection control—Infection Control (Self) Assessment Tool for Primary Health Care Facilities. This Infection Control Assessment Tool (ICAT) is based largely on the hospital ICAT. This PHC-oriented tool includes nine modules addressing key areas within a PHC setting. Each module allows a qualitative grading of infection control practices. The tool can be used as a whole or in a modular fashion, and is intended to be used as part of a continuous quality improvement process.

The proceedings from the Africa Pharmacovigilance meeting held in April 2012 in Nairobi were published in a report that was developed this quarter. As with other reports, the proceedings are available on the SIAPS website. On the other hand, SIAPS developed a flyer that summarizes the preliminary findings of the ongoing Asia Pharmacovigilance Systems assessment study. The flyer is intended for the orientation of USAID/RDMA mission.

During the quarter, SIAPS was also invited to participate on one of the subgroups of the African Medicines Regulatory Harmonization (AMRH) Technical Working Group (TWG). The subgroup addresses regulatory capacity development. SIAPS will support the mapping of regulatory training programs and institutions that can feed to the capacity building efforts. On the other hand, SIAPS was also invited to participate on the Ad Hoc Workgroup on Developing a Global Regulatory Curriculum initiated by the USFDA Office of Strategy, Partnerships and Analytics. The first meeting of the workgroup was held in November 2012. Members of the Workgroup include representatives from the FDA, Institute of Medicine (IOM), Office of Global Affairs of the Health and Human Services (HHS), World Health Organization (WHO), Drug Information Association (DIA), International Food Protection Training Institute (IFPTI), USAID, Bill and Melinda Gates Foundation (BMGF), Regulatory Affairs Professional Society

(RAPS), and SIAPS.

Two new Technical Associate staff joined the technical assistance team in support to the Pharmaceutical Services and the Supply Chain Clusters.

Following the discussions last quarter to the need for a resource allocation tool, SIAPS selected and procured the SAVIOM database tool that will enable the team to track members' availability and commitments. As a next step, the tool will be populated with staff profiles; also standard operating procedures will be developed to guide use of the tool in preparation for its roll-out.

Country program/portfolio quarterly progress

During this quarter, the Portfolio management team worked with Country and Core Portfolios to finalize and submit all work plans to SIAPS Agreement Officer Representative (AOR), Missions and relevant USAID Donor Representatives. We also followed up with applicable revisions to submitted work plans, upon USAID/Mission feedback. By the end of the quarter, we had received mission approvals for Seven (7) Country work plans including Bangladesh, Burundi, Dominican Republic, Ethiopia, LAC AMI, Lesotho, Mali and Philippines. We will continue follow up to ensure approval of all work plans by AOR and missions by the end of January 2013.

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 Ethiopia, Bangladesh and Kenya.

The team conducted a comprehensive on-boarding training for new Country Project Directors (CPDs) during December to strengthen their 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 program covered all aspects of program leadership and management, SIAPS frameworks and tools as well as finance and operations. CPD feedback to the program was very positive. In the next quarter, we will work on developing an online self-directed program to provide on-going refresher for these and other established CPDs.

SIAPS changed its reporting software to Newdea during the last quarter. In preparation for this, the team collaborated with the Monitoring and Evaluation team to develop the Newdea site in preparation for the data import and subsequent user trainings that took place during November 2012. We also conducted a total of 7 trainings to enable participation of all SIAPS country and Arlington based staff. The training oriented users to the site as well as provided a refresher on Quarterly Report content. The migration to Newdea reporting was successfully conducted, with on-time submission of the Quarter 4 SIAPS report by the Portfolio Management team.

A new Portfolio Manager joined the team in November and was appropriately oriented and on-boarded to perform the role effectively.

M&E and reporting activities during the quarter

During the first quarter of FY13, M&E LOE focused on implementation of Newdea, a new monitoring, evaluation, and reporting software for the SIAPS program and continued refinement and finalization of the SIAPS program indicators. Work in the previous quarter focused on developing the Newdea site in preparation for the data import and subsequent user trainings that took place during November 2012. Trainings were arranged to accommodate staff in Arlington, as well as in our offices in the field and focused on a general introduction to the software, and entering and writing quarterly progress reports for SIAPS. By the end of November, a total of 7 trainings were held. In addition, a temporary assistant was hired to assist staff with the data import, including entry of all SIAPS Year 1 and Year 2 work plans and all previous quarterly reports.

Efforts of the M&E team also focused on finalization of the SIAPS indicators, including indicators at the country-level and at the program-level. The final SIAPS Monitoring and Evaluation plan was submitted to USAID/Washington and we are waiting for feedback. In the next quarter, performance indicators reference sheets (PIRS) for each indicator will be completed and the indicators will be distributed and adopted by each portfolio. It is expected that technical assistance in the second quarter will focus on working with countries to adopt and adapt the indicators and begin with baseline collection.

Capacity building and performance improvements

The Capacity Building and Performance Improvement unit has organized and carried out a number of initiatives to strengthen the capacities of both HQ and field staff. The unit recently organized and implemented a two week on-boarding/training program for six new Country Project Directors (CPDs) and Deputy Country Project Directors took part (from November 26-December 7) at MSH's Arlington office. This is phase I of a three-part strategy, developed during the previous quarter, to strengthen the capacity of CPDs and their deputies to develop, implement, monitor, and report on SIAPS technical activities. It was the first time ever that SIAPS has organized an on-boarding in this manner and has put an emphasis on a competency based capacity building training. Instead of the traditional approach to orientation, activities were designed and implemented based on a participatory approach. The unit used a variety of methods (group discussion, simulation, lecture, role play, and demonstration, case studies) to reinforce the acquisition of knowledge, skills and attitudes required for CPDs and DCPDs to be successful in their jobs.

The unit has also been closely involved in the planning and design of the upcoming SIAPS Global Meeting. This Global Meeting corresponds to phase II of the SIAPS staff capacity building and training continuum proposed by the unit in October 2012. Further work has been done on phase III as well. The unit revised the leadership platform strategy and designed the online prototype to be presented to leadership for approval. The purpose of this online distance learning and collaboration tool is to answer the need for continuous engagement of Country Project Directors in a cost-effective manner, and to reinforce the competencies acquired in Phases I and II.

The CB&PI unit, in conjunction with the Knowledge Management unit, organized and conducted After Action Reviews (AAR) to assess two major capacity building activities: the Uganda SURE quantification training and the Country Project Director on-boarding and

capacity building training. Recommendations are being developed based on data collected from these AARs, and will feed into the design of future similar trainings.

The unit has participated in the SIAPS Technical Working group and provided input on ways to provide additional support to country portfolios on pharmaceutical, health elements and management resources issues. The unit also has actively participated in the SIAPS work plan implementation discussion meetings to provide additional targeted support to projects and portfolios in capacity building and training. As a result of these meetings, the unit has made initial contacts with a number of countries to further assess their respective needs and to propose comprehensive intervention strategies. For example, the unit has developed and presented a capacity building strategy to strengthen the capacity of the Afghanistan program and staff. As part of this strategy, the unit has developed a needs assessment tools to be implemented soon.

The unit has planned internal capacity building activities to capacitate SIAPS HQ staff. This is in response to needs expressed by staff in soft skills. The unit has developed a strategy to conduct a series of mini Training of Trainers (ToTs) to strengthen staff's knowledge and skills in adult training design and delivery. As part of this intervention, the unit has developed a needs assessment to disseminate to staff to collect additional information on topics to cover.

Further work on the SIAPS Global TB Core Online Platform progressed with further refinement of the first module's content and design of the e-learning module. The Unit has also been working on the MSH-wide e-Learning strategy. The Unit has also managed the SIAPS Technical Discussion Series, a monthly program that allows staff to showcase their technical work and engage one another on key technical topics.

Knowledge management and communication

The SIAPS knowledge management efforts continued this quarter with no significant challenges. As we move into year two of implementation we will be formalizing the communications and knowledge exchange processes now that the team has had time to learn from the overall start-up efforts and the program's flagship web site is online.

This past quarter SIAPS launched the program's web site - using a flexible, cost effective open source platform and building from the program's governance structure to manage the flow of information. The site is live and continues to be updated regularly at siapsprogram.org.

This quarter the team also completed the management and internal vetting of the Rwanda retrospective study to capture lessons learned to support that country's increased ownership of the support for the pharmaceutical sector. The final submission is expected early in the following quarter pending review and formatting.

The team also completed the following range of ongoing activities and standard services to increase visibility for the project and share information.

The Africa TB Meeting site was updated during the November meeting with daily blog posts and then uploaded all presentations when they became available. Social media platforms Facebook and Twitter were also used to engage stakeholders and broadcast updates on the meeting

Stories for the SIAPS website completed and posted include: S. Sudan MCH, PV meeting in Ukraine, SIAPS presenting at AMR meeting, US Deputy Chief of Mission discussing SIAPS work in Cameroon, Improving access to maternal health commodities, Challenges & Opportunities of NTD medicines management, Guidelines for conducting drug resistant TB DUR, Management of medicines for emergency obstetric conditions in Rwanda.

To help plan engagement and outreach, a list of events/conferences for SIAPS was compiled to aid in setting priorities.
Ongoing support for social media through Facebook and Twitter

Information Services for SIAPS includes:

- 16 Reports submitted to USAID's Development Experience Clearinghouse
- Purchased journal articles, books and subscriptions totaling $1,696 to support technical assistance in the field
- Fulfilled approximately 40 research and reference requests
- Provided orientation for 6 incoming Country Program Directors on information literacy and information services

Editorial Services provided to SIAPS for the quarter included:

- Completion if 10 Flyers, briefs, success stories (documents of just a few pages)
- Review and processing of a collection of selected reports (some printed) on CDs for Rwanda close-out
- Completion of 1 Journal article
- Completion of 15 Technical reports
- Completion of 2 Newsletters
- Completion of 1 Abstract
- Completion of 2 PowerPoints

The team edited and formatted 5 technical Manuals:

- Malaria quantification manual in French & English
- Adapted ICAT
- RMU pre-service curriculum
- e-TB Manager

The team developed and distributed conference materials for:
Africa TB—Tanzania, December 2012
Ukraine stakeholders meeting—Ukraine, December 2012
Union TB—Malaysia, November 2012

The team reviewed and formatted 4 posters:
ASTMH, Atlanta, GA, November 2012
Union TB, Malaysia, November 2012
FIP Congress, The Netherlands, October 2012
Health Systems Research, China, November 2012

System analysis and software products

During this quarter, the team continued its active recruitment for Senior Technical Associate MIS, Java Developer, and Senior Java Developer specifically to support Pharmadex and e-TB

Manager. The process mapping re-design of Quantimed was completed. The team strengthened its management of core SIAPS software and provided enhancements to e-TB Manager for universal data exchange via API for optimal data exchange capabilities. We also initiated upgrade of Pharmadex registration module, expected to be completed in Year 2 Q2. We are currently developing an MIS intervention design and evaluations framework to refine options analysis for LMIS solutions for countries.

Common Agenda

Quarterly progress toward sub-objective 1.2: Capacity for pharmaceutical management and services increased and enhanced

The Accreditation Council for Pharmaceutical Education (ACPE) and SIAPS held a consultation to discuss the accreditation framework activity. A draft concept note was developed by ACPE which was internally reviewed. Based on this, a detailed revised concept note focusing on the priority in-service education has been drafted and will be further discussed with ACPE. This is expected to be finalized in the next quarter and will be the basis for issuing the Task Order enabling the start of drafting of the actual framework.

Based on the discussions held during last quarter, the sub-award to EPN was concluded and submitted to USAID. Also approval was obtained during the quarter. Accordingly, EPN will be conducting two key activities: a) conducting a ToT training in the area of antimicrobial resistance (for three member countries); and b) evaluating the outcomes resulting from the implementation of previous EPN interventions aimed at its constituency. Draft of the training materials for the first activity was developed and planning took place for the AMR ToT workshop to be held in January of 2013.

SIAPS is a member of People that Deliver (PtD) and participates in the three technical working groups of PtD namely, Advocacy and Knowledge management, Research Working Group, and the Technical Working Group. During this period, SIAPS participated in the scheduled as well as the 5th global health supply chain summit in Kigali Rwanda organized by the International Association of Public Health Logisticians (IAPH), Various Higher learning institutions lead by the University of South California, London School of Business, and People that Deliver (PtD) where SIAPS is a member – no presentations were made [November 2012]

As a member of EMTCT IATT, SIAPS participated in the development of the procurement and supply management tool kit concept paper

Quarterly progress toward sub-objective 1.3: Information for decision-making challenges addressed in the pharmaceutical sector

Develop a framework and metrics for describing and measuring the contributions of pharmaceutical systems strengthening interventions to overall health systems strengthening:

A literature review was initiated to identify initiatives that have attempted to define the systems strengthening approach. Results from the first round of such review indicated the need to conduct further targeted literature reviews followed by the synthesis of the identified information to define the boundaries of a pharmaceutical system for which the framework and the metrics are to be developed. SIAPS also reviewed the concept note developed last quarter and recommended refocus of some of the activities. A revised concept note is being developed.

Quarterly progress toward sub-objective 1.5: Quality of pharmaceutical products and services improved

The concept paper for Options Analysis was approved by the mission. The next steps of literature review and methodology definition for options analysis had been initiated.

SIAPS Manual— How to Investigate Antimicrobial Use in Hospitals: Selected Indicators— whose revision and translation into French and Spanish was completed in the last quarter, was published and disseminated during this

quarter. This document can help DTCs, physicians, pharmacists, managers, and researchers monitor and assess antimicrobial use in their facilities. It 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 included as annexes.

During this quarter, SIAPS also finalized and published a new document on infection control—Infection Control (Self) Assessment Tool for Primary Health Care Facilities. This Infection Control Assessment Tool (ICAT) for primary health care facilities is based largely on the hospital ICAT. This PHC-oriented tool includes the following modules: Health Facility Information, Employee Health, Cleaning the Health Facility, Hand Hygiene, Waste Management, Isolation and Standard Precautions, Labor and Delivery, Sterilization and Disinfection of Equipment, Preparation and Administration of Parenteral Medications. Each module has self-assessment questions and a numerical scoring system that allows a qualitative grading of the existing infection control practices. The document also includes several observation checklists and suggested indicators to monitor at PHC facilities. As for the hospital ICAT, the application of the ICAT–PHC either as a whole tool or extracted modules, is intended to be used as part of a continuous quality improvement process.

Quarterly progress toward sub-objective 1.6: Contribute to the generation of new knowledge and dissemination of evidenced-based approaches and best practices

For the WHO collaboration on the essential medicines portal under Common Agenda SIAPS is proceeding on two tracks – funding direct support to the WHO IT contractor and funding for WHO contributions. This approach allows important systems work to continue while the longer term agreement between SIAPS and WHO is put in place. In the past quarter the support through the IT contractor has progressed well under a sub-grant agreement with the following tasks accomplished:

Digital Library interface and structure

- Update the first filtering level by organization
- Add a second filtering level by "language" for all classifiers
- Make "All" the first item in the list on each level

Database re-engineering

- Updates to metadata structure and relationships
- Refinements to data entry screens for improved data quality Digital library install project
- Adapt the install project for the USB drive
- Ongoing systems support

Donor coordination and participation in conferences/seminars/networks –

In November 2012, SIAPS attended the 5th Global Health Supply Chain Summit (GHSCS) held in Kigali Rwanda – November 2012 - The Summit is organized collaboratively between the International Association of Public Health Logisticians (IAPHL), University of Southern California, and London School of Business. The main purpose of the conference was to foster interaction between implementers and academics to build knowledge and learning – bringing supply chain challenges forward from the field to the research agenda and by implementing efficient and effective solutions

Challenges in progress toward sub-objective 1.6

The sub-granting process between SIAPS and WHO has continued to be a challenge to finalize. During this quarter various options to provide funding have been explored including consultations with USAID GC to clarify requirements. A draft template and adjusted scope and budget were in development by the end of the quarter with the expectation the agreement would be in place early in the following quarter. This aspect of the work is most important to enable full participation in the World Health Alliance launch of the site planned for May 2013.

Malaria Core

Year 2 Work Plan

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. 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. Despite the increased flow of malaria commodities, many SIAPS/PMI supported countries are faced with challenges in ensuring uninterrupted supply of high quality medicines and commodities as well as their appropriate use. Some factors contributing to these challenges include poor planning and coordination among in country partners, lack of strategic information for decision making leading to frequent stock outs, weak human resource capacity to perform key pharmaceutical functions resulting into irrational medicine prescribing, dispensing and or use of medicines, and use of substandard or unsafe medicines. 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 redouble emphasis on GHI principles, especially in improving metrics, monitoring, and evaluation, capacitating local governments and organizations, and increasing country ownership. SIAPS will work closely with WHO, the Global Fund, the Center for Disease Control (CDC), the Roll Back Malaria, and other PMI implementing partners to support countries in scaling up the utilization of ACTs and also of new severe malaria medicines

Goal: Improve the supply, quality and use of malaria commodities and other key pharmaceutical products to reduce malaria burden

Overall Quarter Progress

During this quarter, PMI was able to make key procurement decisions based on stock status reports and supply plans for malaria commodities information provided by SIAPS. Additionally, the PMI team was able to plan for LMIS support based on the country profiles provided by SIAPS. At the global level, SIAPS continued to strengthen pharmaceutical sector governance through disseminating lessons learned.

Quarterly Progress for Objective 1: Strengthen pharmaceutical governance

SIAPS participated in the ACTWatch Advisory Committee meeting in Geneva in September 2012 and provided advice on the design of ACTWatch survey and reviewed the finding study in order to strengthen pharmaceutical governance.

Quarterly Progress for Objective 2: Increase utilization of information for decision making

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. Also during this quarter SIAPS provided information on LMIS profiles. PMI uses the information to make procurement decisions and TA planning.

Quarterly progress toward sub-objective 1.1: Enforce good governance principles

Under this sub objective, SIAPS participated in the ASTMH annual meeting in Atlanta in November 2012 and presented on the causes of stock outs in Burundi.

Deliverables: Sub-Objective 1.1

Presentation: "Causes of stock-outs in Burundi"

Quarterly progress toward sub-objective 2.1: Strengthen the use of PMI tolls

During this quarter, countries (Angola, Burundi, and Guinea) were able to complete EUV surveys and submit their reports within the 8-week allotted time period (prescribed by PMI Washington). Support was provided to countries teams in reviews of findings, and feedback was given to the field on viable follow-up activities based on EUV findings. To facilitate procurement decision at PMI, SIAPS aggregated data and reported on stock status of malaria commodities from Angola, Benin, Burundi, DRC, Ethiopia, Kenya, Mali, and Uganda. SIAPS also reported on supply plan of malaria commodities in Angola, Benin, Burundi, Ethiopia, Kenya, Mali, Malawi, Senegal, and Uganda. Also under this objective, SIAPS provided valuable information on LMIS country profile for Angola, Burundi, DRC, Ethiopia, Guinea, Liberia, and to PMI M&E staff at JSI offices on December 21, 2012.

Deliverables: Sub-Objective 2.1

Reports (PPRm, EUV)

MCH Core
Year 1 Work Plan

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

Overall Quarter Progress

This quarter the SIAPS/ MCH portfolio contributed to global initiatives to raise awareness of the importance of appropriate pharmaceutical management of maternal and child health commodities, made progress in the development of new tools to increase access to these commodities and continued to provide technical assistance at the country level. Specifically, SIAPS actively participated in the UN Commission working groups and provided

inputs in their respective work plans. SIAPS also made progress in finalizing two tools- the methodology for estimating medical unmet need of maternal health commodities and the intervention guide for community use of medicines for child illnesses. Finally, SIAPS continued to support SIAPS field offices this quarter including the provision of technical documentation on key MNCH medicines to DRC to assist with the MOH's revision of the National Essential Medicine List, supportive supervision in the two counties in which misoprostol has been introduced in South Sudan and support for scale up of community case management in Guinea and Mali.

Key challenges faced during the quarter

The only challenges faced this quarter were competing schedules and priorities that resulted in delays in two activities: the roadmap and the intervention guide. Much of this was due to the increase in the number of meetings and ad hoc requests related to the UN Commission work.

Key activities planned for next quarter

(1) SIAPS with participate with two presentations in a panel discussion on improving access to essential maternal health medicines at the Global Maternal Health Conference in Arusha, Tanzania in January 2013; (2) SIAPS will also participate in the Maternal Health Supplies Working Group meeting scheduled for the end of January. During this meeting, SIAPS will present on the unmet medical need for maternal health medicines approach; (3) The first draft of the roadmap for program managers to increase access to maternal health medicines will be developed; (4) SIAPS will finalize the unmet need document and organize field testing in at least one country; (5) SIAPS will continue to participate in the UN Commission working groups and define its participation in the implementation of activities proposed in the work plan; (6) SIAPS will continue to participate in the CCM Task Force and specifically in the supply chain working group; (7) The intervention guide for community use of medicines for illness in children will be reviewed internally and finalized; (8) A stakeholder's meeting to increase awareness of the importance of the use of chlorhexidine for umbilical care will be organized in DRC; (9) SIAPS/ MCH will provide support to SIAPS/ Mali and the Malian MoH to in redesigning the LMIS and work with stakeholders to reach consensus on the data collection and reporting tools to be used at each level of the system; (10) In Guinea, SIAPS/ MCH will assist the MoH with planning and estimating the needs for CCM, finalize job aids, participate in the MCHIP training of CHWs, and set up a monitoring system to track availability of medicines.

Quarterly Progress for Objective 1: Capacity for maternal and child health pharmaceutical supply management increased and enhanced

This quarter SIAPS continued to raise global awareness of the importance of appropriate pharmaceutical management of essential commodities for maternal and child health through participation in global initiatives, working groups and conferences. Specifically, SIAPS had two abstracts accepted for presentation at the Global Maternal Health Conference scheduled for January 2013 in Arusha, Tanzania. SIAPS has also been very active in the various working groups formed to support implementation of the recommendations of the UN Commission on Life-Saving Commodities for Women and Children. Finally, SIAPS has continued to participate in the Community Case Management Task Force, especially in the reactivation of its supply chain sub-group.

Quarterly Progress for Objective 2: Utilization of information for decision-making increased

This quarter SIAPS/ MCH has continued to develop tools to help countries increase access to maternal health medicines and improve the use of medicines for the management of child illnesses. Drafts of two key tools have been developed and shared for technical review: a methodology for determining medical unmet need of maternal health medicines and the intervention guide for improving use of medicines for the management of child illnesses at the community level.

Quarterly Progress for Objective 3: Pharmaceutical services for maternal and child health improved

SIAPS continued to assist in developing strategies to increase availability of essential commodities for maternal and child health. Specifically, in Mali and Guinea SIAPS made progress in identifying strategies to improve availability of commodities at CCM sites.

Quarterly progress toward sub-objective 1.1: Capacity of individuals, institutions, organizations to manage maternal health medicines and supplies strengthened

SIAPS/ MCH has been participating regularly in the working groups that are supporting implementation of the UN Commission recommendations. Specifically, SIAPS has participated in the chlorhexidine working group, the pneumonia and diarrhea working group, the maternal health technical reference team and the Recommendation 6 (Supply) working group. SIAPS participated in the work plan design of these groups and then in the meetings to discuss how to move forward with the work plan activities. As a result of these discussions, many working groups divided into smaller groups to move forward with implementation. SIAPS is now the coordinator of two of these sub-groups: a tools group under the maternal health technical reference team and a group to work on activities related to quantification (Outcome 2) under Recommendation 6. Besides these coordination roles, SIAPS is also participating in other sub-groups such as the amoxicillin working group, the Essential Medicines List/Standard Treatment Guidelines sub-group and the Outcome 1 sub-group.

Next quarter, SIAPS will continue to work with the working groups and sub-groups to define specific activities for SIAPS moving forward. In its coordination role, SIAPS will schedule meetings with the relevant sub-groups and assist in defining scopes of work for the specific activities present in the work plans.

The two abstracts that SIAPS/ MCH submitted for the Global Maternal Health Conference on the estimation of medically indicated unmet need for maternal health medicines and the availability and management of essential maternal health medicines, results from Rwanda and Kenya were accepted this quarter. The draft presentations were also developed. They will be presented at the conference in January by Jane Briggs and Maheen Malik.

Quarterly progress toward sub-objective 1.2: Capacity of individuals, institutions, organizations, and to manage child health medicines and supplies strengthened

SIAPS/ MCH participated in a CCM task force meeting in October 2012 and actively participated in initiating the first meeting of the Supply Chain Management sub group on December 10, 2012.

SIAPS/ MCH also participated in all four meetings of the pneumonia amoxicillin and diarrhea working group for the UN Commission. Two of these meetings were for amoxicillin (October and December 2012) and one was regarding ORS and zinc (October 2012). Helena Walkowiak, Jane Briggs and Sheena Patel attended the amoxicillin and diarrhea working group meeting held in New York from November 19-20, 2012. The MCH portfolio further contributed to the revision of the UN commission work plan on amoxicillin and diarrhea and is positioned to take on some key activities in the amoxicillin work plan.

SIAPS has participated in the only Zinc Task Force meeting this quarter in November 2012 and has volunteered to be featured as an expert in supply management on the Zinc Task Force web site.

Beth Yeager and Maheen Malik also attended the working group meetings on chlorhexidine (CHX) and provided inputs in finalizing the commodity work plan. SIAPS also consulted with other units with Management Sciences for Health to sign the application submitted to WHO to include 7.1% chlorhexidine to the WHO recommended list of essential medicines. For country specific work on chlorhexidine, SIAPS/ MCH have been following up with the team in DRC to ensure 7.1% CHX is on the country EML.

Next quarter, SIAPS/ MCH will define which activities SIAPS will implement in the amoxicillin work plan and start implementation; continue participation in the amoxicillin and diarrhea working group of the UN commission, the Zinc Task Force, and CCM task force; jointly plan webinars on supply chain management with the SCM sub group; and define tips on medicines management to post on the CCM task force web site. Also, next quarter in DRC, a stakeholder's meeting will be organized for increasing awareness on use of chlorhexidine for umbilical care.

Quarterly progress toward sub-objective 2.1: Innovative and proven tools broadly available and used

SIAPS/ MCH is developing an approach to engage national stakeholders in a discussion on the current unmet need for maternal health medicines (specifically oxytocin, misoprostol and magnesium sulfate) and how to make better evidence-based decisions regarding the amount of these medicines to procure to reduce this unmet need. The draft document was shared with key stakeholders in December at a technical review meeting to discuss and agree on the assumptions used in the draft related to the incidence of life-threatening conditions-PPH, PE/E, PAC. Next quarter the assumptions will be revised based on the feedback from the technical review meeting and the draft will be recirculated. SIAPS will also plan to test the approach in one country.

Harvard submitted the final draft version of the intervention guide for improving use of medicines for children at the community level for SIAPS review. This version has been shared with senior staff for technical review. The guide will be finalized next quarter and discussions will start on where to test the guide in the field.

Challenges in progress toward sub-objective 2.1

Travel schedules and other conflicting priorities continued to hamper the review process of the intervention guide both by the partner and the SIAPS MCH team. This activity will be a priority to finalize in the next quarter.

Quarterly progress toward sub-objective 3.1: Availability of pharmaceuticals for maternal health improved

Progress towards developing a roadmap for the management of maternal health medicines was stalled this quarter due to activities related to the UN Commission sub-groups and other SIAPS activities.

Challenges in progress toward sub-objective 3.1

The development of the roadmap for national program managers to increase access to maternal health medicines has not progressed this quarter due to competing priorities, especially with regards to the UN Commission work. As a result, it was decided that a senior technical advisor from SIAPS pharmaceutical services technical cluster will begin assisting with this activity.

Quarterly progress toward sub-objective 3.2: Availability of pharmaceuticals for child health improved

SIAPS/ MCH supported the SIAPS/ Mali country team and the MOH to conduct an assessment of the logistics management information system (LMIS) to inform national LMIS strengthening plans for all levels of the health system including the CCM level. Suzanne Diarra from HQ travelled to Mali from September 21 - October 20, 2012 to assist with the assessment.

The major findings of the assessment related to the CCM level included little supervision of community health workers, low data collection and reporting rates, weak distribution of supplies to the community level resulting in frequent stock outs of commodities, and the absence of standard operating procedures describing the LMIS. The results of this assessment will be used by the MOH and its partners to develop and implement interventions to

strengthen the functioning of the system, supervision, data collection and reporting to support decision making for improving the availability of medicines at service delivery points including CCM sites. Findings of the assessment will also serve as 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.

One of the recommendations of the assessment was to update the national tracer medicines list which the MOH tracks regularly. As a result, this quarter, SIAPS/ MCH provided technical assistance to review and adapt the national tracer medicines list to include CCM medicines. Next quarter SIAPS/ MCH will provide support to develop SOPs to guide the functioning of the LMIS by level and work with stakeholders to get a consensus and agree on data collection and reporting tools to be used at each level of the system.

In Guinea, SIAPS staff Mbombo Wathum from Rwanda and Jane Briggs from HQ traveled to Guinea in October 2012 to provide technical assistance to the MoH and MCHIP in aspects related to medicines management. SIAPS attended the meeting of the steering committee for iCCM, stimulated the formation of the supply chain sub group and facilitated its first meeting in October 2012. Mbombo stayed in country for two months providing TA to the MoH and MCHIP on the supply management tools, training material, waste management, procurement of medicines and supplies as well as drafted job aids on aspects of medicines management for the CHWs. During this time, a local consultant was recruited to continue providing TA after Mbombo's departure. SIAPS is now a member of the steering committee and has actively participated in all their meetings.

Next quarter, SIAPS/ MCH will assist the MoH with planning and estimating the needs for iCCM, finalize job aids, participate in the MCHIP training of CHWs to ensure the medicines management module is at the correct level for the CHWs, and set up a monitoring system to track availability of medicines.

Challenges in progress toward sub-objective 3.2

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

(1) Final drafts of implementation guide, training curriculum, algorithms, CHW manual, stock card and medicine order and reporting form with SIAPS inputs accepted; (2) Trip report-Mali-Suzanne Diarra-Oct. 2012; (3) Assessment report: Rapport d'évaluation du système de gestion logistique des médicaments essentiels du Mali - Octobre 2012.

TB Core

Year 1 Work Plan

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 number of cases, incidence and mortality rates has 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: Assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve Global TB goals.

Overall Quarter Progress

This past quarter SIAPS' efforts focused in large part on conducting a workshop at the 43rd Conference of the International Union Against Tuberculosis and Lung Diseases and hosting the three day 2nd Africa TB Regional Conference on Management of TB Medicines in Zanzibar. In both instances SIAPS collaborated with key global TB actors to provide technical assistance and insight into TB medicines management.

Key challenges faced during the quarter

The primary challenge during this quarter was the overlap of many important events, specifically the UNION Conference, Stop TB Board meeting, 2nd Africa TB Regional Conference, and end-of-year reports.

Key activities planned for next quarter

The coming quarter will operate according to the work plan. Activities will focus on further development of an additional module and application for eTB Manager, with plans to incorporate both into the system in the coming quarters. Wrap up from the 2nd Africa TB Regional Conference on Management of TB Medicines will continue as workshop proceedings are documented in the form of a technical report. In preparation for the 44th Conference of the International Union Against Tuberculosis and Lung Diseases in November 2013, SIAPS will be working with the Global Drug Facility to submit a proposal for a workshop, as well as a number of

symposiums on themes including public private mix and treatment of drug-resistant TB.

Quarterly Progress for Objective 1: Pharmaceutical governance for TB strengthened at global level and country level

This past quarter, efforts towards strengthening pharmaceutical governance for TB consisted primarily of the work done to host the 2nd Africa TB Regional Conference on Management of TB Medicines in Zanzibar, Tanzania. The three day interactive conference provided an opportunity for conference participants to work in teams to identify the most pressing challenges in their country and design feasible interventions to overcome them. SIAPS provided technical assistance as teams outlined the root causes of each identified challenge, as well as the technical and financial resources that would be required to address them. The conference provided a unique opportunity for country programs to share ideas, as well as dialogue with key partners such as the Global Drug Facility (GDF) and the United States Pharmacopeia (USP) to address common bottlenecks in TB medicines management.

Quarterly Progress for Objective 2: Capacity for TB pharmaceutical supply management and services increased and enhanced

This past quarter SIAPS' activities around capacity building for TB pharmaceutical supply management were split between continued development of an innovative TB training program and participation in the 23rd Meeting of the TB Training and Education Collaborative for the WHO European Region.

Quarterly Progress for Objective 3: Improved utilization of information for TB control decision making

Progress on MIS for TB tools moved along this past quarter as SIAPS made a number of modifications and updates to both the generic e-TB Manager as well as country-specific versions. A new version of the e-TB Manager User's Guide is being finalized by editorial before it is distributed. Additionally, new features were added to the generic version of e-TB Manager to allow users to be alerted when medicines are at risk of stock out or expiry.

Quarterly Progress for Objective 4: Improved financing strategies for expedited access to new TB tools and pharmaceutical services

The preliminary findings from the SIAPS financing work conducted this summer in Rwanda and Uganda were presented at the 43rd Union TB Conference in Kuala Lumpur. The reports summarizing approach and findings for each country was finalized and submitted to country representatives for validation.

Quarterly Progress for Objective 5: Improved pharmaceutical services and access to TB products to achieve TB Goals

SIAPS made substantial movement towards improved pharmaceutical services and access to TB products the past quarter through progress in a number of activities. With regards to public-private mix activities, SIAPS conducted the first supervision of dispensers in Morogoro, Tanzania one month following training on recognition of TB signs and the process of referral to a TB diagnostic center for clients with symptoms. This supervision involved the design of data collection and analysis tools. SIAPS also provided technical leadership through its role as a member of the European Technical Advisory Group on Tuberculosis Control in WHO European Region (TAG-TB), and through participation in the first meeting of WHO Europe Regional Interagency Coordinating Committee on Tuberculosis Control and Care (RICC-TB).

Quarterly progress toward sub-objective 1.1: Improved global TB medicines policies and strategies in response to National TB control needs

As part of its technical leadership to strengthen GDF, SIAPS continued to support a consultant in Geneva as an interim Manager of the GDF, leading all operations to ensure timely delivery of TB medicines to countries and high standard of the GDF performance in compliance with its ISO:9001 certification. In December 2012, the SIAPS agreement with this outside service consultant expired, and he was replaced by a full time SIAPS employee; USAID funding was secured to support the position of interim GDF manager through at least 2013.

SIAPS provided assistance to the GDF Interim Manager and staff in the development of a number of documents and papers in support of GDF reorganization, including:

- A paper More than a Decade Shaping the Treatment Supply. Global Drug Facility, 2012
- Customer Feedback Survey report
- A study Prices Comparison for FLD and SLD Regimens 2002 – 2012
- A Strategic Framework and the GDF Future Direction in the Context of the New Stop TB Strategy, presented to the Stop TB Board and approved in November 2012

SIAPS supported a member and led the activities of the Stop TB Board Advisory Group on the GDF Strengthening, which counsels the GDF on strategic and operational issues. In November 2012, the Advisory Group reviewed and endorsed the GDF strategy presented to the Stop TB Board.

With regards to specific technical areas, SIAPS continued to support the improvement of the GDR Early Warning and Quantification Systems, as well as performance and order monitoring dashboards. Additionally, through the GDF request, SIAPS assisted Kazakhstan in the development of guidelines for the quantification of TB medicines.

SIAPS led the development of curriculum and submission of a joint SIAPS/GDF application for a 44th UNION TB Conference workshop “Global Drug Facility (GDF): Universal Access to Internationally Quality Assured (IQA) TB Commodities".

Deliverables: Sub-Objective 1.1

- A paper "More than a Decade Shaping the Treatment Supply. Global Drug Facility, 2012"
- "Customer Feedback Survey" report
- A study "Prices Comparison for FLD and SLD Regimens 2002 – 2012"
- A Strategic Framework and the "GDF Future Direction in the Context of the New Stop TB Strategy", presented to the Stop TB Board and approved in November 2012
- Reviewed Guidelines on Quantification for Kazakhstan

Quarterly progress toward sub-objective 1.2: Best pharmaceutical management standards and practices available for the adoption by global and national partners

From December 5-7, 2012 SIAPS hosted the 2nd Africa TB Regional Conference on Management of TB Medicines in Zanzibar, Tanzania. The conference covered a wide range of topics relating to medicines management, including technical areas such as quantification, as well as behavior change issues that ultimately have substantial impacts on the availability of medicines.

In preparation for the conference SIAPS reviewed draft presentations from presenters and provided feedback, finalized and formatted presentations with the MSH editorial team, and finalized travel and lodging arrangements.

The conference brought together representatives from the Global Drug Facility, World Health Organization Africa

Region, and National Tuberculosis Programs, among others. In the first day and a half of the conference presenters highlighted barriers to effective TB medicine management as well as past successes overcoming those obstacles. The remainder of the conference was devoted to designing country action plans; participants identified the most pressing challenges surrounding TB medicines management in their countries and outlined specific, time-bound interventions to tackle them.

Throughout the course of the conference SIAPS facilitated discussions between country programs and key partners, and offered technical input to discussions. During the design of country action plans each country team worked with SIAPS staff to design feasible interventions.

Next steps will include wide dissemination of the plans to solicit technical support as needed.

Deliverables: Sub-Objective 1.2

13 country work plans

Quarterly progress toward sub-objective 2.1: Pharmaceutical management capacity of Stop TB partners and NTPs strengthened

In October 15-26, 2012, SIAPS contributed sessions on Pharmaceutical Management to the WHO Collaborative Center in Tradate, Italy, Course "Implementing the Stop TB Strategy: Skills for Managers and Consultants; TB, MDR-/XDR-TB, TB/HIV"; 22 participants (12 female, 10 male) from 16 countries were trained.

From December 5-6, 2012 SIAPS participated in the 23rd Meeting of the TB Training and Education Collaborative for the WHO European Region. SIAPS presented training work accomplished under both SPS and SIAPS during the time since last Collaborative in May 2011. Additionally, SIAPS presented future plans in the region and opportunities for collaboration with regards to trainings and drug management capacity development in WHO European region.

Quarterly progress toward sub-objective 2.2: Innovative approaches for TB pharmaceutical management capacity building developed and implemented

SIAPS continued to work with the MSH Capacity Building and Performance Management Team to design a platform for TB pharmaceutical management training. During the past quarter the team identified the pilot module and target audience: inventory management for drug coordinators and supervisors. The team then utilized existing internal and external training materials to outline appropriate topics and themes. Lastly, the team reached out to the Management Information Systems Team within MSH to ensure that platform aligns with the appropriate specifications with respect to the hosting solution.

Quarterly progress toward sub-objective 2.3: Capacity for operational research to inform health system interventions

The outline of the activity has been discussed by SIAPS, and activity lead identified.

Quarterly progress toward sub-objective 3.1: Innovative and proven MIS for TB tools available and updated

A new version of the e-TB Manager User's Guide has been updated and sent to editorial for formatting and distribution. SIAPS increased the feasibility of the generic e-TB Manager (e-TBM) and alignment with international standards for TB management. New features were built in, including management of suspect individuals at risk of TB, improved online monitoring of system usage with detailed event log reports, and a

tracking and alert system for medicines at risk of stock-out and expiry. Specific software for project monitoring and tracking changes has been used to support new implementations for the generic and country versions of e-TBM. A comprehensive laboratory management module and a stand-alone application for mHealth are under development to be incorporated into the system by the next quarters. The interoperability for data exchange between the e-TBM, other MIS and the new rapid diagnostic devices, such as GeneXpert and Hain Test, are planned to be developed by the next quarters.

Uzbekistan: The laboratory module of e-TBM is in a final stage of testing in Uzbekistan. The developing and testing of the module in Uzbekistan will be used in the future to inform the generic version of the module. This work was presented on the symposium "Thinking out of the box: catalyzing innovations and expansion of mHealth in TB care" at the 43rd Conference of the International Union Against Tuberculosis and Lung Diseases at Kuala Lumpur.

Namibia: Local MSH focal point performed a joint assessment visit with NTP to one pilot site. Issues regarding misuse of the system and irregular internet connection were identified and indicated that additional capacity building activities and enhanced support on infrastructure are required. Additional technical problems identified during the visit are being addressed by MSH IT team. The visit planned for the second pilot site was postponed due to local constrains. Pilot phase is still in course in both sites until the final assessment probably ending up by the next quarter. Complete assessment reports will be sent to MSH/SIAPS. Finalize pilot assessment, develop a new roll-out plan and budget, and obtain funding with the MoH and other partners for infrastructure and future trainings remain the priorities for completion of implementation in the country. Additional information about the upcoming Integrated Health Information System (supported by the MoH) currently being piloted in the capital Windhoek are needed to define whether adaptations or potential integration with the e-TBM will be required.

Kenya: The implementation process is still standing. MSH/SIAPS contacted the NTP which remains interested in resuming activities. The priorities to resume activities in the capital Nairobi, and later scale up countrywide, include assigning a local MSH staff to lead the process, reviewing and updating the implementation plan including the definition of funding sources, approving the End User License Agreement, defining further customization of country version for DRTB management and conducting new trainings on system operation to local staff. MSH/SIAPS is awaiting confirmation from the NTP for a possible mission planned for the next quarter.

At the 43rd UNION TB Conference, SIAPS e-TBM team - as a partner in the development of electronic systems for TB patient and program management, including mobile health applications - participated in the development of a project on interoperability of e&mHealth systems. The group included stakeholders representing organizations involved in the development and implementation of electronic information tools for TB, including MSH/SIAPS, Partners in Health, i-Solutions, KNCV, and Abt Associates. The group developed and submitted a proposal for a symposium on eHealth TB tools at 44th UNION TB Conference; SIAPS will be co-chairing and presenting at this important symposium ("Airborne data - the application of electronic health in different domains of TB care").

Deliverables: Sub-Objective 3.1

- SIAPS presentation at the 43rd UNION Conference, Proposal for a symposium "Airborne data - the application of electronic health in different domains of TB care".

Quarterly progress toward sub-objective 4.1: Reduced financial barriers to expedite access to new TB tools for diagnosis and treatment

SIAPS collected and analyzed incremental costs and financing by collecting data associated with recent TB diagnostic and treatment tools (GeneXpert and MDR-TB treatment) in Rwanda and Uganda from July to

September 2012. The studies included a desk review of the Uganda National Tuberculosis and Leprosy Program (NTLP), the Rwanda National TB Program (NTP), and ministry of health documents and budgets from both countries. In addition, there were consultations with key stakeholders involved in TB control on decision-making and planning processes, resources requirements for diagnosis and treatment, introduction plans of new TB interventions, and challenges to TB financing.

During the last quarter, the reports summarizing approach and findings for each country were finalized and submitted to country representatives for validation. Additionally, preliminary findings from this work were presented at the 43rd Union TB Conference in Kuala Lumpur.

Next steps include dissemination of the reports at the MOH and SIAPS levels.

Deliverables: Sub-Objective 4.1

The UNION presentation at SIAPS/GDF workshop, the UNION poster (Poster sessions), Finalized Rwanda assessment report

Quarterly progress toward sub-objective 5.1: Improved access to TB and ancillary medicines in public sector

SIAPS participated in the Stop TB MDR-TB Working Group by chairing and facilitating a session on the management of SLD and making a presentation on forecasting and quantification at the MDR-TB WG meeting at the 43rd UNION TB Conference.

SIAPS participated and contributed to a meeting and discussion of USAID implementing partners and regimen developers "Planning for the Introduction of New TB Regimens"; it was agreed that SIAPS would continue to provide expertise to the TB Alliance ReMOX regimen development and its supply options.

In December 3, 2012 SIAPS participated in the seventh meeting of the European Technical Advisory Group on Tuberculosis Control in WHO European Region (TAG-TB) as a member. The meeting discussed the following issues:

- Designing the "Minimum package for cross border TB control and care in the WHO European region: a Wolfheze consensus statement";
- Methods to maintain and further improve the European Joint TB Surveillance Network currently coordinated jointly by WHO/Europe and ECDC;
- Challenges in anti-TB drug supply and management in the WHO European Region;
- Challenges related to introduction of the upcoming new TB medicines.

TAG-TB elaborated recommendations on each of these issues. SIAPS provided key recommendations on drug management issues, which were accepted by members of TAG-TB and reflected in the final version of the recommendations.

On December 4, 2012 SIAPS participated in the first meeting of WHO Europe Regional Interagency Coordinating Committee on Tuberculosis Control and Care (RICC-TB). The primary objective of the committee is to strengthen involvement and improve coordination and collaboration of national and international partners in TB prevention, control and care. The main point for discussion was the Term of References (ToR) of the RICC-TB. It was decided that the ToR will be edited according to the suggestions and will be circulated among the members of RICC-TB for the comments and final approval. SIAPS contributed input to these discussions.

Deliverables: Sub-Objective 5.1

- Presentation for Stop TB MDR-TB Working Group "Pharmaceutical Management and Scaling up MDR-TB Care Delivery: "Last mile" Challenges and Solutions", trip report (in same report as 23rd Meeting of the TB Training and Education Collaborative for the WHO European Region), draft recommendations from the TAG-TB meeting.

Quarterly progress toward sub-objective 5.2: Innovative approaches for engagement of private sector in pharmaceutical services for TB developed

SIAPS continues to work on the model of public-private partnerships, namely, the engagement of private pharmacy networks (Pakistan pilot), and accredited community drug sellers and private sector pharmacies (Tanzania pilot).

This quarter SIAPS conducted two TDYs to Tanzania to continue work with the Tanzania National Tuberculosis and Leprosy Program (NTLP) involving private sector pharmacies and Accredited Drug Dispensing Outlets (ADDOs) in the management of TB. The first trip focused on the initial follow up of dispensers and TB diagnostic centers following a training conducted approximately one month earlier. Activities included the following:

- Finalized monitoring and evaluation materials, including those needed for data collection, entry, and analysis;
- Conducted training on the administration of the supervision tools; participants included private pharmacists, representatives from the Ministry of Health and the NTLP;
- Four supervisory teams covered one to two districts each visiting ADDO and pharmacy dispensers who had participated in the training, assessing the number of TB referrals and dispenser attitudes towards the referral system. Teams then visited corresponding TB diagnostic centers to follow up on referrals from ADDOs and assess staff attitudes toward the referral process.

During the second trip, the SIAPS team conducted the following activities:

- Participated in the review of the first monitoring visit for the pilot intervention to engage the private retail sector in TB control and discussed strategies to improve future supportive supervisory visits in light of lessons learned from the first monitoring visit conducted at ADDOs in Morogoro in October 2012,
- Contributed to the planning for data collection for the retrospective TB case notification review,
- Contributed to the revision of TB Information, Education and Communication (IEC) materials - aimed at enhancing private sector engagement in early TB case detection in Tanzania and at increasing community awareness on TB disease and the availability of services- during a meeting with the MOH communication officer.

A representative from the Kenya Association for the Prevention of Tuberculosis and Lung Disease (KAPTLD) presented the successful contributions of KAPTLD in TB control at the 43rd Conference of the International Union Against Tuberculosis and Lung Diseases.

Challenges in progress toward sub-objective 5.2

- Progress in public-private partnership work in Kenya moved slowly as the team in Kenya awaits additional staffing resources.

Deliverables: Sub-Objective 5.2

- Draft supervision tools in Tanzania, including data collection survey and Excel file for data entry and analysis;

2 trip reports; presentation slides at the 43rd UNION TB Conference.

Quarterly progress toward sub-objective 5.3: TB patient safety and treatment effectiveness assured

RISK MANAGEMENT ACTIVITY - The risk management protocol has been reviewed internally for technical content and flow. The protocol has been revised based on comment received. The final draft has been sent to editorial for grammar and language review. Five external technical reviewers have been identified for the protocol review. SIAPS has initiated communication with identified reviewers to provide an overview of the activity and to find out their availability for the review. Two countries (Swaziland and Philippines) have also been identified for implementation of the protocol and tools once finalized. Next steps include; sending protocol out for external review and to research and begin development of risk management tools.

ACTIVE SURVEILLANCE ACTIVITY - SIAPS developed the Data Collation and Analysis Tool (DCAT) and the Sentinel Site-based Active Surveillance (SSASSA) tool for the implementation of active surveillance activities to monitor safety and quality of TB/HIV medicines. These tools were adapted from existing tools and have been used in Vietnam for HIV/AIDS active surveillance. The adaption included incorporating TB specific elements, ensuring standard interoperability interface, enhancing site-based reporting features, etc. A comprehensive DCAT manual has been also been developed that includes: user's manual, data analysis and validation guide, guide for exporting and importing data, and standard interoperability guidelines. SIAPS has finalized the generic protocol and implementation guides for TB/HIV active surveillance, this includes:

(a) Data collection tool for TB/HIV safety monitoring,
(b) Guide for processes and patient recruitment,
(c) Guideline for completing data collection forms and interviewing patients,
(d) Guideline for follow up on missing data,
(e) Guideline for orientation and training of staff, and
(f) Guide for supervisory visit.

Next steps include:
(a) To agree on a timeframe with Swaziland for the launch and implementation of protocol and tools
(b) To develop SOPs and a guidance manual on how to use tools
(c) Develop training materials for the launch
(d) To revise supervisory tools for monitoring activities
(e) To begin talks with Philippines about the initial visit to conducting a mapping exercise to develop a protocol.

Quarterly progress toward sub-objective 5.4: Use of medicines in TB programs improved

SIAPS presented the DR-TB DUR tool at the 43rd Union World Conference on Lung Health in Kuala Lumpur, and designed a proposal to conduct a symposium on Targeting DR-TB Through the Rational Use of Second-line Drugs for the 44th Union World Conference on Lung Health (submission will take place in January, 2013). SIAPS is also finalizing the DUR Guidelines for MDR-TB and planning roll out in Kenya. We are currently working with the Kenya NTLP to plan a TDY in January 2013 to begin the process of roll out.

SIAPS conducted a one day workshop in collaboration with the Global Drug Facility (GDF) at the 43rd Conference of the International Union Against Tuberculosis and Lung Diseases on November 14, 2012. This workshop was attended by over 95 national TB program staff, TB medicines managers, TB laboratory managers, TB consultants, international and local partner organizations involved in TB programs, donors' representatives and professional associations from over 26 countries around the world. The main objectives of the workshop were to:

(a) Bring to the forefront essential elements and requirements for a sustainable pharmaceutical system for

TB control and

(b) To provide participants with best practices, feasible strategies and relevant tools for enhancing country ownership, improving pharmaceutical systems and sustaining quality TB pharmaceutical service delivery.

Workshop attendants learned about strategies, procedures and experiences to ensure involvement of key country stakeholders, improve pharmaceutical systems and promote sustainability, responsibility and ownership in TB pharmaceutical service delivery by the country. SIAPS staff also participated in several side meetings and symposiums during the conference.

USFDA Core

Year 1 Work Plan

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

Overall Quarter Progress

"Year II Quarter 1" activities focused on drafting assessment findings for the Asia Pharmacovigilance Assessment in Bangladesh, Cambodia, Nepal, the Philippines, and Thailand.

Key challenges faced during the quarter

Key challenges that were encountered during the quarter under review with the implementation of the activity include delays in receipt and finalization of all five country reports for the Pharmacovigilance assessment due to challenges with local consultant preparing the individual country reports and reviewing with national regulatory authorities according to anticipated timelines was reviewed and approved together with the national regulatory authority. 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 was scaled down and SIAPS country portfolio funding is being leveraged to expand the features of existing tools to include important PV features identified as priorities.

Key activities planned for next quarter

Activities planned for the next quarter include finalization of the Asia Pharmacovigilance Assessment in Bangladesh, Cambodia, Nepal, the Philippines, and Thailand and the synthesis report.

Quarterly Progress for Objective 1: Assess and disseminate findings on the pharmacovigilance and post-market surveillance systems performance in the Asia/Pacific region

Drafting of the Asia Pharmacovigilance assessment reports was conducted in THIS QUARTER for the five study countries: Bangladesh, Cambodia, Nepal, the Philippines, and Thailand. In all countries, local consultants contributed to drafting of the individual country report. The Bangladesh assessment report was disseminated through an in-country workshop in November 2012.

Quarterly Progress for Objective 2: Conduct a workshop for the development of pharmacovigilance tools and conduct a conference for the dissemination of findings of the SSA study

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 proceedings were published in this quarter.

Quarterly progress toward sub-objective 1.1: Assess pharmacovigilance systems and performance in selected Asia/Pacific countries

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 was conducted in Q4. 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. Assessment reports were in the process of being drafted for finalization in this quarter.

Challenges in progress toward sub-objective 1.1

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 the 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

- Individual country reports were received from all consultants for review by MSH technical staff and country national regulatory authorities.

Quarterly progress toward sub-objective 1.2: Document and disseminate results of the study

Dissemination of results of the pharmacovigilance systems and performance assessment in selected Asian countries is planned for 2013. During this quarter, the country specific reports were drafted and the review process was conducted to ensure consistent quality in the reports to be generated from the assessment. Also literature review to support the report was conducted. The Bangladesh assessment report was alsoshared with the regulatory authority.

Challenges in progress toward sub-objective 1.2

The key challenges encountered during the quarter under review included delays in the finalization of individual country reports together with National Regulatory Authorities. This finalization is anticipated in early 2013. Timelines have been moved along as quickly as possible with study countries and communicated with the client.

Deliverables: Sub-Objective 2.1

- The Africa Pharmacovigilance Meeting 2012 workshop report was finalized in this quarter, including a summary of the various sessions and technical conclusions.

Quarterly progress toward sub-objective 2.2: Disseminate findings of the SSA study

The Africa Pharmacovigilance Meeting 2012 conference and workshop report was finalized in this quarter.

Deliverables: Sub-Objective 2.2

- The Africa Pharmacovigilance Meeting 2012 conference and workshop report was finalized in this quarter.

LAC AMI

Year 1 Work Plan

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 founded 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: 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

Overall Quarter Progress

AMI countries have progressed in the implementation of revised pharmaceutical management strategies in low incidence areas. The incidence of malaria has decreases in areas of high incidence where SIAPS is providing decentralized technical assistance.

Key challenges faced during the quarter

The pace of implementation of proposed TA activities decreased by the end of the year in most AMI countries. The elaboration of research protocols for regional studies was postponed due to conflicting agendas of principal researchers.

Key activities planned for next quarter

By the end of next quarter, SIAPS will start undertaking studies (baseline and impact evaluations) on: competences for diagnosis and treatment in low incidence areas; impact of revises criteria for programing and distribution in low incidence areas, results of PM interventions in decentralizes areas.

Quarterly Progress for Objective 1: Coordinate joint activities with AMI partners to strengthen the governance of the pharmaceutical sector

Following on the Quito regional meeting (Sept 12) agreements, SIAPS has identified and discussed with PAHO consultants the "bottle necks" in the procurement of antimalarials through the strategic fund.

Quarterly Progress for Objective 2: Support evidence base decision making on malaria pharmaceutical management

SIAPS continued supporting the dissemination of the quarterly bulletin on malaria medicines stocks in AMI countries. The completion and dissemination of in-depth assessments has been postponed for the next quarter.

Quarterly Progress for Objective 3: Provide technical assistance to institutionalize best practices on malaria pharmaceutical management to provide desired outcomes

SIAPS completed the collection of information for baseline studies in Colombia, Bolivia and Honduras. The introduction and institutionalization of practices promoted by AMI will be measured against this baseline information

Quarterly progress toward sub-objective 1.1: Provide evidence to support the revision of plans and policies

SIAPS consultants, with PAHO malaria focal persons, have followed on and supported the implementation of activities agreed upon at the Quito meeting (September, 2012). In collaboration with PAHO local consultants, SIAPS elaborated the first draft of antimalarials requisition and dispatch SOPs for Honduras. For the next quarter, SIAPS will provide –in coordination with other AMI partners- support to countries requesting direct technical assistance to improve their procurement through the PAHO strategic fund.

With SIAPS assistance, DIGEMID issued the quarterly bulletin for the third quarter of 2012. Eight countries (including some in Central America) provided data. SIAPS and DIGEMID revised the MS Excel tool to correct a few glitches. The revised version was distributed to all AMI countries on December 2012. For the next quarter, the

bulletin corresponding to the 4th quarter 2012 will be edited and distributed by DIGEMID. SIAPS will start coordinating with PAHO the transfer of the consolidation and editing of the quarter bulletin to the regional medicines platform promoted by PAHO.

SIAPS participated in the regional programming meeting (Bogota, October 2-5, 2012). During this meeting SIAPS consultants supported the elaboration of country plans following the activity lines agreed on the SIAPS regional meeting (Quito, September 2012). For the next quarter: Next steering committee meeting scheduled for March 25-30, 2013.

Challenges in progress toward sub-objective 1.1

The pace of implementation of proposed TA activities decreased by the end of the year in most AMI countries.

Deliverables: Sub-Objective 1.1

SIAPS and DIGEMID revised the MS Excel data collection tool to correct a few glitches. The revised version was distributed to all AMI countries in December 2012.

Quarterly progress toward sub-objective 2.1: Pharmaceutical management information will be immediately available to support products and services

The completion and dissemination of in-depth assessments ("adequacy" studies for Central American countries and Brazil, and the "bottle neck" in the procurement through the strategic fund study has been postponed to the next quarter). For the next quarter, these studies will be completed and distributed to AMI partners and counterparts. SIAPS will also finalize research protocols for studies proposed in the current work plan: (1) competencies of personnel for malaria diagnosis and treatment in low incidence areas; (2) Monitoring of performance ("gap closure") in the implementation of malaria access and use of medicine strategies; (3) Access and use of antimalarials in artisanal gold mining areas.

AMI activities on pharmaceutical management were posted on the SIAPS webpage (http://siapsprogram.org/wherewework/ami/). The webpage includes a summary of the most recent activities supported by AMI, and links to the relevant documents. For the next quarter, SIAPS will complete the edition of the Malaria Pharmaceutical Management in 2012, a compilation of the information gathered during the September 2012 Quito workshop. SIAPS will also disseminate the studies on the performance of malaria control strategies (adequacy studies) and the "bottle neck" study for the procurement through the PAHO's Strategic Fund.

Challenges in progress toward sub-objective 2.1

Provide technical assistance to AMI countries to conduct assessments on their pharmaceutical management systems: Due to conflicting agendas of principal researchers, the protocols of national and regional studies couldn't be completed during this quarter, as planned.

Deliverables: Sub-Objective 2.1

Deliverables have been postponed one quarter due to conflicts in principal investigator scheduling.

Quarterly progress toward sub-objective 3.1: Improve the availability of antimalarials and its correct use to prevent the emerge of resistance

SIAPS completed the collection of baseline information in Colombia and Bolivia. For the next quarter, and based

on problems detected in the baseline study, SIAPS will support the introduction of good pharmaceutical practices promoted by AMI: SOPs for distribution in Honduras, Colombia and Loreto, Peru; pharmaceutical guidelines for primary health facilities in Colombia.

SIAPS developed the final version of a research protocol to assess the implications of the implementation of revised criteria for programing and distribution on early treatment and costs. SIAPS also supported the elaboration of the final version of a programing and distribution electronic tool and standard operational procedures in Colombia. For the next quarter, SIAPS will support the implementation of revised criteria for programming and distribution of malaria medicines in low incidence areas, and collect information to assess the implications of the implementation of revised criteria for programing and distribution on early treatment and costs. SIAPS will also finalize and validate programing and distribution (requisition and dispatch) procedures in Honduras.

During this quarter the SIAPS consultants addressed problems in the supervision system identified during the Quito meeting. Corrective interventions were introduced in Colombia, Bolivia and Brazil. For the next quarter, SIAPS will continue supporting the introduction of corrective interventions in Colombia, Bolivian and Brazil. A monitoring exercise is scheduled for the second quarter of 2013. SIAPS will visit Guyana on the first quarter of 2013, to discuss –among other topics- the situation of the malaria supervision system and the technical assistance that may be required to confront implementation problems.

Deliverables: Sub-Objective 3.1

SIAPS also supported the development of the final version of a programing and distribution electronic tool and standard operational procedures in Colombia.

LAC SAIDI

Year 1 Work Plan

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: 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

Overall Quarter Progress

SIAPS and other partners supported interventions to strengthen TB control strategies in urban areas. The incidence of TB decreases during the same period but cause-effect causality cannot be proved. An alternative model for the provision of TB services for miners has not been implemented yet.

Key challenges faced during the quarter

There are few personnel willing to provide health services in the harsh conditions of the mining areas. Hiring continues to difficult for the local TB program.

Key activities planned for next quarter

SIAPS will visit MDD to assess the results / impact of the interventions supported during the past two years. A technical report will be completed by the 2nd quarter, 2013.

Quarterly Progress for Objective 1: TB treatment outcomes in Madre de Dios improved

SIAPS supported various components of the supply chain: warehouses conditioning and good storage practices in Puerto Maldonado, distribution and standard operating procedures. The institutional pharmaceutical system has been improved, but the benefits have not reached underserved communities (miners) yet.

Quarterly progress toward sub-objective 1.1: Review and improve pharmaceutical services standards in Madre de Dios.

SIAPS visited MDD the last week of September 2012. A trip report, including agreements for the implementation of a short term work plan, was distributed to local counterparts and cooperation agencies. For the next quarter, SIAPS will visit MDD to assess the progress in the implementation of the work plan and elaborate a final technical report.

Deliverables: Sub-Objective 1.1

A trip report, including agreements for the implementation of a short term work plan, was distributed to local counterparts and cooperation agencies.

Quarterly progress toward sub-objective 1.2: Safety of therapeutic strategies improved

The implementation of the pharmaceutical guideline for primary health facilities has been delayed, because it hasn't been validated by local counterparts yet. For the next quarter, SIAPS will support the implementation of distribution standard operational procedures and the guideline for primary health facilities.

During this quarter, SIAPS also provided technical assistance to improve the conditions of the regional and reference hospital warehouses. For the next quarter, SIAPS will assess and report on the final conditions of these warehouses.

Angola

Year 1 Work Plan

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 artemesinin-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: Improved and sustainable health service delivery and impact

Overall Quarter Progress

During this reporting period, SIAPS continued to provide technical support to DNME to organize an interagency coordination meeting in logistics (ICC/Logistics). Besides, both assessment on medicine regulatory system and CECOMA/Supply chain and LMIS assessment took place and preliminary findings were shared with the Mission,

DNME, CECOMA and PNME. In the same period, planned End-User verification targeting antimalarial products but also including other essential medicines was conducted in 10 provinces. SIAPS facilitated the clearance, reception and distribution of new consignments of USAID funded ACTs and RDTs in all provincial warehouses. SIAPS participated in different USAID stakeholders meeting with regard to RH/FP annual planning of the national reproductive health program.

Key challenges faced during the quarter

Delay in getting all the administrative and financial staff on board so that the operations of the office can be facilitated. There is a hope that in the following quarter all the needed supportive staff will be hired. -Insufficient technical skills in country, main activities of the office being done by internal and external consultants.

Key activities planned for next quarter

Disseminate and Implement some of the recommendations from the baseline assessment in medicine regulatory functions.

Disseminate and Implement some of the recommendations from the baseline assessment in Medicine Supply Chain and LMIS in Angola. Finalize the review of the national list of essential medicines.

Conduct quantification exercise for malaria, HIV and RH/FP health commodities. Initiate the development of the Standard Treatment Guidelines for Primary health Care.

Organize the next bi-annual coordination meeting in pharmaceutical management with all national public health programs and provincial supervisors and warehouses.

Assist DNME and CECOMA in capacity building sessions in pharmaceutical management using an innovative participatory approach.

Quarterly Progress for Objective 1: Medicines policy governance strengthened

- The medicine regulatory baseline assessment was conducted with participation of DNME, PNME, Inspection General of the MoH. Preliminary findings were shared with the mission and participating entities. The first draft of the entire report is under review for finalization.

DNME was assisted to organize 2 ICC/logistics meetings (in October and in November) where updates on work plan implementation and new activities plans were shared among participating stakeholders in pharmaceutical management.

Quarterly Progress for Objective 2: Local capacity for pharmaceutical supply management enhanced

SIAPS participated in different meetings with USAID implementing partners to align the work plans with the national reproductive health program annual plans.

Quarterly Progress for Objective 3: Information for pharmaceutical management decision-making improved

CECOMA/Supply Chain and LMIS assessment was conducted by SIAPS and LMI team with the participation of DNME, CECOMA, PNME, provincial warehouses and public health programs. Preliminary findings were shared with the Mission and participating institutions. The draft final report has been submitted for review before its finalization and dissemination.

EUV assessment was conducted in 40 health facilities from 10 provinces. Results were shared in a meeting under coordinated by the National Malaria Control Program.

Quarterly Progress for Objective 4: Pharmaceutical services strengthened to achieve desired health outcomes

A meeting was held between SIAPS and the Department of Pharmacovigilance within DNME to assess the current progress of pharmacovigilance activities after a round of advocacy meetings in selected hospitals and to discuss on the areas of priority for the coming period.

Quarterly progress toward sub-objective 1.1: DNME capacity to regulate medicines strengthened

During this quarter, the assessment on medicine regulatory system in Angola was conducted using SIAPS country Regulatory System Assessment Tool complemented by in-depth interview with key informants. Preliminary findings were shared among participating entities and the Mission. The draft for review is under development before its finalization and dissemination.

Quarterly progress toward sub-objective 1.2: Coordination and collaboration among local pharmaceutical management stakeholders at the central level improved to promote knowledge exchange

Two Interagency Coordination Committee meeting for logistics was held under the coordination of DNME in October and November 2012 facilitated by USAID/SIAPS. These meetings served as a forum to coordinate information sharing among partners on planned and realized activities and for the improvement of pharmaceutical management. Past recommendations were reviewed and planned activities in the coming month were presented by all participants. All participants suggested that the next ICC meeting will be held in SIAPS new office.

Deliverables: Sub-Objective 1.2

- ICC/logistics meeting minutes for October and November 2012.

Quarterly progress toward sub-objective 2.1: Health facility human resource pharmaceutical management capacity improved

(31 Dec 2012) - Discussions to introduce an innovative and participatory approach in pharmaceutical management which will be tailored to the local needs have been initiated together with Center for Pharmaceutical Management Capacity Building and Performance Improvement team to identify consultant to provide this approach to the Angola national facilitators team so that this approach can be used nationwide in improving pharmaceutical management knowledge and skills.

Quarterly progress toward sub-objective 3.1: LMIS strengthened to enable evidence-based decision-making

SIAPS/LMI assessment to strengthen CECOMA/Supply chain and LMIS has been concluded. Different approaches to gather necessary information were used including in depth interview with key informants, focus group discussions, observations, and field visits. Preliminary findings were shared with the stakeholders including the Mission and the report is under development for its dissemination.

Quarterly progress toward sub-objective 3.2: Strategic monitoring tools implemented to improve pharmaceutical management decision-making

End-user verification was conducted in 40 facilities localized in 10 provinces from October 16 to November 1st, 2012. Key findings include stock-outs in 11/40 health facilities, one provincial warehouse reporting overstocking of ACTs, low level of submission of reports on consumption (40%), and presence of other antimalarials including ACTs from the government and private sources in municipal warehouses which can contribute to the lower consumption of USAID funded ACTs. Findings were shared with the National Malaria Control Program and other stakeholders for action.

Deliverables: Sub-Objective 3.2

- EUV report

Quarterly progress toward sub-objective 4.2: MOH PV system strengthened to improve safety and use of medicines

SIAPS held a meeting with the head of the department of pharmacovigilance in DNME to discuss on the progress so far made in ADR and medicine with poor quality reporting after advocacy training held in selected hospitals. The meeting also discussed on the priority areas to be focused on during the following period including organizing a formal training with pharmacovigilance committees in selected hospitals and in establishing PV satellite sites in selected hospitals to serve as good examples for the country. Besides, more involvement of all public health programs within the ministry of health in pharmacovigilance is needed especially for their respective health commodities.

Bangladesh

Year 1 Work Plan

Overall Quarter Progress

SIAPS BD extended its activity during this quarter in the area of capacity building and systems strengthening within the Ministry of Health and Family Welfare (MOHFW) especially the newly formed PLMC (Procurement and Logistics Management Cell). SIAPS staff embedded in the MOHFW worked with PLMC team steadily and effectively provided technical assistance in procurement. SIAPS's technical assistance has been appreciated by the ministry, especially the Senior Secretary of the MOHFW who expressed his appreciation and requested that SIAPS BD gradually extend technical assistance to cover all relevant health areas. MOHFW SCMP (Supply Chain Management Portal) and other management tools are in use by relevant staff in the MOHFW and its directorates. The Senior Secretary and other managers are closely monitoring the effective use of these tools. During this reporting period, SIAPS BD facilitated two days User Acceptance Testing (UAT) sessions on the MOHFW SCMP for the PLMC team. With active involvement of the Directorate General of Drug Administration (DGFP), based on DGFP experience, SIAPS BD assisted the MOHFW to draft the structure and terms of reference of the Supply Chain Coordination Forum (SCCF) to be established for the Directorate General of Health Services (DGHS).

National TB Control Program (NTP) has strengthened in record keeping system as SIAPS supported the NTP to introduce a drug management reporting mechanism. SIAPS BD team worked with the NTP for further roll–out e-TB Manager to 80 new sites. An assessment was conducted of 'TB Pharmaceutical Management in Bangladesh' in this quarter. Additionally, an assessment of the regulatory system and pharmacovigilance was conducted and findings were disseminated with key stakeholders. The Senior Secretary was involved and played a vital role with DGDA in disseminating the assessment findings and action plan.

Key challenges faced during the quarter

- Political unrest hampered timely implementation of UIMS training;
- Lack of adequate focus on holding DGFP monthly supply chain management meetings due to other priority activities;
- Prior to the SIAPS intervention, CMSD/DGHS monthly meetings were not held. Time was necessary to build consensus on objectives and terms of reference, and to introduce the meeting to participants;
- Previously key performance indicators (KPI) for the procurement management system were not established; and
- Consensus building took time within the CMSD team to introduce quarterly Supply Chain Coordination Forum meetings with relevant stakeholders.

Key activities planned for next quarter

- Conduct a Logistics Management Workshop for DGFP Supply Officers and Store Keepers/Pharmacists
- Support DGFP to launch the revised supply manual
- Support the DGFP/MOHFW to launch the procurement procedures manual (PPM) and SM
- Develop a TOT manual for logistics management training
- Conduct a Logistics Coordination Forum (LCF) at DGFP
- Conduct a procurement audit trail and post review training for DGFP Logistics and Supply Unit Procurement Assistants
- Support a five-year forecasting and quantification exercise for essential medicines and maternal, neonatal, and child health (MNCH)products
- Continue to roll-out e-TB Manager

- Update and customize SIAPS supported tools
- Functional ADRM cell in DGDA
- Introduce RDQA
- Facilitate monthly Supply Chain Management meetings with DGHS/CMSD
- Facilitate annual procurement/ tendering process conference of CMSD/DGHS potential suppliers to improve transparency and governance
- Facilitate quarterly DGHS Supply Chain Coordination Forum (SCCF) to ensure health commodities security
- Update the Table of Organization and Equipment for each level of health facilities
- Update existing standard operating procedures (SOPs) for drug supply management
- Support the National TB Program (NTP) to strengthen the Procurement and Supply Management (PSM) Unit in collaboration with relevant stakeholders
- Provide basic e-TB Manager training to relevant staff in 80 new upazilas/sites

Quarterly progress for objective 1: Supply chain management systems of the MOHFW and component procuring entities strengthened

During this quarter, SIAPS BD provided technical assistance to the MOHFW to improve transparency and accountability in supply chain management. To streamline lead time for ministry procurements, SIAPS BD conducted a successful workshop on lead time review. As part of capacity building for ministry staff, SIAPS BD sponsored four MOHFW staff members to participate in a three-week procurement training in Malaysia. During the quarter, extensive training on DGFP UIMS for 313 upazilas was completed in order to strengthen the logistics management system. In addition, SIAPS BD facilitated two batches of five-day basic training on procurement for the Engineering Staff College to enable the college to provide capacity building for government staff.

The monthly supply chain co-ordination meeting of CMSD/DGHS continued as part of system strengthening of MOHFW. The structure and terms of reference of the Supply Chain Coordination Forum (SCCF) was developed to facilitate quarterly meetings and ensure health commodity security.

An assessment, entitled 'TB Pharmaceutical Management in Bangladesh', was conducted. SIAPS BD worked with the NTP to introduce several reporting tools in spreadsheet format for TB drug inventory management reporting at the central and district/upazila levels. SIAPS BD provided technical support to form a Procurement and Supply Management (PSM) unit and 'TB Partners Coordination Meeting' with key stakeholders.

Quarterly progress for objective 2: Transparent and evidence-based decision making increased

The MOHFW Supply Chain Management Portal (SCMP) was updated with active participation of stakeholders. The SCMP provides easy links to other key tools such as DGFP SCIP, UIMS, WIMS, and e-TB Manager. Government ownership of the tools is exemplary in this case and user demand for the tools is increasing daily. These tools save time, money, and labor, and provide accurate data for decision making.

The e-TB Manager tool was introduced in 20 new sites and 80 new sites were selected for further roll out. UIMS has been installed in 150 new sites. A local consulting firm was hired to maintain and update these tools.

Quarterly progress for objective 3: Pharmaceutical regulatory capacity and medicine safety strengthened

The program conducted a comprehensive assessment of the Bangladeshi national medicines regulatory system. An assessment of the pharmacovigilance system capacity and performance, which is co-funded through an inter-agency agreement between the US Food and Drug Administration (FDA) and USAID, formed part of the comprehensive regulatory systems assessment. At a three-day workshop in November, conducted in conjunction

with SIAPS' partner, the University of Washington, results and findings of the assessments were disseminated and action plans developed. The workshop also included basic training on pharmacovigilance.

Quarterly progress toward sub-objective 1.1: Procurement management systems improved

SIAPS BD supported two DGHS/CMSD monthly supply chain management meetings to facilitate systems strengthening. A decision was taken to hold the CMSD annual procurement/tendering process conference in the next quarter. Draft key performance indicators were developed and shared with key stakeholders to build consensus on procurement efficiency measurement.

A one-day workshop on procurement lead time review was facilitated to ensure more efficiency in the procurement process. SIAPS supported the MOHFW to draft its procurement procedures manual (PPM) which will be shared with relevant stakeholders in the next for necessary inputs to finalize the manual. Background information was collected and a draft scope of work developed for developing a 5 year forecast and quantification of tracer drugs including selected MNCH products, such as misoprostol, oxytocin, mag. sulphate, etc. for DGHS and DGFP. In this quarter, a draft and structure was developed to implement centrally coordinated forecasting, quantification, and supply planning within DGHS at national level. This draft will be reviewed by the CMSD Director.

The consolidated procurement plan for the request for procurement action (RPA) was approved by the World Bank through regular facilitation by SIAPS. As part of system strengthening of the MOHFW, five standard bid documents of goods for procurement were reviewed before sending to World Bank under RPA 2012-13.

Challenges in progress toward sub-objective 1.1

PLM Cacell of MOHFW, requested a very wide array of technic**a**l assistance support from SIAPS BD. SIAPS will work with the ministry to prioritize request which fall under the SIAPS mandate.

In order to implement a centrally coordinated mechanism, it requires more time which is tough to incorporate the timeline.

As there were no monthly CMSD/DGHS meetings held before SIAPS intervention, building consensus objectives, terms of reference, and participants took time to introduce.

There were no key performance indicators (KPI) established to measure performance of the procurement management system. Brainstorming to develop indicators and build consensus with partners took time.

Deliverables: Sub-Objective 1.1

- Copy of expert opinions procurement packages.
- Draft SOW for developing a 5 year forecast and quantification of selected MNCH products.
- Meeting minutes of monthly supply chain management meeting
- Draft key performance indicator (KPI) reports

Quarterly progress toward sub-objective 1.2: Logistics management systems strengthened

The structure and terms of reference of the DGHS Supply Chain Coordination Forum (SCCF) was drafted to facilitate quarterly meetings with relevant stakeholders and ensure health commodity security. The formal notification will be issued in the next quarter.

Challenges in progress toward sub-objective 1.2

Lack of enthusiasm for regular monitoring visit by the DGFP high officials

Deliverables: Sub-Objective 1.2

- Draft SCCF terms of reference and structure

Quarterly progress toward sub-objective 1.3: TB logistics management systems improved

SIAPS BD continued to provide technical assistance to strengthen the TB supply management system. A rapid assessment report on 'TB Pharmaceutical Management in Bangladesh' was shared with the NTP, WHO, and other key TB stakeholders. Based on the assessment report, reporting tools in a spread sheet format were shared with NTP and have been successfully introduced at central TB warehouse drug inventory management report. At the same time, a simple version of the same excel spreadsheet was developed and shared with NTP to introduce in the district/upazila level TB drug inventory management report. NTP with technical assistance from SIAPS BD has formed a PSM Unit committee. SIAPS facilitated a TB Partners Coordination Meeting with participation of relevant partners (e.g. URC, WHO, BRAC etc.). To introduce new changes in the revised e-TB Manager websites and new options in system, refresher training has been arranged for relevant TB staff in six pilot sites. As per the SIAPS BD work plan, SIAPS BD supported the NTP and WHO to select 80 new e-TB Manager sites for roll out. These new sites have been selected and approved by the NTP Line Director. During this period, SIAPS BD sponsored two government representatives and one program staff member to participate in the 43rd World Union TB Conference held in Kuala Lumpur, Malaysia.

Challenges in progress toward sub-objective 1.3

Delay in forming PSM Unit Committee.

Deliverables: Sub-Objective 1.3

- TB logistics management system review report.
- Meeting minutes of TB partners' coordination meeting.
- Spreadsheet for TB drug management report.
- Training report on e -TB Manager
- International Union Conference Trip Report

Quarterly progress toward sub-objective 1.4: Capacity of MOHFW, its directorates, and local institutions to effectively manage supply chain functions improved

During this quarter, SIAPS BD provided training on procurement management roles to the PLMC. A Memorandum of Understanding (MoU) was signed with Engineering Staff College to collaborate with indigenous institutions to organize professional training on procurement and supply chain management. Two batches training were completed. A huge task has been successfully completed in this quarter which was training 313 Upazillas to run DGFP-UIMS. In this endeavor, a master trainer from DGFP was utilized.

A three-day training for all DGDA staff on drug regulatory and pharmacovigilance systems was also held in this quarter with support from SIAPS/HQ and the University of Washington. As the mandate of SIAPS BD is to 'Support government counterpart staff/program staff to attend national and international conferences/ seminars/

workshops on supply chain, pharmaceutical management, MCH, and related issues', four representative from government (including one from DGFP, 2 from DGHS and one from the MOHFW's PLMC) attended a procurement training in Malaysia.

Challenges in progress toward sub-objective 1.4

- Political unrest slightly hampered the last couple of batches of UIMS training.
- Hiring local staff at DGDA.
- It took time to issue a government order for government staff to participate in a foreign training.

Deliverables: Sub-Objective 1.4

- PLMC Training Report (Draft).
- Report on pharmacovigilance system training.
- Report on procurement training Malaysia.

Quarterly progress toward sub-objective 2.1: Availability of quality data increased

SIAPS facilitated preparation of the DGFP stock status report, TB stock status report, TB case line listing, PPMR, etc for policy makers to have up to date information for evidence based decisions. SIAPS BD initiated discussion with NTP to introduce a data quality assessment (DQA) mechanism to verify quality data input and use at every level. Eighty new sites have been selected for e-TB Manager roll out in consultation with the NTP and WHO. SIAPS BD quarterly Newsletter was drafted and will be finalized and shared in the next quarter.

Challenges in progress toward sub-objective 2.1:

Ensure timely update of procurement process data
Building consensus standardized specifications
Timely flow of information and actions required

Quarterly progress toward sub-objective 2.2: Innovative tools for commodity management developed, deployed and used

A local IT firm was under a purchase order to upgrade and maintain management tools developed under the program e.g. (DGFP SCIP, MOHFW SCMP, e-TB Manager, TB-LMIS, UIMS, WIMS etc.).

UIMS installation in 150 new sites was been completed during the quarter. Initially a pool of trainers from DGFP has created to foster the installation process and functioning. DGFP master trainers are providing on-site support to ensure functioning of the tool.

Challenges in progress toward sub-objective 2.2

- In few cases, DGFP master trainers were not granted supervisor permission to visit other areas
- Building consensus standardized specifications
- Timely flow of information and actions required
- Improving the information and communication technology (ICT) infrastructure at all levels
- Delay in hiring a local IT firm

Deliverables: Sub-Objective 2.2

- Data back -up of the IT tools
- Installation report
- Performance matrix of the local IT firm

Quarterly progress toward sub-objective 3.1: Drug administration (DGDA) and regulatory capacity improved

SIAPS facilitated an assessment of the DGDA's regulatory capacity and a three-day workshop for DGDA staff on RSAT. A long and short term action plan was designed the workshop. The Senior Secretary of the MOHFW hosted the dissemination session while the Director General of Drug Administration was present as Workshop Chair. An initial discussion was held with DGDA on the automated regulatory management system e.g. PharmaDex. The workshop participants suggested that SIAPS BD support the MOHFW to conduct a situational analysis on customization of the tools according to the DGDA requirements.

Challenges in progress toward sub-objective 3.1

Limited availability of regulator documents was a great challenge in conducting the assessment

Deliverables: Sub-Objective 3.1

- Draft assessment report on regulatory capacity of DGDA
- Dissemination workshop report on regulatory capacity of DGDA

Quarterly progress toward sub-objective 3.2: Medicine safety improved.

SIAPS BD facilitated an assessment of the DGDA pharmacovigilance system and sponsored a three day pharmacovigilance workshop for DGDA staff. At the workshop, a short and long term action plan was designed.

Challenges in progress toward sub-objective 3.2

The recruitment process for SIAPS BD focal point for drug administration is underway.

Deliverables: Sub-Objective 3.2

Assessment report and notification of ADRM cell

Brazil

Year 1 Work Plan

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

Overall Quarter Progress

SIAPS has continued to implement all planned activities, despite all difficulties/barriers faced. Highlight for the past quarter was SITETB implementation which concluded our planned goals in accordance with our agreement with Brazilian NTP's demand. This will be our main goal to be achieved by the end of our project (planned for April 2013). We have conducted trainings in 19 states. Eleven (11) more trainings are programmed for the upcoming months, to ensure that training has covered the whole country.

Key challenges faced during the quarter

SIAPS had significant problems during last quarter since we had staff changes in our team that compromised seriously our capacity of managing our challenges. Senior Technical Advisor Luis Gustavo Bastos was transferred to headquarters (by the end of September), our Director Joel Keravec was named Director of GDF, our Java Programmer Ricardo Memoria had his supervision changed to MSH/Arlington and many of our consultants were relocated in other Brazilian institutions. Beside all those problems, we also 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 as happened before during the implementation of our work plan.

Due to unknown reason USAID local mission requested all documents (work plans) from the beginning of our project in Brazil (2004) generating difficulties since that required a significant time to gather all the information.

Key activities planned for next quarter

- SITETB training for 11 new states of Brazil achieving 100% of all states.

  Develop final report measuring the impact of SIAPS support given to Rio de Janeiro state municipalities.

  Complete all planned activities to support Hélio Fraga laboratory accreditation.

  New meeting planned for all partners involved in the new rapid TB tests PPP.

  SIAPS shutdown event, with the participation of all our partners.

Quarterly Progress for Objective 1: Strengthen TB pharmaceutical management and information systems

SIAPS has continued to support Brazilian government towards the transmission of SITETB ownership, 70% of Brazilian states were already trained in SITETB. Agreement was to capacitate all states of Brazil as well as preparing SITETB documentation and reporting module, these will be our key goals for the upcoming quarter.

Quarterly Progress for Objective 2: Support TB state programs in strengthening DOTS and community DOTS implementation

Final report with detailed evaluation of the support given to DOTS implementation was requested to Rio de Janeiro State TB Program. Activities proposed by São Paulo State TB Control Program (PEC-TB SP) were performed

Quarterly Progress for Objective 3: Strengthen Hélio Fraga National TB Reference Center activities and the Public Health TB Laboratory network

SIAPS provided technical support for strengthening CRPHF‘s capacity specifically linked to its accreditation, Hélio Fraga Center accreditation process was fully incorporated by Fiocruz foundation quality committee, all activities performed with SIAPS support will be key to complete the requirements for accreditation established by Joint Commission.

Quarterly progress toward sub-objective 1.1: Support incorporation of key drug management achievements and policies within the public health system

Production of Isoniazid 300 mg was approved by Brazilian government and is on-going. 4 FDCs and 2 FDCs production still pending since there was yet no approval from Anvisa

Challenges in progress toward sub-objective 1.1

4 FDCs and 2 FDCs production are still pending since there was no approval from Anvisa

Deliverables: Sub-Objective 1.1

- Isoniazid 300 mg is under production and all process towards this new production was supported by SIAPS

Quarterly progress toward sub-objective 1.2: Support SITETB (Brazilian e-TB Manager specific version) long term sustainability, management and use countrywide

SIAPS has continued supporting Brazilian NTP program overcoming the planned states for SITETB training. Decision was to cover the whole country, attending NTP's demand for SITETB implementation.

SITETB reporting module is 50% concluded.

Software documentation and transfer to MoH's server will only be done after all 27 states are trained, as agreed with NTP.

NTP SITETB Committee was defined last December with medical professionals and pharmacists responsible for validating cases and managing medicines through SITETB.

Challenges in progress toward sub-objective 1.2

Interoperability between SITETB and São Paulo-SP TB electronic system (TBWEB) activity was cancelled due to delay on the definition of the type of consultancy responsible for the interface between both systems. It would only be possible through a 3rd part company, which is not compatible with MSH requirements. The interoperability between both systems will be negotiated by São Paulo State TB Program directly with DATASUS in the future.

Deliverables: Sub-Objective 1.2

- 7 trainings conducted in the following states: Ceará, Maranhão, Piauí, Minas Gerais, Rio de Janeiro, Rio Grande do Norte and Sergipe (Total staff trained: 206 (F-172 / M-34))
- Reference centers SITETB units using case management and medicine management: 88 (total planned: 46)
- States using SITETB: 16 (total planned: 16)
- Number of professionals trained in SITETB during current quarter: 206 (34 men and 172 women)
- States using SITETB: 16 (planned total: 16)
- Percentage of registered cases in SITETB regarding MDR-TB cases reported in the System: 5426/5849 X 100 = 92%
- Number of registered users in SITETB: 311 (cumulative total: 461)
- Number of registered institutions in SITETB: 44 (cumulative total: 107)
- No. of transactions: 17.395 (cumulative total: 47.919)
- Number of cases of DR-TB managed by SITETB: 1.363 (cases on treatment)
- Attendance on meetings held: 1 (planned total: 1)
- Two meetings with the NTP’s information working group to discuss issues relating to Sinan system’s new version and SITETB cases inputs and outputs.
- # of cases of CE, MA, MG, PI, RJ e RN migrated from TBMR System: 2.491
- # Number of cases of CE, MA, MG, PI, RJ e RN notified directly in SITETB: 36
- # Cases migrated from TBDR system and those that were reported directly in SITETB: 5.426

Quarterly progress toward sub-objective 2.3: Support the SP State TB program in implementing specific TB control activities

3 activity lines 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 were conducted. Final reports will be sent to SIAPS team.

Quarterly progress toward sub-objective 3.1: Support Hélio Fraga Center in delivering its key mandate as National TB Reference Center

The guideline for Pharmaceutical Care was finalized.

Fiocruz Foundation Quality Committee has taken the responsibility for Hélio Fraga Center accreditation process, through Joint Commission. All support provided by SIAPS will be used for their accreditation.

Constraints linked to Biosafety requirements will not interfere anymore for the Pharmacy accreditation process since there was a decision to move the Pharmacy Care will be moved to Hélio Fraga Center Ambulatory.

All SOPs for the laboratory were reviewed by SIAPS consultant.

WHO Biosafety Manual was translated into Portuguese and is currently available to Hélio Fraga Center Lab staff

Challenges in progress toward sub-objective 3.1

Hélio Fraga Center has no staff available with the required background to take responsibility overall activities linked to laboratory accreditation process.

Deliverables: Sub-Objective 3.1

- 43 SOPs reviewed for Hélio Fraga Center Laboratory;
- WHO Biosafety Manual translated into Portuguese;
- All documents developed with SIAPS support were transferred to Fiocruz Quality Committee;

Quarterly progress toward sub-objective 3.2: Support Public Health Laboratory Network in using Labmost methodology to strengthen Laboratory Quality Management Systems and accreditation process

SIAPS carried out jointly with INCQS new Labmost workshop (second one) for 25 staff (24 females and 1 male) of Adolfo Lutz Institute (São Paulo City Public Health Lab) focused on products area (medicines, cosmetics, sanitizers and food).

Quarterly progress toward 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

(31 Dec 2012) - SIAPS has delivered all expected supplies for the project's conduction. Remaining participation of SIAPS will be on the edition of the final report.

Challenges in progress toward sub-objective 3.3

Due to a long strike at Brazilian customs authority, raw materials imported by BD (Becton, Dickinson and

Company) for MGIT test were not delivered, turning impossible comparison analysis with GeneXpert results, delaying the project schedule.

Burundi

Year 2 Work Plan

Quarterly Report Background

In 2011, the National Malaria Control Program (PNILP) with its stakeholders, embarked on a review of the malaria program to evaluate the performance and impact of malaria control interventions. An in-depth analysis identified major achievements, in particular, universal access to bed nets , and routine distribution of nets to pregnant women and children under 1, free rapid and microscopy tests for malaria diagnosis and treatment of women and under-5 children in the public sector, introduction of indoor residual spraying in two high burden districts, a pilot to introduce community case management in selected districts; strong commitment from the Government of Burundi (GoB) and key stakeholders to a coordinated joint annual work plan, and an increase of resources available for interventions and procurement of malaria commodities. These factors increased access to malaria diagnostic and treatment services, thereby significantly reducing mortality due to malaria. At the end of the malaria program review, the GoB and key stakeholders signed an agreement, reaffirming commitment to join efforts in fighting malaria in alignment with the 2011-2015 National Health Development Plan (NHDP II). The agreement defines the strategic direction that will guide interventions of the GoB and partners towards the achievement of goals defined in the NHDP II and Millennium Development Goals during the period of 2011-2015. Key relevant issues, gaps, concerns, and opportunities for improvement related to the management of the PNILP, coordination of stakeholders and the pharmaceutical management systems were identified and have guided the development of the SIAPS Year2 work plan.

The Strengthening Pharmaceutical Systems (SPS) Program received funding from USAID/Burundi from 2009-2011 to address pharmaceutical management challenges in malaria control, 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 malaria short-term technical assistance in Burundi. Based on the successful implementation of SPS, the follow on program, the Systems for Improved Access to Pharmaceutical and Services (SIAPS) Program received funds to provide technical assistance to the PNILP and other key partners (Directorate of Pharmacy, Medicines and Laboratories (DPML); Directorate of Pharmacy, Medicines, and Laboratories (DPML); Centrale d'Achat de Medicaments Essentials du Burundi (CAMEBU); Direction de l'Offre et de la Demande des Services (DODS); and districts) in the successful implementation of interventions recommended by the malaria review program. SIAPS assisted the PNILP to review national standard treatment guidelines, develop an annual joint work plan, organize quarterly review meetings to track progress and adapt future interventions accordingly, obtain equipment as necessary, and design a supervision system and tools for central and district levels. Additionally, SIAPS organized trainings/refresher trainings for stock managers to ensure proper management of malaria commodities, etc.

During Year 2 (FY13), SIAPS continues to build strong partnerships and coordinate efforts with Global Fund, United Nations Children's Fund (UNICEF), DPML, and CAMEBU to assist the PNILP and USAID to implement successful interventions towards reducing the morbidity and mortality due to malaria through strong case management and the availability of needed commodities. FY13 funding will be used to ensure that leadership and governance is strengthened for both the pharmaceutical and malaria sectors; the capacity for pharmaceutical supply management of malaria commodities and services is increased and enhanced; information for decision-making challenges in the malaria and pharmaceutical areas are addressed; and case management of malaria and organizational capacity of the PNILP and DPML are improved to achieve desired health outcomes.

Goal: Strengthen keys institutions (PNILP, DPML, CAMEBU and Districts) in reducing mortality and morbidity due to malaria through strong case management and availability of malaria commodities.

Overall Quarter Progress

To improve the organizational structure of the PNILP and DPML, SIAPS assisted the PNILP and Roll Back Malaria (RBM) in-country stakeholders to strengthen coordination through a collaborative process of developing a joint annual work plan for 2013. The team defined objectives and targets for 2013, as well as key interventions aimed at reducing morbidity and mortality due to malaria in 2013. The joint work plan will be validated during in January 2013 and monitored on a quarterly basis.

SIAPS assisted PNILP to flow national planning to the district level through a workshop with district heads. PNILP presented national objectives and targets to be integrated into district work plans and provided feedback on findings from supervision visits. Recommendations were made to improve the case management of malaria through a correct diagnosis and confirmation of malaria cases before treatment, appropriate dosages with proper counseling to patients to improve adherence, as well as strategies to ensure a continuous availability of malaria commodities with accurate reporting on consumptions at all levels.

In November, SIAPS assisted the PNILP to conduct the first national quantification training for 20 national experts representing various institutions involved in quantification of health commodities. The training provided basic concepts and methods of quantification in general, with a focus on malaria commodities. A practical exercise that quantified malaria commodities needed in 2013 was conducted. The training produced draft quantification and forecasting for all needed malaria commodities, as per the new standard treatment guidelines.

Despite global efforts to scale up the use of artemisinin-based combination therapies (ACTs) in Burundi through PMI and Global Fund procurements, nation-wide coverage remains poor, with public sector health facilities frequently plagued by stock-outs while products are available at the central medical stores (CAMEBU). During the quarter, SIAPS collaborated with DPML and PNILP to conduct a qualitative survey on deep causes of stock out of ACTs and RDTs at peripheral level. SIAPS will organize a dissemination meeting with the DPML, PNILP, and all districts teams to share findings and identify approaches to ensure uninterrupted availability of ACTs at all levels.

During the quarter, the Procurement Planning and Monitoring Report (PPMR) for October to December 2012 found that all formulations of ACTs and RDTs are available in sufficient quantities to cover needs of the country in 2013. An order should be placed to complete the 6-months buffer stock at national level and quantities per commodity were calculated and shared with USAID/PMI and the Global Fund.

To strengthen the case management of malaria, SIAPS assisted the PNILP with its stakeholders to review and update the national malaria treatment protocol as per the recent recommendations from WHO. SIAPS collaborated with PNILP in the dissemination of new treatment guidelines training a pool of trainers to form the basis of a cascading training.

Due to the end of the Improving Malaria Diagnosis project in Burundi, a consensus meeting was held between all involved parties to coordinate all efforts to ensure 365 laboratory technicians would be trained. During the quarter, SIAPS took over the organization and completed the training of laboratory technicians.

SIAPS is supporting a pilot of community case management of malaria in two districts to determine the whether utilizing community health workers (CHWs) to diagnose and treat malaria cases is a feasible strategy for reducing mortality in children under 5. SIAPS assisted the PNILP to conduct a situational analysis of the program, called PECADOM, and to identify areas that need strengthening in the coming months before the end-evaluation of the pilot in March 2013. A new monthly report template was also introduced to ease compilation and reporting processes.

Key activities planned for next quarter

- Support PNILP and partners to disseminate new malaria standard treatment guidelines (STG) at the district level
- Implement community case management (CCM/PECADOM) pilot in two districts
- Collaborate with PNILIP to develop internal control procedures for the PNILP
- Train PNILP staff on key identified courses
- Support monitoring and supervision of districts managers on the pharmaceutical management of malaria commodities
- Orient the pharmacovigilance technical committee to develop guidelines for a pharmacovigilance system in Burundi
- Support a feedback meeting with district teams to disseminate the qualitative study results on the deep roots of ACTs stock outs

Quarterly progress toward sub-objective 1.1: Leadership and governance of the PNILP improved

From December 17- 21, SIAPS participated in the supervision of the MIS in Ruyigi and Gitega provinces. The objective of the supervision was to check on quality of data collection with a household questionnaire approved for the MIS. The data collection will conclude end of January 2013. Main indicators related to malaria are: number of households that have used a method of prevention and vector control (IRS, LLIN). Preliminary results with key indicators will guide the development of the PNILP strategic plan for 2013-2016, and will be available in April 2013.

During the quarter, SIAPS assisted the PNILP and Roll- Back Malaria (RBM) in-country stakeholders to collaboratively develop a joint annual work plan for 2013. The work plan development exercise started with 3-day retreat of the PNILP key staff and all stakeholders organized October 23- 25, 2012. The retreat resulted in defined objectives and targets for 2013, as well as key interventions aiming to reduce morbidity and mortality due to malaria in 2013. All stakeholders work plans were adapted to those objectives and targets. The final draft of 2013 PNILP joint work plan was validated during the RBM in-country quarterly meeting held January 17-18, 2013. New RBM partners were introduced, such as Networks (a USAID funded NGO assisting the PNILP in the development of a strategy of a continuous access to LLINs), the Word Relief (international NGO working with UNICEF to integrate the case management of malaria and diarrhea at community level), Abt Associates (USAID funded project with a mandate to assist the PNILP in its vector control strategy), the US Pharmacopeia (USAID /PQM funds to assist the PNILP to ensure quality assurance of malaria commodities). Validation of the 2013 PNILP joint work plan will be conducted in January.

Quarterly coordination meetings between PNILP and its stakeholders will be conducted in April, July, and October 2013 to monitor and evaluate the implementation of the joint annual work plan.

SIAPS assisted the PNILP to organize a 1-day meeting with all 45 heads of districts on October 26, 2012. During this meeting, PNILP presented objectives and targets defined for 2013 to be integrated in district work plans for smooth implementation and synergy. PNILP provided feedback on findings from supervision visits conducted in 42 districts (out of 45) during the quarter using the check-list for supervision integrating all aspects of malaria developed in June 2012. Recommendations were made to improve the case management of malaria through a correct diagnosis and confirmation of malaria cases before treatment, appropriate dosages with proper counseling to patients to improve adherence, as well as strategies to ensure a continuous availability of malaria commodities with accurate reporting on consumptions at all levels.

A list of policies to be developed was integrated in the work plan, such as (1) the community case management policy that will guide the scale-up after the end-evaluation of the pilot project in 2 districts, (2) the IPTp policy, and

the (3) PNILP 2013-2016 strategic plan depending on the MIS results, (4) the internal management standard operating procedures (SOPs) of the PNILP which will be developed in February to improve managerial capacity of both financial and human resources.

Quarterly progress toward sub-objective 1.2: Efficient and transparent pharmaceutical management systems developed

During the quarter, SIAPS assisted the DPML to organize a 2-day meeting with its stakeholders to develop the 2013 joint work plan. The work plan is finalized and validated. The activity will be done in collaboration with SCMS. A consultant is being recruited by SCMS to design a distribution system. The activity will start in the next quarter.

During the quarter, the thematic working group meeting was not held by the DPML due to conflicting of agendas. A meeting is planned in January 2013 around pharmacovigilance.

Quarterly progress toward sub-objective 2.1: Pharmaceutical management of health districts, DPML, PNILP, and CAMEBU strengthened

From November 27-30, 2012, SIAPS assisted the PNILP to conduct the first national quantification training for 20 national experts representing various institutions involved in quantification of health commodities, such as DPML, CAMEBU, PNILP (Malaria), PNLS (HIV), PNLT (TB), PNSR (HR), PEV (vaccines), CNTS (Blood transfusion), SEP/CNLS- HIV, SEP/CNLS-Malaria, RBP+, INSP (laboratory services), FHI 360, MSF/Belgique, and PSI (LLINs). This first quantification training provided basic concepts and methods of quantification in general with a focus on malaria commodities. A practical exercise that quantified malaria commodities needed in 2013 was conducted. An excel sheet was used to facilitate the experts to quantify needs for malaria commodities. At the end of the training, drafts of quantification/forecasting of all needed malaria commodities, such as ACTs, RDTs, LLINs, and laboratory commodities and medicines for severe malaria (quinine, clindamycin, artesunate injectable) as per the new STG were completed. The draft quantification report will be validated through a consensus meeting in January 2013.

SIAPS performed a pipeline analysis for malaria commodities, together with PNILP, DPML, and SEP/CNLS-Malaria to identify and anticipate problems with stock outs and expiries. From the analysis, all formulations of ACTs and RDTs are available in sufficient quantities to cover needs of 2013 and distribute to all the 45 districts based on the most accurate Average Monthly Distribution (the AMD were updated in all the districts, as well as the AMC at health center level).

Quarterly progress toward sub-objective 3.1: Pharmaceutical management information systems (PMIS) support both products and patients

During the quarter, SIAPS collaborated with DPML and PNILP to conduct a qualitative survey on deep causes of stock out of ACTs and RDTs at peripheral level. Despite efforts to scale up the use of artemisinin-based combination therapies (ACTs) in Burundi through procurements made by PMI and Global Fund, nation-wide coverage remains poor, with public sector health facilities frequently plagued by stock-outs while products are available at the Central medical stores (CAMEBU). A data collection with a questionnaire developed by SIAPS was concluded from October 8-12 in 11 district pharmacies and 29 health centers chosen randomly to cover geographically the whole country. Focus groups were performed to collect views of staff at the peripheral level. Data were collected on: (1) flow of requisition, (2) process of reporting, (3) requisition and consumption analysis. Findings showed that causes of stock-outs vary, but often reflect poor planning and weak supply chain management systems. SIAPS will organize a dissemination meeting with the DPML, PNILP, and all districts teams to share findings and identify approaches to ensure uninterrupted availability of ACTs at all levels. An appropriate

improvement plan for 2013 will be adopted. The survey results were presented during the American Society of Tropical Medicine and Hygiene meeting on November 20, 2012.

During the quarter, a feedback meeting on the qualitative survey conducted on deep roots of ACTs stocks outs was postponed due to conflict of agenda. The meeting is rescheduled end of February 2013.

Quarterly progress toward sub-objective 3.2: Tools (EUV, PPMRm) used to generate necessary information on commodity availability and case management of malaria

During the quarter, the PPRM for October to December 2012 was conducted. All formulations of ACTs and RDTs are available in sufficient quantities to cover needs of 2013. An order should be placed to complete the 6-months buffer stock at the national level. Necessary quantities per commodity (ACTs, RDT) to procure were calculated and shared with USAID/PMI and the Global Fund.

Quarterly progress toward sub-objective 4.1: Diagnosis, prescription and dispensing practices are complying with the new standard treatment guideline to improve the quality of case management of malaria

To strengthen case management of malaria, SIAPS assisted the PNILP with its stakeholders to review and update the national malaria treatment protocol as per the recent recommendations from WHO. In preparation of the dissemination of the new treatment guidelines, SIAPS completed the printing of all materials necessary to disseminate the new STG malaria, including 1,200 STG documents with all algorithms and annexes. The dissemination will coincide with the trainings of trainers at district level starting in January 2013, with heads of districts, including medical doctors, supervisors, and HMIS managers.

A dissemination plan of the new STG malaria with all trainings (TOT, cascades trainings) was developed and validated by all involved parties (PNILP, DPML, SEP/CNLS- GF Malaria, districts). From November 13- 16, 2012 refresher training of trainers (TOT) on the new STG malaria was conducted for a pool of 15 experts at the national level. The experts represented various institutions such as PNILP, DPML, selected districts, and SEP/CNLS. Facilitators were identified within WHO, PNILP, SIAPS, and DPML.

Starting next quarter in January 2013, a TOT will be organized for 238 representatives of districts who will take responsibility for the cascades training to 1,650 healthcare providers in all health facilities. Copies of STG will be available throughout all districts.

A new activity was given to SIAPS in October, following to the end of IMAD (Improving Malaria Diagnosis) project in Burundi to ensure trainings of laboratory technicians are organized in 24 districts staff that were not yet trained, nine districts were supported with WHO funds. The IMAD was mandated by the USAID to provide assistance to the PNILP and DPML to improve diagnosis of malaria, the new STG of malaria recommends to diagnosis all presumed malaria cases before treatment. At the end of IMAD, a consensus meeting was held between all involved parties in improving malaria diagnosis (PNILP, DPML, INSP, SEP/CNLS-Malaria, USAID, and SIAPS) to coordinate all efforts to ensure 365 laboratory technicians being trained. During the quarter, SIAPS took over the organization and completed the trainings of the laboratory technicians.

Challenges in progress toward sub-objective 4.1

Conflicts of agenda within our counterparts (PNILP and DPML) delayed the implementation. In the future, SIAPS will take steps to improve planning.

Quarterly progress toward sub-objective 4.2: Community case management implemented to improve access

to diagnosis and treatment of malaria in 2 pilot districts

SIAPS worked closely with the Extending Service Delivery (ESD) program managed by Pathfinder International to support the implementation of a community case management (CCM/PEDACOM) pilot program in two districts. This pilot works with community health workers to diagnose and treat malaria cases to reduce mortality in children under 5 years. During the pilot project, SPS, and later SIAPS, provided technical assistance to the PNILP and ESD on management of commodities. With the conclusion of the ESD project in September 2012, SIAPS took over the CCM pilot activity with an official hand-over ceremony held in October 2012 between PATHFINDER and SIAPS, in the presence of the PNILP and USAID. The end-evaluation is now included in the scope for SIAPS for 2012-2013.

To support the implementation the community case management of pilot in two districts (Kayanza, Muyinga), SIAPS will assist the PNILP to conduct a situational analysis to understand the current status of PEDACOM implementation and to identify areas that need strengthening in the coming months. The situational analysis used a community health worker assessment and improvement matrix, called AIM. A dissemination meeting of the rapid assessment was held for the two districts teams and all the 25 head of centers where the PECADOM is being implemented. Findings were shared and recommendations agreed upon.

The assessment led to the following: Necessary equipment is being procured to complete the CHW kit. A recruitment of ten new CHWs who needed to be replaced was organized in December and their orientation is planned in January 2013 with two weeks of practical exercise in their respective health centers to be fully operational. All 402 CHWs need a refresher training after more than 6 months of work. The refresher trainings will emphasize the use of rapid diagnosis test (RDT) and treatment with ACTs, as well as the key messages and counsels provided to mothers to improve awareness on prevention of malaria and also to improve adherence to treatment. Best practices introduced will be the continuous refresher training coupled to the monthly meetings at health center where CHWs will be provided a refresher on a particular theme and do practical exercise through direct observation on the use of RDT.

To strengthen the resupply system and ensure uninterrupted availability of commodities (ACTs, RDTs, gloves, security boxes), SIAPS reviewed the requisition process of ACTs and RDTs and distributed a top up stock in December to ensure all the CHWs have a maximum stock of commodities. A stock of gloves was procured while waiting the advocacy to health centers to integrate needs of CHWs in their respective budgets. The supervision system is weak and irregularly done. SIAPS advocated to all 25 health centers to avail funds (equivalent to 50 $/month) for supervision of CHWs. Only three health centers will not be able to dedicate funds to supervision. Currently, SIAPS is in discussion with the PNILP and the Ministry task force managing performance based financing to remunerate services provided by CHWs. The funds provided through the performance based financing mechanisms could be used to ensure resupply of commodities, refresher trainings of CHWs, as well as supervision.

During the quarter, a new monthly report template was introduced and discussed with the heads of all health centers. Currently, all 402 CHWs are entered in a database which managed by the ESD Project. Starting November, a new monthly compiled report was available at health centers and will ease the compilation and reporting on PECADOM activities. Only the 25 complied reports will be submitted to the districts. A new database with key indicators was developed. HMIS managers in the two districts will be oriented on the management of the database in January 2013.

Deliverables: Sub-Objective 4.2

- Quantification training materials and training report
- Quantification report on malaria commodities
- Training material on the new malaria standard treatment guidelines (STG)

- Training report on the TOT for the new malaria standard treatment guidelines
- PECADOM implementation report
- Training report on diagnosis of malaria
- Support to the development of 2013 PNILP work plan

Cameroon

Year 1 Work Plan

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 are 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.

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

Overall Quarter Progress

SIAPS Cameroon continued to use its Year 1 funding to finalize implementation of year 1 work plan. During the quarter between October and December 2012, SIAPS Cameroon program made progress toward 4 work plan objectives (Objectives 1, 2, 3 and 4). Under Objective 1, SIAPS initiated with the Directorate of Pharmacy of the Ministry of Public Health, the development of standards operating procedures for the management of HIV/AIDS commodities at regional and health facilities levels. Under Objectives 2 and 3, SIAPS initiated the development of the CNLS Pharmaceutical Supply Management (PSM) action plan for HIV/AIDS commodities. This plan included the trainings for pharmaceuticals managers at all levels of the chain, and training to address improvement of information system as well. Under Objective 4, SIAPS revised the CNLS manual for the procurement and management of HIV/AIDS commodities based on the Global Fund feedback.

Key challenges faced during the quarter

MSH has been able to complete one part of the country registration process. The Ministry of Territorial Administration and decentralization had provided last November 12th to MSH an official authorization to operate in Cameroon as a foreign association. MSH to be able to get tax exemption and custom duties exoneration, is still exploring with the Ministry of Public Health on how through a partnership MOU, MSH could be officially granted exoneration.

Key activities planned for next quarter

During next quarter, SIAPS will:

- work with DPM and the National Aids Control commission (CNLS) to finalize the Standards Operating procedures manual(SOPs)for the management of HIV Aids commodities at the region and health facilities levels;
- Continue to work with DPM and key other partner like ESTHERAID, CHAI, etc. on area of collaboration

to support mechanism of coordination for the procurement and quantification of HIV Aids commodities.
- Provide equipment to central and regional medical stores (CENAME and 4 CAPRs) in the South West, North West, East and Adamawa regions of Cameroon in order to increase storage and distribution capacity.
- support CNLS in the coordination of their PSM action plan with other partners
- support CNLS to start implementation of training plan
- Support the Disease Control Program (DLM) through its Neglected Tropical Disease (NTD) program to explore feasibility of implementing their NTD commodities Supply chain management plan.

Quarterly Progress for Objective 1: Pharmaceutical sector governance strengthened

Under this objective, SIAPS did provided financial and technical support to DPM and CNLS to develop standards operating procedures (SOPs) for the management of HIV Aids commodities at region and health facilities levels. A workshop of 3 days was held in Ebolowa where all the CAPRs, 2 representative of the Groupe Technique Regional (GTR) of CNLS. As a result, a draft SOPs was developed.

Quarterly Progress for Objective 2: Capacity for pharmaceutical supply management and services increased and enhanced

SIAPS used the Ebolowa platform during the SOPs development to complete the validation process of the CAPR warehouse capacity improvement plan of the remaining regional medical stores CAPRs.

SIAPS also launched the tendering process for CENAME storage equipment. This equipment will help CENAME to increase storage and warehouse management capacity.

Quarterly Progress for Objective 3: Utilization of information for decision making

There was no progress made under this objective during that period. However, SIAPS supported CNLS to develop their PSM action plan which include training plan that will address information system and tools for HIV/AIDS commodities management.

Quarterly Progress for Objective 4: Financing strategies and mechanisms to improve access to medicines strengthened

Starting December 2012, SIAPS provided technical assistance to CNLS to revise the CNLS Manual of Procedures for the procurement and management of HIV Aids commodities based on the GF feedback and comments.

Quarterly Progress for Objective 5: Pharmaceutical services improved to achieve desired health outcomes

SIAPS work under Objective 1 to develop the SOPs for HIV Aids commodities at region and health facilities levels. During the next two quarters, SIAPS will implement the basic pharmaceutical management tools during training which will help to address other pharmaceutical services aspects.

Quarterly progress toward sub-objective 1.1: Improved medicines policies, legislation, regulations, norms and standards

SIAPS had made progress on Sub objective 1.1. SIAPS had provided financial and technical support to the DPM last November to develop the SOPs for HIV Aids commodities management at region and ART sites levels. A draft of the SOPs was developed and will be finalize within the next quarter. Once finalize, SIAPS will then

organized with DPM and CNLS a consensus workshop to agree on the SOPs and on the calendar for SOPs implementation.

Quarterly progress toward sub-objective 2.1: Pharmaceutical management capacity of individuals, institutions, organizations and networks strengthened

SIAPS progressed with this sub-objective focused on building capacity of pharmaceutical entities within Cameroon. SIAPS during this quarter completed the process to validate warehouse improvement action plans with the 6 remaining CAPRs. 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).During the quarter, SIAPS also support the development of CNLS PSM plan that includes capacity building plan and training.

Quarterly progress toward sub-objective 3.1: Pharmaceutical management information available and used for decision at different levels of the health system

During this quarter, no progress has been made as such but SIAPS helped the CNLS to develop their PSM plan which includes aspects related to the improvement of information flow and system for HIV Aids commodities and trainings that will improve PMIS.

Quarterly progress toward sub-objective 4.1: Financial resources available to the pharmaceutical sector increased

During this quarter, SIAPS helped the CNLS to develop their PSM plan which will address warehouse management capacity and PMIS for HIV Aids commodities management.

Quarterly progress toward sub-objective 5.1: Pharmaceutical services standards defined, adopted and implemented

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.

Democratic Republic of the Congo

Year 2 Work Plan

Quarterly Report Background

The Democratic Republic of the Congo (DRC) is a country characterized by numerous public health challenges, due to 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. Additionally, the vastness of the country combined with lack of transportation infrastructure, renders distribution of health products difficult, and contributes to the stocks-outs frequently found at health facilities.

To address the challenges mentioned above, the United States Agency for International Development (USAID) 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. The current Systems for Improved Access to Pharmaceuticals and Services project (SIAPS), follows the Strengthening Pharmaceutical Systems (SPS) Program, also managed by Management Sciences for Health. Under both SPS and SIAPS, the following major achievements were realized:

-The National Drug Regulatory Authority (NDRA) is now functional and holds quarterly reviews of new drug applications. As of December 2012, the committee registered close to 1000 medicines.

-The MOH has finally taken leadership in the essential medicine procurement coordination: coordinating all partners involved in medicine procurement, available stocks, pipeline, and orders, and statement of available funds, for the first time in decades. Based on this information now available, the MOH has correctly quantified and budgeted for essential medicines and commodities to be procured for the entire country. -Norms and guidelines for maternal, neonatal and child health, were produced 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), amongst others.

-Created with SPS assistance, Provincial Pharmaceutical Committees (CPM) now serve as the only mechanism for planning and coordinating pharmaceutical activities and resolving supply chain bottlenecks at the provincial level.

-Medicines and Therapeutics Committees (MTCs) created in 9 of 80 of the DRC's General Referral Hospitals all received training in MTC management and in how to conduct interventions to improve rational use in health facilities. During Year 1 of SIAPS, these MTCs conducted baseline studies and began implementing corrective interventions.

-After assisting the DRC to become the 99th country to join the WHO Uppsala Monitoring Centre (UMC), the country increased adverse event reporting by health facilities. To date, over 1,900 adverse drug event notifications have been submitted to the WHO Vigiflow database.

-An internal evaluation of the pilot phase of the implementation of the Electronic Dispensing Tool (EDT). The results are to be published during Q2.

Through its provision of field support funds to the new SIAPS project, USAID/DRC is continuing its commitment to improving the functioning of the pharmaceutical sector in the DRC, thus ensuring the availability of quality essential pharmaceuticals and better health outcomes for the Congolese population.

Goal: Improved Access to pharmaceuticals and services

Overall Quarter Progress

Overall SIAPS progressed with SIAPS/DRC project goal of assuring the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health. In Q1 of Year 2, SIAPS/DRC continued improving the functioning of the medicines registration system. The list of medicines registered during Q1 was posted, and this quarter SIAPS supported the printing and dissemination to the provinces of the compiled list of all registered medicines in DRC, as a tool for inspection purposes. The MOH has taken over the leadership of the National Essential Medicines List (NEML) Review Committee by organizing a preparatory meeting to present its roadmap of the 2012 NEML review which is planned for Q2, including the appointment of the review committee members by the MOH at national level and throughout all provinces. The MOH has included this activity in the annual budget at national and provincial level, for the first time.

SIAPS supported the Diarrhea Program of the MOH to launch and disseminate the diarrhea national policy, norms and directives. SIAPS/DRC assistance to the National Medicines Committee (CNM) continued jointly with WHO in organizing a workshop that produced a roadmap to streamline the DRC national medicines procurement and distribution system. The Provincial Medicines Committees continued with their activities of coordinating all partners' pharmaceuticals in the provinces. SIAPS assisted in the preparation of 2013 operational plan of all 4 USAID-assisted provinces in ensuring all resolutions from CPM meetings were included in their operational plans.

MOH, IHP and SIAPS joint supervision visits on medicines management in health zones facilities have provided an opportunity to the MOH to monitor availability of tracer medicines, management tools, inventory, and rational use of medicines. SIAPS monitored closely the delivery of PMI commodities procured through DELIVER and worked with the NMCP in the distribution of ACTs to health zones in the 4 USAID-supported provinces. SIAPS provided technical and financial assistance to the PNAM to update pharmaceutical management tools. These tools are used at all facility levels for pharmaceutical management in the 4 USAID-focus provinces. SIAPS worked closely with IHP in an emergency essential medicines order placed to a newly USAID-approved procurement agent in order to avert an impending stockout in health zones. SIAPS also managed to clear IHP medicines from Missionpharma, consigned in Lubumbashi customs, and distribute them to 3 provinces.

In November 2012, on USAID request, SIAPS shared with the Belgian Technical Cooperation (BTC) the cost of training on "Quality Assurance" organized by QUAMED for all pharmacists responsible for CDR in DRC. SIAPS joint formative visits with the MOH to 99 new PMTCT sites in 2 provinces under PMTCT Acceleration Program allowed the MOH to redistribute overstocked ARVs, analyze the causes of medicines expiry in some PMTCT sites, and recommend medicines disposal procedures. SIAPS organized in October 2012 a briefing on the use of management tools for PMTCT staffs from Kinshasa PEPFAR implementing partners. During this briefing, all PEPFAR partners (8) agreed to use a unique and standardized form for their report on medicines management and to meet quarterly for information sharing.

With assistance from SIAPS/DRC, the national reproductive health program (PNSR) has taken the lead in the procurement and management of FP commodities by calling all partners together to discuss FP commodities distribution and plan for the future. Following the baseline studies conducted in 8 health zones referral hospitals MTCs, and the subsequent related action plan produced by each MTC, the last 2 MTCs have completed the training in medicines rational use. Correctives measures have been implemented in the respective hospitals, as well as introduction to pharmacovigilance. During Q1 these MTCs produced 31 ADE notifications submitted to the CNPV.

Key challenges faced during the quarter

Stock outs at health facilities still occurred during this quarter as the solutions proposed to solve the many causes, external to SIAPS/DRC, are not yet fully addressed. However, an intensive action aimed at clearing from customs IHP medicines ordered from Mission pharma, and distributing them to their destination assisted in mitigating these stock-outs.

Medicines from ASRAMES, the newly USAID approved procurement agent, started very well in November 2012 but were halted by the war that broke up in the eastern DRC, till December 2012.

Key activities planned for next quarter

- Installation and operationalization of the PharmaDex software
- Train 30 pharmaceutical Inspectors
- Improve CDR physical condition and management of CDRs
- End User Verification survey
- Provide support to implement 4 additional EDT sites in Lubumbashi

Quarterly Progress for Objective 1: Pharmaceutical sector governance strengthened

During Q1, 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/SIAPS projects 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 171 medicines being registered out of 255 applications received, bringing the cumulative figures, respectively to 79% of the registered medicines annual cumulative target, and 95% of the cumulative annual target of reviewed dossiers. The list of registered medicines was publicly posted. SIAPS/DRC also assisted in the printing of the compiled list of medicines registered in DRC till end of September 2012, and the dissemination of this list to the 4 USAID-provinces. The MOH organized the dissemination to the other provinces. This list will assist provincial and health district pharmacist inspectors to monitor medicines circulating in the local market in the provinces.

SIAPS DRC assisted the MOH in the process of taking over the National Essential Medicines Lists (NEML) Review. The MOH/DPM presented to all partners the roadmap on the way the MOH has decided to conduct this process for the 2012 Review.

SIAPS/DRC also continued its support to the National Medicines Committee (NMC), which is the entity at the central level of the DRC's health system that coordinates pharmaceutical activities. This has been done through the participation of SIAPS to a MOH workshop on streamlining the DRC national procurement and distribution system. This workshop produced a roadmap accepted by all partners in health.

With SIAPS support, the national Maternal and Child Health program, in holding a national workshop to launch and disseminate the diarrhea national policy. Twenty five staff from central level and 40 from partners were oriented on the impact of diarrhea on child morbidity and mortality rates, and on the importance of correct diarrhea treatment. Copies of the policy were distributed. Partners committed to assist with the printing of more copies for the provinces

At the provincial level of the health system, SIAPS has continued to assist the four USAID-focus provinces of Kasai Oriental, Kasai Occidental, Sud Kivu and Katanga with coordinating pharmaceutical activities for the 4 provinces through the holding of meetings of the ‘Comites Provinciaux de Medicaments’ (CPMs).

During Q1 SIAPS participated in joint supervision visits with the MOH and IHP in 29 health zones in 3 provinces.

During these visits, the MOH has been able to monitor the physical availability of tracer medicines and management tools, the inventory of all assets, verify the medicines pricing, the rational use of medicines, and monitor the use of health facilities credit lines.

The percentage of health facilities with tracer medicines stock outs has reduced from 20% the previous quarter to 13% towards the set target of 0%.

Quarterly Progress for Objective 2: Capacity for pharmaceutical supply management increased and enhanced

During Q1, SIAPS/DRC made progress towards the objective of building capacity of both individuals and institutions in pharmaceutical supply management. SIAPS followed very closely the reception of PMI commodities at all the DRC health pyramid levels, primarily for ACTs purchased by Deliver.

SIAPS detected some mistakes from the logistics forwarder which resulted in stock outs of ACTs in Sankuru district. These stock-outs were quickly brought under control with the intervention of SIAPS recommending a rapid redeployment in Sankuru of ACTs from Kinshasa. SIAPS worked closely with the NMCP in the distribution of ACTs to health zones in all USAID supported provinces. This helped the NMCP to replicate the process to other provinces.

On request from USAID, SIAPS shared with BTC the cost of training on "Quality Assurance" organized by QUAMED for pharmacists responsible for CDRs in DRC, from 5 to 9 November 2012 in Kinshasa. The training covered the current 17 existing CDRs in the DRC.

Following the training of PMTCT sites staff and PEPFAR partners in management of PMTC commodities, in Katanga and Kasai Occidental provinces, held during the previous quarter, SIAPS held from 15 to 16 October 2012 a briefing on the use of management tools for 22 PMTCT staffs from eight Kinshasa PEPFAR implementing partners (EGPAF, UNC/ ESP, ICAP, PROSANI, ProVic, SCMS, and SIAPS. During this briefing, all PEPFAR implementing partners agreed to use a unique and standard template proposed by SIAPS for their report on pharmaceuticals to PEPFAR. They also agreed on meeting quarterly for sharing information.

USAID has added the Kisangani Town in Province Orientale and the Lubumbashi Town in Katanga Province to its PMTCT Acceleration program. SIAPS was commissioned to support these new sites in the ARVs and HIV/AIDS commodities management. SIAPS supported joint formative visits with the MOH and ProVic to 99 PMTCT sites in these 2 provinces. The MOH could discover overstocks of ARVs caused by lack of rapid HIV tests in some PMTCT sites, and take the right decisions on the spot, like redeployment of ARVs close to expiry.

Following the approval of ASRAMES, a local procurement agency, as USAID procurement agent, SIAPS assisted in the quantification of an emergency order for essential medicines for 6 months of consumption confirmed with ASRAMES in November 2012. SIAPS followed up the entire process and the last consignment of medicines was delivered on December 27, 2012, despite the war that broke out in the eastern DRC

Quarterly Progress for Objective 3: Pharmaceutical management information available and used for decision making

During Q1, SIAPS contributed to the objective of ensuring that pharmaceutical management information generated through SIAPS is used for decision-making. In agreement with USAID, SIAPS and IHP have started producing a 2-weekly summary report on medicines stock level and status of USAID purchased medicines distribution.

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). Data from the PPMRm and PPMRc were used to make recommendations on health product procurement to the US government.

Quarterly Progress for Objective 5: Pharmaceutical services improved to achieve desired health outcomes

During Q1, the national center for pharmacovigilance, SIAPS and the Health Zones authorities jointly conducted formative sessions to hospitals that conducted baseline studies with SIAPS assistance. These visits focused on corrective actions to the findings of the above mentioned baseline study, introduction to pharmacovigilance, and medicines rational use in 8 hospitals.

Quarterly progress toward sub-objective 1.1: Increased efficiency and transparency, and enforcement capacity of the drug registration system

During Q1, with SIAPS support, 255 registration applications were received and reviewed thus reaching the cumulative figure of 1425 dossiers reviewed toward the set annual target of cumulative 1500 dossiers for Y2. Medicines registered this quarter were 171, bringing the total cumulative number of registered medicines to 951, against the annual cumulative target of 1200 registered medicines. This represents respectively 95% of dossiers planned to be reviewed and 79% of medicines planned to be registered. Three (3) dossiers were rejected, while 27 needed more information and 54 dossiers were postponed to the next review. The list of registered medicines was publicly posted, as it has become a routine now. SIAPS/DRC also assisted in the printing of the updated list of medicines registered in DRC till end of September 2012, and the dissemination of this list to the 4 USAID-provinces. The MOH organized the dissemination to the other provinces. This document will assist provincial and health district pharmacist inspectors to monitor medicines circulating in the local market in the provinces.

The medicines registration session has become a normal and regular activity of the MOH; it has now been included in the MOH budget. The annual cumulative target of 1200 medicines registered is likely to be reached.

The installation of the automated drug registration process and the introduction of the Web-based version of PharmaDex are still to be finalized.

No progress has yet been made towards the training of pharmacists. The survey of % of registered medicines circulating in the DRC market will be conducted as the updated list of registered medicines has been distributed to the provinces.

Challenges in progress toward sub-objective 1.1

Unavailability of SIAPS Home Office staff specialized in installation and training in the Web-based version of Pharmadex made it difficult to make progress on this activity during Q1. We expect this to occur in Q2.

Quarterly progress toward sub-objective 1.2: Improved medicines policies, legislation and regulations

SIAPS made progress on this objective of improving policies, legislation and regulations by assisting the Ministry of Health to hold a meeting on November 15, 2012 to present the MOH roadmap for the 2012 NEML review. In this meeting the MOH stated the principles to apply, following the international accepted principles: selection criteria, tools for selection, conflicts of interest to be declared, etc. and the Minister of Health's decision to appoint the review committee members at both national and provincial level through a ministerial decree. Activities related to this sub-objective have been inserted in the MOH budget (national and provincial) for the Fiscal Year 2013

(January to December). The MOH has planned the distribution of the updated NEML for April 2013.

The DTC end line study to assess the % of medicines prescribed at health facilities which are on the NEML had to wait for the distribution of the NEML to all 80 health zones.

SIAPS supported the national Maternal and Child Health program, in holding a national workshop from October 29 to 31 October 2012, to launch and disseminate the diarrhea national policy. Twenty five staff from central level and 40 from partners were oriented on the impact of diarrhea on child morbidity and mortality rates, and on the importance of correct diarrhea treatment. Copies of the policy were distributed. Partners committed to assist with the printing of more copies for the provinces.

Quarterly progress toward sub-objective 1.3: Improved coordination of supply chain management activities by national and provincial authorities

Technical assistance from SIAPS to both national and provincial levels of the DRC Ministry of Health during Q1 contributed to the continuous improvement in the coordination of supply chain management activities by national and provincial authorities (Objective 1.3). SIAPS/DRC assistance to the National Medicines Committee (CNM) continued. Instead of the formal quarterly meeting, the MOH organized a workshop that produced a roadmap to streamline the DRC national medicines procurement and distribution system. The workshop was led by a WHO Consultant and was attended by all partners involved in medicines procurement in DRC. This is a historical milestone in the strengthening of the Congolese national procurement and supply system.

The Provincial Medicines Committees continued with their activities of coordinating all partners' pharmaceuticals in the provinces. SIAPS assisted in the preparation of 2013 operational plan of all 4 USAID-assisted provinces in ensuring all resolutions from CPM meetings were included in the 2013 operational plans.

From October to December 2012, SIAPS supported supervision visits on medicine management jointly conducted with the MOH and IHP in 29 health zones in 3 USAID-supported provinces Kasai Occidental, Kasai Oriental, Sud Kivu.

All the above mentioned activities are aimed to manage medicines in all USAID-focus 1514 facilities, and prevent or mitigate any stock-outs. The percentage of health facilities with stock outs has reduced from 20% the previous quarter to 13%.

Technical assistance to FEDECAME and CADIMEK continued through this quarter. All eight IHP contracted CDRs had good storage conditions during Q1.

Quarterly progress toward sub-objective 2.1: Pharmaceutical management capacity of individuals, institutions, organizations increased

During Q1, SIAPS/DRC made progress on sub-IR 2.1 Pharmaceutical management capacity of individuals, institutions, organizations increased by following up very closely the reception of PMI commodities in all the 4 USAID-focus provinces, primarily for ACTs purchased through Deliver.

SIAPS detected a mistake from the logistics forwarder in the distribution of PMI commodities that caused stock-outs in all health zones in Sankuru District in Kasai Oriental Province. SIAPS managed to locate the consignments destined to Sankuru Health District in Kasai Oriental Province, recommended a rapid redeployment in Sankuru of ACTs from Kinshasa.

SIAPS worked closely with the National Malaria Control Program (PNLP) in the distribution of ACTs to health

zones in all USAID supported provinces.

Part (60%) of the IHP medicines ordered from Mission pharma was consigned in Lubumbashi customs since October 2012. SIAPS worked with IHP to clear these medicines in December 2012. An interim arrangement with and support to CAMELU (Lubumbashi CDR) helped IHP to store these medicines in their warehouse in Lubumbashi before their dispatch to the various destinations in 3 provinces.

To mitigate the risk of stock-outs foreseen with the Year 2 Task Order of IHP medicines placed to a new supplier, MEG, IHP and SIAPS, with the green light from USAID, placed another medicines order for 6 months of consumption at ASRAMES in November 2012, as there was assurance to receive medicines within 2 weeks. ASRAMES is a local state/private procurement agency that SIAPS assisted to qualify as a USAID approved procurement agent. The quantification for this order started in October 2012 and the order for medicines for 80 IHP health zones was confirmed in early November 2012. SIAPS then monitored every step of the process, released staff to physically oversee the process at ASRAMES warehouse. The consignment for Sud Kivu Province arrived in Bukavu on November 15, 2013. The delivery of consignments to other provinces was halted by the war that broke in the eastern DRC then restarted on December 10, 2012 for Kasai Occidental, and covered the other 3 provinces up to December 27, 2012 when the last consignment reached Kolwezi in Katanga Province. SIAPS supported the MOH and IHP on:

- Distribution plans of medicines from CDRs to each of the 80 IHP supported health zone and their respective general referral hospital.
- Updating of the credit lines of all 80 health zones
- Follow up of Year 2 Task Order medicines that had arrived in Sud Kivu, in the meantime.
- Quick distribution of PMTCT commodities (Determine HIV tests) received with a close expiry date (March 2013),
- Reception and delivery of laboratory kits for Mwene Ditu in Kasai Oriental,
- Supervision of all 8 IHP contracted CDR/depots,
- Worked with the MOH of Kasai Oriental to prepare the USA Ambassador's visit to Kasai Oriental.
- Assessment of the storing conditions and management of the 2 IHP warehouses in Kinshasa, and provided the needed corrections.
-

In November 2012, on USAID request, SIAPS shared with BTC the cost of training on "Quality Assurance" organized by Quantimed for pharmacists responsible for CDRs in DRC.

SIAPS supported the trip and accommodation cost in Kinshasa for pharmacists from CADIMEK (Kasai Occidental), CADMETA and CAMELU in Katanga Province, and CADMEKO (Kasai Oriental). Other partners supported other CDRs.

SIAPS provided technical and financial assistance to the PNAM to update pharmaceutical management tools. These tools are used at all facility levels for pharmaceutical management and have been availed to all IHP supported health facilities in the 4 provinces.

No upgrade work to CDR was performed this quarter, as we are still waiting for clarification from the USAID Mission on new USAID/Washington regulations.

Quarterly progress toward sub-objective 3.1: Pharmaceutical management systems (PMIS) support both products and patients

The Procurement Planning and Monitoring Report for contraceptives (PPMRc) and for Malaria commodities (PPMRm), conducted with the MOH national and provincial levels, and partners were submitted to USAID Washington. In agreement with USAID, SIAPS and IHP have started producing a 2-weekly summary report on

medicines stock level and status of USAID purchased medicines distribution throughout to all more than 1500 health facilities in the 80 health zones, in the 4 USAID-focus provinces.

Data used from the PPMRm and PPMRc were used to make recommendations on health products procurement to the US government.

The preparation of the PPMRm has been another opportunity for the DRC NMCP to learn how to organize a PPMRm, toward eventually handing over of this process to the MOH.

Quarterly progress toward sub-objective 5.1: Stock outs of TB medicines reduced at health zone level

During Q1, hospitals with MTCs have submitted 31 notifications of drug adverse events to the CNPV, cumulating to 81 for 2 years of SIAPS and representing 40% of the Y2 target of 200 notifications.

The second issue of the CNPV newsletter has been published and distributed electronically. The hard copy is to be distributed health zone hospitals during Q2. The draft of the 3rd issue is already under discussion.

Quarterly progress toward sub-objective 5.2: Adverse drug event reporting is increased

The national center for pharmacovigilance (CNPV) and SIAPS jointly conducted formative sessions to hospitals that conducted baseline studies with SIAPS assistance. These visits focused on corrective actions to the findings of the above mentioned baseline study, introduction to pharmacovigilance, and medicines rational use in 8 hospitals. Nineteen health workers were trained in Lodja hospital (Kasai Oriental) and 43 in Kolwezi (Katanga).

The results of the assessment were shared with each hospital. Each hospital subsequently developed an action plan for implementing medication use interventions to address its respective findings. A specific training addressing the findings for each MTC was organized concurrently with the training of the pharmacovigilance focal points.

Quarterly progress toward sub-objective 5.3: Medicines use is improved at hospitals with DTCs

The transfer of TB medicines from the TB program provincial offices to CDRs is still under finalization and costing discussions with the MOH, Global Fund and SIAPS.

Dominican Republic

Year 1 Work Plan

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 and TB and HIV/AIDS.

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

Overall Quarter Progress

The stock monitoring system supported by SAIDI shows a slight improvement in the availability of medicines for non-communicable diseases, and disease control programs. This has been largely due to a more efficient distribution system supported by SIAPS.

Key challenges faced during the quarter

SUGEMI is generating evidence to document that financing issues are at the root of current problems in the availability of medicines, with SIAPS support. Due to conflicting agendas, these problems have not been discussed with local authorities yet.

Key activities planned for next quarter

Based on the financial analysis supported by SIAPS, national counterparts and SIAPS will present technical evidence supporting the lack of financial resources as the major cause of stock-outs to national authorities.

Quarterly Progress for Objective 1: Increase the governance in the Dominican Republic pharmaceutical sector through the implementation of a national pharmaceutical integrated system (SUGEMI)

Technical documents supported by SIAPS were discussed and analyzed by counterparts. High level political meetings are scheduled for next quarter.

Quarterly Progress for Objective 2: Increase the capacity of the supply management system in Dominican Republic

SIAPS continued supporting the on-site training of the central pharmaceutical unit team (UNGM). The certified

course on pharmaceutical management started on November 17th.

Quarterly Progress for Objective 3: Improve the performance of the pharmaceutical system through the PMIS

Ninety percent of the regional health services are already reporting consumption and availability of medicines. A few glitches in the electronic tool were corrected during previous quarter. The revised version was installed in regional health services during this quarter.

Quarterly progress toward sub-objective 1.1: Transparent and accountable pharmaceutical management systems in Dominican Republic

Technical assistance for the implementation of a national pharmaceutical management system: Information generated on the programing exercise conducted during the previous quarter, was included in technical reports. The reports show critical problems in financing and programming. SIAPS consultants visited DR on October and November to discuss with MoH authorities the incorporation of additional disease control programs to SUGEMI. The elaboration and publication of the last SUGEMI standard operational procedure –Selection- was concluded. For the next quarter, SIAPS will present and discuss with MoH authorities the problems identified in the programing exercises for next year procurement. SIAPS will organize a workshop to plan the incorporation of additional disease control programs to SUGEMI.

Support the analysis and implementation of alternative procurement mechanism: During a visit to DR on November 2012, SIAPS presented the tender of prices for decentralized procurement proposal to the professional appointed as head of the MoH procurement unit. For the next quarter, the Procurement Unit Director will present the tender of prices proposal to the Ministry of Health. If the new authorities approve the proposal and request for USAID/SIAPS technical assistance, SIAPS will support the elaboration of the tender invitation documents and will provide technical assistance for the implementation of the first bid process.

Support good programming and procurement practices of TB and HIV/AIDS medicines and diagnostic materials: Based on the programming exercises conducted during the previous quarter, SIAPS determined the financial gap to cover the current ARV demand. These figures were officially accepted by the MoH and were used for the Global Fund procurement plan. For the next quarter SIAPS will complete the elaboration of a policy option analysis and discuss these findings with national counterparts and cooperation agencies to mobilize the necessary resources.

Deliverables: Sub-Objective 1.1

Technical assistance for the implementation of a national pharmaceutical management system: The elaboration and publication of the last SUGEMI standard operational procedure –Selection- was concluded.

Support the analysis and implementation of alternative procurement mechanism: SIAPS presented the tender of prices for decentralized procurement proposal to the professional appointed as head of the MoH procurement unit.

Quarterly progress toward sub-objective 1.2: Support the generation of evidence for the development of the pharmaceutical sector in Dominican Republic

Participate in national and international conferences to present SUGEMI and internal and external evaluations of the TB and HIV/AIDS: No activities programmed for this quarter.

Quarterly progress toward sub-objective 2.1: Strengthen the capacity of individuals and institutions

Support the institutional development of the national pharmaceutical management unit

SIAPS continued providing technical assistance to the National Pharmaceutical Unit (UNGM) in the elaboration of technical documents. SIAPS is still supporting –through two short term consultants - the operations of the UNGM. For the next quarter, SIAPS will insist with the new MoH authorities on the need to absorb SIAPS consultants, as regular MoH employees. The MoH has included in the 2013/14 budget the expenses of the UNGM.

Technical assistance for the improvement of storage and transportation conditions and the implementation of good practices: On November 2012, SIAPS facilitated a training workshop on good storage practices. Regional pharmacists and warehouse personnel of all regional services participated in the workshop. An inventory on the current conditions of all regional stores was conducted during the workshop. For the next quarter, SIAPS will elaborate a technical report on the structural conditions of regional warehouses and the financial investments that are still necessary for conditioning or construction. The results will be presented to national counterparts and potential donors.

Support the training of personnel in all the SUGEMI components and the organization of a certified course on pharmaceutical supply management: SIAPS continued supporting the training in situ, of personnel for the implementation of SUGEMI procedures. On October 2012, SIAPS facilitated the training for tutors of the certified course on pharmaceutical management. The certified course started on November 17. Tuition fees were sponsored by USAID/ SIAPS and USAID/Centros de Exelencia projects and local NGOs. Eight out of nine Regional Pharmaceutical Unit pharmacists are taking the course. For the next quarter, the first certified course on pharmaceutical management will be completed. SIAPS will systematically assess the comments and suggestions to improve the course, and elaborate a revised version of the modules for the second promotion.

Quarterly progress toward sub-objective 3.1: Improve the performance of the pharmaceutical system through the PMIS

Technical assistance for the implementation of a national pharmaceutical management information system (PMIS): During this quarter SIAPS adjusted the electronic tool to facilitate the consolidation and reporting in regional health services and the National Pharmaceutical Unit. The revised version was installed in all regional health services. For the next quarter, SIAPS will assess the opportunity and precision of the reporting routines, after the introduction of the revised e-tool. Corrective actions will be implemented, if needed.

Ethiopia

Year 1 Work Plan

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

Overall Quarter Progress

SIAPS-Ethiopia works with relevant stakeholders to increase efficiency and effectiveness of the pharmaceutical sector workforce to manage pharmaceuticals at all levels. This includes assessing bottlenecks and gaps and developing interventions so as to resolve these shortcomings with the full participation of stakeholders, thereby

strengthening the capacity of staff to assure ownership and sustainability of the interventions.

Integrated Supportive Supervision has been conduct with which more than 67 health facilities (6 hospitals, 38 health centers and 23 private health facilities) were assessed and supported on each technical area.

Technical and material support was provided to the pharmacy sections of health facilities in order to improve the quality and validity of both ART and AMDM data on regular basis. To further strengthen the pharmaceutical recording and reporting activities at facility level the following activities were performed: Onsite training on real time dispensing, collection of patient uptake and regimen reports, PMIS format and CD-RW /backup drive and computers distribution, supporting HFs to follow proper backup procedures of the database (EDT/ADT), Hardware & Software maintenance, and Kaspersky antivirus installation support

A functional DTC in hospitals and health centers provides a forum to bring together all stake holders to jointly work to improve health-care delivery. As such, DTC is regarded as a tool for promoting more efficient and rational use of medicines. The DTC is involved in developing drug policies and procedures, evaluation and selection of formulary drugs, identifying and assessing drug use problems, promoting interventions to improve drug use, managing ADRs and medication errors, etc. The DTC participates in hospital and health centers committees and departments in all matters related to drugs.

EHRIG assessments were also made in Debere Berhan and Dessie hospitals. According to the results of the assessments, Debere Berhan Hospital achieved 83% from 58% and Dessie 71.4% from 33% in implementing EHRIG Pharmacy Chapter standards. Similar assessments were done in another two hospitals and the result indicated that implementation of EHRIG Pharmacy chapter increased from 31% to 62% at Mizan Aman Hospital and from 30% to 41% at Mettu Karl hospital.

Strengthening of the pharmacovigilance system of the country is fundamental to ensure the safety of medicines provided to the public. As part of this endeavor, availing reporting forms at all facilities, creating awareness in the form of training or face to face discussion on the importance and practice of pharmacovigilance, follow-up of the facilities' ADE monitoring activity, use of drug safety information generated from FMHACA's database, familiarization of the National Pharmacovigilance Framework, initiation of active surveillance system are important activities that are being carried on.

Key challenges faced during the quarter

Weakness of some RHBs to provide active leadership that would accelerate capacity building, ownership and sustainability.

Key activities planned for next quarter

- Supportive supervision and mentoring to EHRIG Model sites (on EHRIG standards, DTCs, DIS, APTS, PMIS, Good prescribing and Dispensing Practices)
- Assist RHBs in the drafting /adaption of regulation on APTS
- Follow up implementation of APTS at model sites
- Organize clinical pharmacy training
- Conduct baseline assessment to measure key indicators of COP12
- Collaborate with USAID and CDC implementing partners on PMIS training for pharmacy personnel
- Follow and support the provision of onsite training and launch of DIS Provide mentoring and on-site training to conduct ABC value analysis and ABC/VEN reconciliation by DTCs

- Revise, Print and Distribute and follow-up Use of the "Medicines Good Prescribing and Dispensing Manuals" to public and private health facilities
- ADT to EDT conversion for the remaining ADT sites
- EDT maintenance
- On job training of dispensers on EDT
- PMIS - developing a comprehensive tool for dispensing, including APTS
- Strengthen the National AMR Committee
- Establishment of HRIC at FMHACA
- Strengthening collaboration between Health Regulatory Directorates of RHBs and FMHACA Regional Branches
- Progress follow-up for all EDT sites

Quarterly Progress for Objective 1: Pharmaceutical sector governance strengthened

Joint supportive supervision was organized to assess the status of health facilities to initiate APTS. The team comprised of members from ARSHB and USAID/SIAPS. The team visited three hospitals (Woldia, Dessie and Debre Berhan) that are chosen to implement the system. The major findings of the team were communicated and discussed with the hospital management and responsible pharmacy staff.

In collaboration with Addis Ababa RHB a two days consultative workshop on APTS was organized to create awareness and build consensus on the requirements and implementation process for selected stakeholders. Following the consultative workshop, vouchers, formats and register books needed for APTS implementation were edited as per the comments forwarded during the workshop and submitted to Addis Ababa Region Finance and Economic Development Bureau for printing. The regional health bureau is delegated to execute the printing process.

USAID/SIAPS supported Dire Dawa city Administration in popularizing the regulation on APTS to key stakeholders of the city administration. The meeting created consensus on the way forward about its implementation and how to ensure the continuity of the Administration's ownership. The workshop was attended by 33 participants drawn from health, finance and economic development, civil service and audit bureaus as well as Dil-Chora hospital and health centers of the City Administration. Most of the participants have supervisory position in the institutions they delegated.

In the reporting quarter, APTS was officially launched at St. Mary hospital in Axum, the first in Tigray region, and Debre Berhan hospital in Amhara region

USAID/SIAPS provided technical assistance to Debre Tabor hospital on APTS implementation. During this period:

- Together with the hospital staff conducted baseline assessment for APTS implementation
- In consultation with hospital management, pharmacy staff and committee members were selected to facilitate the implementation process; action plan for initiation of APTS was developed, discussed and communicated to concerned bodies for implementation within a specified time frame.
- Results of the baseline assessment on EHRIG pharmacy chapter implementation status were presented and discussed.

Quarterly Progress for Objective 2: Capacity for pharmaceutical supply management and services increased and enhanced

A functional DTC in hospitals and health centers provides a forum to bring together all stake holders to jointly work to improve health-care delivery. As such, DTC is regarded as a tool for promoting more efficient and rational use of medicines. The DTC is involved in developing drug policies and procedures, evaluation and selection of

formulary drugs, identifying and assessing drug use problems, promoting interventions to improve drug use, managing ADRs and medication errors, etc. The DTC participates in hospital and health centers committees and departments in all matters related to drugs.

FMHACA in collaboration with USAID/SIAPS has given three rounds of trainings for health providers at private hospitals in addition to carrying out a half-day consultative meeting with owners of private hospitals in Addis Ababa on rational medicine use (RMU) and Drug and Therapeutics Committee (DTC).

Following the training, FMHACA has designed a follow-up scheme on the establishment of DTC and implementation of the planned activities at private hospitals. As part of the follow-up scheme, a team composed of FMHACA and USAID/SIAPS has conducted supportive supervision at six private hospitals in Addis Ababa. A similar supportive supervision was also made at three private hospitals outside Addis (Sher-Ethiopia hospital in Zeway, and S/r Aklesia Memorial and Medhanealem Hospitals in Adama) to assess the DTC status of these hospitals and give technical support regarding Drug and Therapeutics Committee. The discussions and observations during the supportive supervision indicated that close follow up and monitoring of all DTC and other activities will be required until capacity has been built at private health facilities and the management of the facilities has fully bought into the usefulness of these interventions.

In the reporting quarter, facility specific drug lists that were developed and printed with the technical and financial support of USAID/SIAPS handed over to 12 health facilities – nine hospitals and three health center (Tikur Anbessa, Zewuditu memorial, Chiro, Assosa, Dembi Dolo, Motta, Borumeda, Dessie Mizan-Aman Hospitals and Merawi, Shewa Robit and Mekoye health centers).

To fill the gap in the management of pharmaceuticals by the private sector, it was found necessary to conduct an introductory course on drug supply management (DSM) focusing on regulatory issues, storage, inventory control and waste management. The training specifically targeted store keepers and store managers of private pharmaceuticals importers and distributers. The training also familiarized store managers with the regulatory requirements of Ethiopian Food, Medicine and Health Care Administration and Control Authority (FMHACA). Two rounds of DSM training were conducted in collaboration with FMHACA for 68 store keepers and store managers drawn from private pharmaceuticals and medical supplies importers and distributers.

USAID/SIAPS, in collaboration with FMHACA, organized three rounds of workshops on the following topic: “Popularization Workshop on Medicines Waste Management and Disposal Directive and Implementation National Framework”. The workshops were attended by 212 participants, including facilitators and support staff selected from RHBs, zonal health department, district health office, Federal FMHACA and its branches, PFSA branches, medicines importers and distributors, City Administration Environment Protection Bureau, public and private hospitals and municipalities that were drawn from Addis Ababa City Administration, Tigray and Oromia regional states.

Quarterly Progress for Objective 3: Utilization of information for decision-making increased

Technical and material support was provided to the pharmacy sections of health facilities in order to improve the quality and validity of both ART and AMDM data on regular basis. To further strengthen the pharmaceutical recording and reporting activities at facility level the following activities were performed: Onsite training on real time dispensing, collection of patient uptake and regimen reports, PMIS format and CD-RW /backup drive and computers distribution, supporting HFs to follow proper backup procedures of the database (EDT/ADT), Hardware & Software maintenance, and Kaspersky antivirus installation support

USAID/SIAPS collaborated with an MSH sister project (ENHAT-CS) and the Amhara Regional Health Bureau to organize two rounds of trainings on M&E: Standard Operating Procedures (SOP) for ARV Drugs

Management at Health Facilities as part of the in-service Comprehensive Basic ART Training for Pharmacist. Participants of the training were 56 pharmacy professionals (26 in Bahir Dar and 30 in Dessie) drawn from Health centers that were initiating ART services.

Thirty four health facilities (20 hospitals and 14 health centers) were reached through supportive supervision. During the supervision visits, computers, external hard disks and PMIS formats were distributed to 13 health facilities, Antiretroviral Dispensing Tool (ADT) was converted to Electronic Dispensing Tool (EDT), Hardware/software Maintenances were made, and Kaspersky Antivirus was installed.

On-site training was provided to 16 pharmacists and three data clerks on how to manage Patient and Pharmaceutical Information using Electronic Dispensing Tool (EDT).

A two-day training was organized in two rounds jointly by USAID/SIAPS and PFSA to 40 dispensers (pharmacist/Druggist) drawn from different ART sites to enhance the capacity of pharmacy professionals in practicing real time dispensing using EDT and to improve skills of dispensers to efficiently and effectively use the database/EDT.

Various PMIS tools (suspension file, PIS, adult register, pediatrics register and ARV prescription) have been distributed to ART sites and the necessary technical support provided.

Patient Uptake and cumulative regimen reports were collected, compiled and shared with the RHBs, PFSA, USG partners, SCMS and EHNAT–CS.

Hardware/software maintenance services were provided to 13 health facilities

Quarterly Progress for Objective 4: Financing strategies and mechanisms to improve access to medicines strengthened

The Amhara Regional Health Bureau (ARHB), in collaboration with USAID/SIAPS, endorsed the implementation of EHRIG at all public health facilities in the region. As part of implementing EHRIG, USAID/SIAPS- E developed an implementation tool that was piloted and accepted. To ensure the uniform implementation of EHRIG throughout the region, a regulation was developed and endorsed by the regional state council. Currently, the ARHB in collaboration with USAID/SIAPS-E has a plan to introduce the system in six referral hospitals. Accordingly, successive trainings were given to pharmacy professionals, accountants, cashiers and internal auditors working in these hospitals. The tools (vouchers and sales tickets) have been printed and are ready for use. EHRIG assessments were also made in Debere Berhan and Dessie hospitals. According to the results of the assessments, Debere-Berhan Hospital achieved 83% from 58% and Dessie 71.4% from 33% implementation of EHRIG Pharmacy Chapter standards. Similar assessments were done in another two hospitals and the result indicated that implementation of EHRIG Pharmacy chapter increased from 31% to 62% at Mizan Aman Hospital and from 30% to 41% at Mettu Karl hospital.

Training on APTS/EHIRIG Pharmacy chapter was organized for 35 persons (pharmacy personnel, accountants, cashiers from Hossana, Butajira and Arbamich Hospitals). To strengthen future monitoring of APTS implementation, pharmacy personnel and auditor from SNNP RHB participated in this training.

Quarterly Progress for Objective 5: Pharmaceutical services to achieve desired health outcomes improved

Strengthening of the pharmacovigilance system of the country is fundamental to ensure the safety of medicines provided to the public. As part of this endeavor, availing reporting forms at all facilities, creating awareness in the form of training or face to face discussion on the importance and practice of pharmacovigilance, follow-up of the

facilities' ADE monitoring activity, use of drug safety information generated from FMHACA's database, familiarization of the National Pharmacovigilance Framework, initiation of active surveillance system are important activities that are being carried on.

In order to get ADE reports from health providers it is necessary to ensure the availability of reporting forms and allergy card at health facilities. In the reporting quarter, 325 forms, 350 allergy cards, 60 PV newsletters and 40 PV Framework document were distributed.

Face to face discussions were carried out at Jimma Shanan Gibe hospital and St. Gabriel private hospital in Addis Ababa.

Three teaching institutions (Black Lion Medical Faculty, AAU School of Pharmacy and Addis Ababa Health Science College (private)) followed up regarding their use of the PV training material that was developed, enriched through a workshop. The objective of the provision of the material was for the subject matter to be included in their course content and be used during teaching of undergraduate health science students.

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- Comments that were obtained from the workshop were incorporated and final document produced for use.
- In collaboration with Addis Ababa Health Bureau, FMHACA with support from USAID/SIAPS prepared "good prescribing" and "good dispensing" practice manuals and distributed to all health facilities to promote good prescribing and good dispensing practice; 64 wooden pallets were distributed for 10 health facilities to improve their pharmaceutical inventory management and storage condition. In response to a request from a health center a half-day DTC sensitization workshop was organized.

Quarterly progress toward sub-objective 1.3: Strengthen the legal framework of APTS to increase transparency and accountability

Joint supportive supervision was organized to assess the status of health facilities to initiate APTS. The team comprised of members from ARSHB and USAID/SIAPS. The team visited three hospitals (Woldia, Dessie and Debre Berhan) that are chosen to implement the system. The major findings of the team were communicated and

discussed with the hospital management and responsible pharmacy staff.

In collaboration with Addis Ababa RHB a two days consultative workshop on APTS was organized to create awareness and build consensus on the requirements and implementation process for selected stakeholders. Following the consultative workshop, vouchers, formats and register books needed for APTS implementation were edited as per the comments forwarded during the workshop and submitted to Addis Ababa Region Finance and Economic Development Bureau for printing. The regional health bureau is delegated to execute the printing process.

USAID/SIAPS supported Dire Dawa city Administration in popularizing the regulation on APTS to key stakeholders of the city administration. The meeting created consensus on the way forward about its implementation and how to ensure the continuity of the Administration's ownership. The workshop was attended by 33 participants drawn from health, finance and economic development, civil service and audit bureaus as well as Dil-Chora hospital and health centers of the City Administration. Most of the participants have supervisory position in the institutions they delegated.

In the reporting quarter, APTS was officially launched at St. Mary hospital in Axum, the first in Tigray region, and Debere Berhan hospital in Amhara region

USAID/SIAPS provided technical assistance to Debre Tabor hospital on APTS implementation. During this period:

- Together with the hospital staff conducted baseline assessment for APTS implementation
- In consultation with hospital management, pharmacy staff and committee members were selected to facilitate the implementation process; action plan for initiation of APTS was developed, discussed and communicated to concerned bodies for implementation within a specified time frame.
- Results of the baseline assessment on EHRIG pharmacy chapter implementation status were presented and discussed.

Quarterly progress toward sub-objective 2.1: Strengthening the effectiveness of DTCs

FMHACA in collaboration with USAID/SIAPS has given three rounds of trainings for health providers at private hospitals in addition to carrying out a half-day consultative meeting with owners of private hospitals in Addis Ababa on rational medicine use (RMU) and Drug and Therapeutics Committee (DTC).

Following the training, FMHACA has designed a follow-up scheme on the establishment of DTC and implementation of the planned activities at private hospitals. As part of the follow-up scheme, a team composed of FMHACA and USAID/SIAPS has conducted supportive supervision at six private hospitals in Addis Ababa. A similar supportive supervision was also made at three private hospitals outside Addis (Sher-Ethiopia hospital in Zeway, and S/r Aklesia Memorial and Medhanealem Hospitals in Adama) to assess the DTC status of these hospitals and give technical support regarding Drug and Therapeutics Committee. The discussions and observations during the supportive supervision indicated that close follow up and monitoring of all DTC and other activities will be required until capacity has been built at private health facilities and the management of the facilities has fully bought into the usefulness of these interventions.

In the reporting quarter, facility specific drug lists that were developed and printed with the technical and financial support of USAID/SIAPS handed over to 12 health facilities – nine hospitals and three health center (Tikur Anbessa, Zewuditu memorial, Chiro, Assosa, Dembi Dolo, Motta, Borumeda, Dessie Mizan-Aman Hospitals and Merawi, Shewa Robit and Mekoye health centers).

USAID/SIAPS supported the dissemination of prescription review assessments and ABC value analysis results to health professional at three hospitals (Zewditu, Tikur Anbessa, Debre Markos referral hospitals). The studies were

conducted by hospital pharmacy staff under supervision of the hospital DTC in collaboration with USAID/SIAPS. The assessments were done using WHO core drug use study indicators (prescribing, patient care, and facility indicators). Intervention strategies were suggested to curb the identified prescribing and dispensing gaps.

Quarterly progress toward sub-objective 2.2: Scale up the establishment of Drug Information Services (DIS) to provide unbiased information on medicines to providers and patients

- USAID/SIAPS provided technical assistance to Gondar University hospital. The support included:
- Facilitation of Drug Information center establishment
- Baseline assessment on EHRIG pharmacy chapter implementation status to identify gaps;
- Initiation of Clinical pharmacy service at the hospital
- Provision of onsite training for newly assigned drug information pharmacist from the Hospital and school of pharmacy on:
- Establishing a Drug Information Service (DIS) at hospital level.
- The function of DIS and responsibilities of the DI pharmacist
- How to develop SOP for drug information service,
- Types of references and searching techniques.
- How to receive, answer and document DI queries,

Quarterly progress toward sub-objective 2.4: Strengthen pharmaceutical human resource at different levels to ensure proper management and use of pharmaceuticals and related commodities

To fill the gap in the management of pharmaceuticals by the private sector, it was found necessary to conduct an introductory course on drug supply management (DSM) focusing on regulatory issues, storage, inventory control and waste management. The training specifically targeted store keepers and store managers of private pharmaceuticals importers and distributers. The training also familiarized store managers with the regulatory requirements of Ethiopian Food, Medicine and Health Care Administration and Control Authority (FMHACA). Two rounds of DSM training were conducted in collaboration with FMHACA for 68 store keepers and store managers drawn from private pharmaceuticals and medical supplies importers and distributers.

Rational use of medicines and DTC sensitization training was organized by Dire Dawa City Administration to equip health facilities and providers with the necessary knowledge and skills on how to establish/strengthen a functional DTC, investigate drug use problems, and find interventions to promote the Rational Use of Drugs and effective inventory management.

A total of 42 participants drawn from Dire Dawa Administration Health Bureau(2), 16 health centers(32) in the Administration, 1 hospital(6) and Dire Dawa PFSA(2) attended the training.

The USAID/SIAPS Regional Technical Advisor (RTA) in Amhara participated in monthly hub meetings at PFSA Bahir Dar led by RHB and PFSA branch manager to discuss issues related to logistics and service improvement. Participants of the meeting were representatives from PFSA Bahir Dar branch, Amhara RHB, USAID/SIAPS, USAID Deliver, SCMS, USAID/Heal TB, and MSH ENHAT CS.

Quarterly progress toward sub-objective 2.5: Strengthen national capacity for safe, accountable management and timely disposal of pharmaceutical waste.

USAID/SIAPS, in collaboration with FMHACA, organized three rounds of workshops on the following topic: “Popularization Workshop on Medicines Waste Management and Disposal Directive and Implementation National Framework”. The workshops were attended by 212 participants, including facilitators and support staff selected from RHBs, zonal health department, district health office, Federal FMHACA and its branches, PFSA branches,

medicines importers and distributors, City Administration Environment Protection Bureau, public and private hospitals and municipalities that were drawn from Addis Ababa City Administration, Tigray and Oromia regional states.

Quarterly progress toward sub-objective 3.1: Strengthen Pharmaceutical Management Information System at the dispensing level to improve quality of patient care

USAID/SIAPS collaborated with an MSH sister project (ENHAT-CS) and the Amhara Regional Health Bureau to organize two rounds of trainings on M&E: Standard Operating Procedures (SOP) for ARV Drugs Management at Health Facilities as part of the in-service Comprehensive Basic ART Training for Pharmacist. Participants of the training were 56 pharmacy professionals (26 in Bahir Dar and 30 in Dessie) drawn from Health centers that were initiating ART services.

Thirty four health facilities (20 hospitals and 14 health centers) were reached through supportive supervision. During the supervision visits, computers, external hard disks and PMIS formats were distributed to 13 health facilities, Antiretroviral Dispensing Tool (ADT) was converted to Electronic Dispensing Tool (EDT), Hardware/software Maintenances were made, and Kaspersky Antivirus was installed.

On-site training was provided to 16 pharmacists and three data clerks on how to manage Patient and Pharmaceutical Information using Electronic Dispensing Tool (EDT).

A two-day training was organized in two rounds jointly by USAID/SIAPS and PFSA to 40 dispensers (pharmacist/Druggist) drawn from different ART sites to enhance the capacity of pharmacy professionals in practicing real time dispensing using EDT and to improve skills of dispensers to efficiently and effectively use the database/EDT.

Various PMIS tools (suspension file, PIS, adult register, pediatrics register and ARV prescription) have been distributed to ART sites and the necessary technical support provided.

Quarterly progress toward sub-objective 3.2: Produce information related to medicines use patient uptake, lost to follow-up and regimen breakdown reports

Patient Uptake and cumulative regimen reports were collected, compiled and shared with the RHBs, PFSA, USG partners, SCMS and EHNAT–CS. Hardware/software maintenance services were provided to 13 health facilities.

Quarterly progress toward sub-objective 4.1: Support regional health bureaus and health facilities to implement EHRIG –pharmacy chapter

The Amhara Regional Health Bureau (ARHB), in collaboration with USAID/SIAPS, endorsed the implementation of EHRIG at all public health facilities in the region. As part of implementing EHRIG, USAID/SIAPS- E developed an implementation tool that was piloted and accepted. To ensure the uniform implementation of EHRIG throughout the region, a regulation was developed and endorsed by the regional state council. Currently, the ARHB in collaboration with USAID/SIAPS-E has a plan to introduce the system in six referral hospitals. Accordingly, successive trainings were given to pharmacy professionals, accountants, cashiers and internal auditors working in these hospitals. The tools (vouchers and sales tickets) have been printed and are ready for use.

EHRIG assessments were also made in Debre Berhan and Dessie hospitals. According to the results of the assessments, Debre-Berhan Hospital achieved 83% from 58% and Dessie 71.4% from 33% implementation of EHRIG Pharmacy Chapter standards. Similar assessments were done in another two hospitals and the result indicated that implementation of EHRIG Pharmacy chapter increased from 31% to 62% at Mizan Aman Hospital

and from 30% to 41% at Mettu Karl hospital.

Training on APTS/EHIRIG Pharmacy chapter was organized for 35 persons (pharmacy personnel, accountants, cashiers from Hossana, Butajira and Arbamich Hospitals). To strengthen future monitoring of APTS implementation, pharmacy personnel and auditor from SNNP RHB participated in this training.

Quarterly progress toward sub-objective 5.2: Rational dispensing of medicines by pharmacy professionals to improve treatment outcomes

In collaboration with Addis Ababa Health Bureau, FMHACA with support from USAID/SIAPS prepared "good prescribing" and "good dispensing" practice manuals and distributed to all health facilities to promote good prescribing and good dispensing practice; 64 wooden pallets were distributed for 10 health facilities to improve their pharmaceutical inventory management and storage condition. In response to a request from a health center a half- day DTC sensitization workshop was organized.

Quarterly progress toward sub-objective 5.3: Improve medicines use by clients

Integrated Supportive Supervision has been conducted with more than 67 health facilities (6 hospitals, 38 health centers and 23 private health facilities). These were assessed and supported on each technical area. Report of the supportive supervision was compiled and will be shared to partners through Addis Ababa health bureau.

Quarterly progress toward sub-objective 5.5: Provide technical assistance to strengthen ADR monitoring and Pharmacovigilance PV) systems

In order to get ADE reports from health providers it is necessary to ensure the availability of reporting forms and allergy card at health facilities. In the reporting quarter, 325 forms, 350 allergy cards, 60 PV newsletters and 40 PV Framework document were distributed.

Face to face discussions were carried out at Jimma Shanan Gibe hospital and St. Gabriel private hospital in Addis Ababa.

Three teaching institutions (Black Lion Medical Faculty, AAU School of Pharmacy and Addis Ababa Health Science College (private)) followed up regarding their use of the PV training material that was developed, enriched through a workshop. The objective of the provision of the material was for the subject matter to be included in their course content and be used during teaching of undergraduate health science students.

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- Comments that were obtained from the workshop were incorporated and final document produced for use.

Guinea

Year 1 Work Plan

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: Improved Access to pharmaceuticals and services

Overall Quarter Progress

During the first quarter of Year 2, the SIAPS Guinea program accelerated its activities and made significant progress towards the implementation of key aspects of the program, thus contributing in a robust manner to the overall Goal of ensuring the availability of quality pharmaceutical products and effective pharmaceutical services in Guinea. Some of the activities during this quarter were carried over from Year 1, while others were new activities proposed under the Year 2 work plan. While Objective 1 (strengthening pharmaceutical governance) had been the primary focus of Year 1 activities, the focus shifted to Objectives 2, 3 and 4 in the beginning of Year 2.

All the objectives in the SIAPS work plan are inter-related and require long-term commitment from all the in-country partners, in particular PNLP (the National Malaria Control Program), PCG (the Central Pharmacy of Guinea), DNPL (the National Medicines Regulatory Authority) and other departments within the Ministry of Health such as SNIS (the National Health Information System) as well as from regional, district and facility-level health authorities.

The SIAPS Guinea team contributed to Objective 4 (improving the availability of pharmaceuticals and services) by organizing, in collaboration with PNLP, PCG, MCHIP, Faisons Ensemble and other partners, the emergency distribution of a new shipment of ACTs and RDTs procured by PMI/USAID. This activity was not in the work plan but was conducted by SIAPS on USAID/PMI request. The Nov-Dec 2012 distribution was country-wide (approximately 450 public health centers and hospitals in Guinea benefited from ACTs directly), and followed an exercise of rapid data collection which allowed for a better estimation/quantification of needs at the facility level. More than 160,000 ACTs and more than 40,000 RDTs were distributed to cover short-term needs (imminent or actual stock outs) – but importantly, this distribution served as an opportunity to introduce a reporting system that will ensure a more consistent flow of information/data from the facility to the district to the central level, according to which resupply of facilities will be based on monthly consumption reports and regular orders placed with the PNLP and PCG.

This activity was thus related to Objective 2 (building capacity for pharmaceutical supply management and services) and to Objective 3 (facilitating the availability of pharmaceutical management information for decision-making) and was implicitly intended to help avoid future stock-outs of malaria products. Two main activities during the quarter contributed to Objective 3. The first was a 4-day national workshop intended to design ways to improve the pharmaceutical management information system (PMIS), including aspects such as the circuit of information, updated reporting tools/forms, a stronger monitoring and evaluation system including quarterly review meetings held at the regional/district level, and better coordination among actors at the central level responsible for acquiring and managing data. The workshop recommendations will shape and influence the new PMIS which will be implemented with SIAPS's support over the coming quarters.

Also contributing to Objective 3, SIAPS and PNLP, along with a range of partners, conducted the first End Use Verification (EUV) survey at a sample of 25 health centers, hospitals and warehouses in PMI zones in Dec 2012. This baseline survey evaluated facilities on both drug management indicators and malaria case management indicators. The results of the survey will further serve to improve the supply chain for malaria products and essential medicines, as well as to strengthen pharmaceutical management and treatment practices. Additionally, the survey built capacity among PNLP, PCG, SNIS, National Inspectors and district pharmacists/physicians who participated as data collectors/supervisors (contribution to Objectives 2 and 4).

Key challenges faced during the quarter

The emergency distribution of ACTs was an important activity, implemented by SIAPS at the request of the PMI/USAID Guinea mission and in response to the request of the National Malaria Control Program (PNLP), given new stock-outs of ACTs throughout the country. While the urgency of the situation required moving fast to distribute the products, one of the challenges encountered was that the second shipment of ACTs did not arrive in Guinea in time for the planned distribution. Therefore, only the infant and child forms of AS-AQ (with minimal quantities of the adolescent form in PMI zones) were distributed in Nov-Dec 2012; this satisfied the need of issuing products for the population group most affected by malaria in Guinea (children under the age of 5). The second shipment of ACTs (containing the adolescent and adult forms of AS-AQ) arrived after the emergency distribution and will therefore become part of a regular distribution process through the PCG and its regional warehouses (along with all the other products recently procured by PMI).

The absence of information on malaria drug consumption at the health facility-level significantly impairs the

estimation of ACT needs. A rapid data collection exercise such as the one conducted by SIAPS and PNLP in early Nov 2012 was seen as critical in order to avoid under-supply or over-supply of facilities and was an improvement over the quantification done in the previous PMI emergency distribution of late 2011 (which was based on population estimates). However, this exercise did not necessarily ensure that the facilities/districts transmitted accurate data on drug consumption and patients treated (when the data was transmitted at all). Therefore, while the quantification estimates were better this time around, the overall information challenge that exists at the national level must be tackled through an improved and continuous pharmaceutical management information system (PMIS) – which will be at the core of SIAPS's activities over the coming year.

A convention (Memorandum of Understanding) detailing the terms and costs of the regular distribution of anti-malarial products supplied by PMI does not exist between the Central Medical Stores (PCG) and the National Malaria Control Program (PNLP). The absence of such a convention, which SIAPS has also recommended, delays the process of regular distribution to facilities of the products recently acquired by PMI (all forms of ACTs, SP, injectable Quinine and rapid diagnostic tests). Such a convention is expected in early 2013, which will ensure the release of these products towards the public health facilities in Guinea.

Key activities planned for next quarter

Key activities planned for Jan-Mar 2013 will include follow-up from the emergency distribution and the PMIS national workshop – including on the one hand the constant flow of data from the local to the central level (for better quantification and procurement planning) and on the other hand the constant flow of anti-malarial medicines and products from the central level to the local level. The improvement of the information system is a key concern and will be partially addressed through regular review meetings at the regional/district level, through new reporting tools/forms, and through an improved PNLP database (continuous monitoring of use and stock levels of products). Results from the baseline EUV survey and the formal discussions that will follow on priority actions to be implemented in the areas of pharmaceutical management and case management will also contribute to strengthening the information system, the supply chain and services for patients.

The establishment of an MOU between PNLP and PCG is underway with support from SIAPS and should provide a long-term solution to how PMI-procured malaria products are distributed to the regions and all the way down to the health centers and hospitals in the country. Based on the success of the emergency distribution of ACTs, the PMI/USAID Guinea mission has approached SIAPS to request technical and logistical support for the upcoming universal malaria bed net distribution in Guinea, planned for 2013. The bed net distribution will be the key preventive intervention at the national level and SIAPS is currently advising the national commission as well as the logistical sub-commission on best practices and approaches for the distribution, and for the rapid census required prior to this activity.

Quarterly Progress for Objective 1: Pharmaceutical sector governance strengthened

The SIAPS Country Director participated in discussions/workshops related to a long-overdue revision of the national list of essential medicines. The Director was also involved in a "Medicines for All" workshop and training of trainers at the central level with the aim of improving pharmaceutical management practices (the training will take place next at the regional level). SIAPS Guinea is providing technical and strategic support to PNLP in establishing a convention (Memorandum of Understanding) with the Central Pharmacy of Guinea (PCG), similar to the MOU that PCG has for Global Fund procured products. This new MOU would determine the terms and conditions, as well as associated costs, for PCG to store and distribute (via its regional warehouses) the PMI malaria products brought into the country at the end of 2012 and expected in early 2013. This activity is progressing based on recommendations provided by SIAPS to PNLP and PCG, but the MOU has not been drafted or signed yet. Such an MOU is of critical importance to achieving Objective 1 and to solidifying the central role of PCG in the supply of anti-malarial products to public health facilities throughout the country.

Quarterly Progress for Objective 2: Capacity for pharmaceutical supply management and services increased and enhanced

Prior to conducting the emergency distribution of ACTs in Nov 2012, and in the absence of regular consumption data available at the national level, SIAPS and PNLP performed a rapid exercise to collect such data from most public health facilities in the country (with support from the USAID-funded Faisons Ensemble project).

This quick exercise provided some information about the average monthly consumption (AMC) at the facility-level, and allowed for a better estimation of ACT needs. Together with PCG and PNLP, SIAPS analyzed the data received, established criteria for the number of months of stock to provide during the emergency distribution (by type of ACT and depending on quantities received in country to date) and quantified needs by facility. This information was further used by the PCG for preparing specific packets of ACTs for each health district and provided an opportunity for capacity building in the area of quantification and supply planning, contributing to Objective 2. There remains much work to be done in order to increase the National Malaria Control program's capacity in quantification, forecasting and supply planning, which will be the focus of SIAPS activities in the quarters to come.

Quarterly Progress for Objective 3: Pharmaceutical management information is available and used for decision-making

An initial assessment of Guinea's information system and of the existing reporting forms, registers and stock cards was conducted by a team of HQ technical staff in Q4 of last year. Following this assessment, the SIAPS Guinea team, with TA from HQ's Country Portfolio Manager and Principal Technical Advisor, organized a 4-day national workshop at PCG in Conakry in late Nov/early Dec 2012. This workshop reunited approximately 50 representatives from the national, regional, district and facility level to discuss improvements to the malaria commodity information system, including the flow and frequency of data, monitoring and evaluation through quarterly regional review meetings, better coordination and sharing of information among the concerned actors, revision/harmonization of reporting tools, and resources needed. The action plan that was drawn out during the workshop and in follow-up meetings under the direction of PNLP and the Ministry of Health represents a significant milestone towards meeting Objective 3, as it outlines next steps, timelines, and the roles and responsibilities of the principal actors in the pharmaceutical system.

Also contributing to Objective 3, SIAPS and PNLP in coordination with PCG, other departments within the Ministry of Health and USAID/PMI partners MCHIP and Faisons Ensemble conducted a baseline survey on malaria commodity management and case management practices at 25 public health facilities (hospitals, rural and urban health centers and PCG warehouses) in Dec 2012. The survey uses the End Use Verification (EUV) methodology developed for PMI countries and is the first survey of its kind in Guinea (follow-up surveys will be conducted in 2013). Data analysis is currently in progress, with results expected in the next month, however preliminary observations have already been shared with each facility and health district authorities.

The survey not only contributes to Objective 3 by allowing the collection of key data (not available from other sources) that can lead to immediate corrective actions – it also contributes to the capacity building objective (Objective 2) through the participation of PNLP, PCG, SNIS staff, National Health Inspectors and District Pharmacists/Physicians who typically are called upon to conduct supervisory visits at the facility-level.

Quarterly Progress for Objective 4: Pharmaceutical services improved to achieve desired health outcomes

Significant progress was made during this quarter to achieve Objective 4, by providing assistance to the USAID Guinea mission in preparing for the emergency distribution of ACTs (and on a smaller scale, RDTs) which had

arrived in country in Oct 2012. The importance of this activity stems from its nature as a corrective action to address imminent or actual stock-outs of malaria medicines in the country, and thus to improve access by the population to urgently-needed products.

SIAPS was the lead behind the implementation of this country-wide distribution, working closely with PNLP, PCG and other USAID/PMI partners, such as MCHIP and Faisons Ensemble. District-level authorities were involved and the monthly reporting process was re-emphasized and tied to resupply of products in the future. The emergency distribution took place in the capital city of Conakry first, followed by distribution at the district level, in all of Guinea's regions. The vast majority of the public health centers (including community health works and health posts) and hospitals were supplied with ACTs for the treatment of uncomplicated malaria in infants and small children (facilities in some PMI zones were also supplied with the adolescent form of AS-AQ based on availability).

At the request of the PMI/USAID mission in Guinea in Dec 2012, SIAPS has begun to play an advisory role to the national commission established by the Ministry of Health and PNLP for the planned 2013 universal distribution of malaria bed nets. This is a new activity, not currently captured in the SIAPS Year 2 work plan, but that would contribute significantly to Objective 4 which is intended to improve pharmaceutical services and access to malaria products. The bed net distribution is a major prevention intervention, complementary to the distribution of medicines for treatment that SIAPS has conducted so far.

To this effect, SIAPS has submitted a concept note and budget to PMI/USAID outlining its proposed technical assistance role in logistical activities prior to the distribution (including the oversight of transporting and storing 1.59 million bed nets financed by PMI and conducting a rapid census of the population in PMI zones). The concept note also highlights the strategic support that SIAPS can provide, such as the coordination of all the donors and implementing partners to agree on one national distribution plan.

Quarterly progress toward sub-objective 1.2: Improved medicines policies, legislation, and regulations

The SIAPS Guinea Country Director provided technical assistance towards the process of validation of the newly-revised National Essential Medicines List (long overdue for an update). The Ministry of Health is due to introduce the new list in early 2013. The Country Director also participated in the "Medicines for All" initiative and the training of trainers that took place in Kindia in Nov 2012, aiming to improve the effectiveness of this pharmaceutical management training at the central level. The cascade training will be replicated in the coming months at the regional level. SIAPS has provided suggestions to PNLP and PCG to ensure that a convention is signed between the two parties for the regular distribution to all public health facilities of PMI-procured anti-malarial products that are currently stored (or expected shortly) at the PCG. SIAPS has expressed the urgency of such an action and held meetings with PNLP, PCG and the USAID Guinea mission.

Challenges in progress toward sub-objective 1.2

Due to several major activities during the quarter and an emphasis being placed on the planned national bed net distribution, the convention between PNLP and PCG is yet to be signed.

Quarterly progress toward sub-objective 2.1: Inventory and pharmaceutical management capacity of individuals and institutions strengthened

In connection with the emergency distribution of ACTs in Nov 2012, SIAPS worked together with PNLP and PCG to collect data on consumption of ACTs and other malaria products from all health centers and hospitals and to quantify short-term needs at the facility-level. However, an important aspect of this second PMI emergency distribution (the first one had taken place in late 2011) was that health facilities were provided with a sufficient, but

limited quantity of ACTs (for example, 3 months of stock of AS-AQ for infants and children). This was done in order to avoid over-supply and to encourage facilities and health districts to transmit monthly consumption reports and to place regular orders in an effort to switch from a "push system" (products sent by allocation) to a continuous "pull system" (based on verifiable information on patient cases and malaria drug use).

Challenges in progress toward sub-objective 2.1

The absence of consistent epidemiological and consumption data at the central level (PNLP) required a rapid data collection exercise from all districts in the country (for quantification purposes), although this is not necessarily the most accurate or efficient way of obtaining such data. Not all of the data could be collected through Faisons Ensemble meetings with the health districts (in the PMI-supported zones) or through PNLP phone calls/emails (in non-PMI supported zones), and some of the data collected was inconsistent, thus highlighting the importance of establishing a system of monthly reporting, with checks and balances (such as quarterly review meetings).

Deliverables: Sub-Objective 2.1

Preliminary database with patient data and ACT consumption data, used to calculate the estimated average monthly consumption (AMC) of public health facilities in Guinea (who provided this information). This database was used to quantify needs for the emergency distribution.

Quarterly progress toward sub-objective 3.1: Pharmaceutical management systems (PMIS) support both products and patients

From Nov 28 to Dec 1, 2012, the SIAPS Guinea and HQ team held a national workshop with representatives from all levels to discuss improvements to the pharmaceutical management information system (PMIS) in Guinea. The workshop was held at the PCG under the auspices of the Ministry of Health, PNLP, PCG and the USAID/PMI Guinea mission. Discussions focused on all aspects of the information system with the aim of ensuring a constant and accurate flow of data from the facility level to the central level. Revisions/updates to the reporting forms and pharmaceutical management tools proposed by SIAPS's HQ team were also discussed, and an action plan was drafted, outlining next steps, timelines and the institutions responsible for ensuring the launch of an improved system of data collection. PNLP and SIAPS were congratulated for involving both central level actors and regional/district/facility level representatives, since the decisions surrounding data collection affect the local level, who will be ultimately responsible for ensuring the success of the proposed new process.

The SIAPS technical assistance team had made the strategic decision to use the emergency distribution as an entry point to jumpstart the creation of a well-functioning PMIS for malaria commodities. This was done by ensuring that an initial tranche of commodities was delivered to health facilities in line with needs expressed by the facilities. In order to receive resupply, health facilities would subsequently have to submit monthly reports to PNLP and the Ministry of Health. In the next quarters, an important area of activity for SIAPS and PNLP will be to launch the newly-improved PMIS, initially through pilot activities, to obtain buy-in at all levels, including participation in regional review meetings, and to conduct the appropriate trainings. This sub-objective will be achieved successfully only when monthly stock status and patient data from a majority of health facilities in Guinea reaches PNLP and is used for quantification and forecasting.

The End Use Verification (EUV) survey is a routine assessment of the supply chain of malaria medicines/products and of the diagnosis and treatment of malaria at the health facility level. The first EUV survey in Guinea took place at 25 facilities in PMI zones (15 rural and urban health centers; 6 hospitals; and 4 warehouses) from Dec 17 to 22, 2012. The survey was implemented by SIAPS in collaboration with data collectors from: PNLP; PCG; SNIS; national Pharmacists, Inspectors and Statisticians; district Pharmacists and Physicians; and M&E supervisors from MCHIP and Faisons Ensemble. The EUV survey was first introduced and explained by SIAPS staff during the

PMIS workshop in Nov 2012. This was followed by three working sessions at the SIAPS office in early Dec 2012, which resulted in a national committee updating and customizing the EUV survey questionnaire for Guinea.

An orientation for all the data collectors took place at SIAPS on Dec 11-12, 2012; the orientation included a pre-test at two health facilities in Conakry. The Regional and District Health Directors (DRS/DPS) were notified in advance of the survey, along with the health facilities that had been selected for evaluation (all of the facilities were in PMI zones, including Conakry and the regions of Labe, Boke, Kindia, Faranah). Following a debrief of all the survey teams in late Dec 2012, the data was cleaned and entered into a newly-developed Excel database. The data analysis is currently ongoing and the reports from the survey will become available in late Jan 2013. Preliminary observations were shared on site with the health facilities and with the DPS/DRS level and the final aggregated results will be shared at the national level. The EUV survey will be repeated 2-3 times per year in Guinea, each time with a different sample of facilities.

Challenges in progress toward sub-objective 3.1

The only challenge encountered was related to the timing of the PMIS workshop relative to that of the emergency distribution of products. Ideally, the PMIS discussions would have taken place in advance of the distribution to allow time for the validation of the new reporting process and tools. However, given the urgency to avoid stock-outs and distribute ACTs especially for children under the age of 5, the PMIS workshop was timed to take place immediately after the distribution; lessons learned from the distribution were presented on the first day of the workshop and carried out throughout the debates and discussions.

Deliverables: Sub-Objective 3.1

A report and action plan from the PMIS workshop has been drafted by PNLP and Ministry of Health partners. SIAPS is in the process of providing input into this deliverable and to summarize proposed changes to the reporting forms and pharmaceutical management tools. The final report will be shared and acted upon in early 2013.

Two reports will result from the EUV survey: a summary report of key indicators for PMI (in English) and a full report to be shared at the national level (in French). The second report will be drafted by PNLP's Monitoring and Evaluation team, with technical assistance from the local SIAPS consultant.

Quarterly progress toward sub-objective 4.1: Availability of pharmaceuticals improved

SIAPS Guinea responded to a request from USAID Guinea to develop a detailed distribution plan for malaria commodities (ACTs and rapid test kits) purchased by PMI on an emergency basis. SIAPS worked with PNLP, PCG and all the major actors in ensuring an efficient distribution process to Guinea's 8 regions (38 health districts and approximately 450 health facilities), including for the first time a supply of ACTs for public military health centers). This activity was not in the work plan but was conducted by SIAPS on USIAD/PMI request. The distribution took place during the last two weeks of Nov 2012.

SIAPS managed the data collection and analysis process to inform the distribution; conducted an orientation for the distribution teams; labeled the products with the PMI logo and funded the transport of products to regional warehouses; participated in distribution activities in 4 regions; hosted two debrief sessions; and collected all the product delivery receipts and individual team reports, including a summary report from Peace Corps volunteers that were involved with the distribution throughout the country. SIAPS funded the emergency distribution with funds remaining from Year 1. More than 160,000 ACTs and more than 40,000 RDTs were distributed in Nov 2012.

Overall, several shipments of PMI-procured anti-malarial products arrived at the Central Pharmacy (PCG) during the quarter. These included shipments of 75,900 doses of AS-AQ (infants); 301,475 doses of AS-AQ (children);

188,950 doses of AS-AQ (adolescents); 188,400 doses of AS-AQ (adults); 100,000 RDTs (with 1 million more expected); 325,000 doses of SP (with 50,000 more expected); and 10,000 doses of injectable Quinine (with 30,000 more expected). SIAPS is discussions with PNLP and PCG to finalize a plan for the regular distribution of these products throughout the year. Following the successful distribution of ACTs country-wide (as well as of RDTs for trained community health workers and health centers in PMI zones), the SIAPS Guinea team was approached by the PMI/USAID mission and asked to advise PNLP and the national commission for the Universal Distribution of Malaria Bed Nets (planned to start in April 2013). SIAPS is currently involved in the national commission and helps co-host the logistical sub-commission. These commissions involve representatives of all the bed net donors (Global Fund/CRS, BID/UNICEF) and many in-country NGO partners. PMI will procure 1.59 million bed nets, with the first shipment expected in country in mid Jan 2013. SIAPS will oversee the transport and storage of these products and will also help organize a rapid census of the population in PMI zones. This will be followed by a national distribution plan/strategy, informed by the data collected in both PMI and non-PMI zones.

Challenges in progress toward sub-objective 4.1

The main challenges surrounding the emergency distribution involved timing (part of the activities overlapped with the National Vaccination Days which delayed the distribution in several provinces). Additionally, since some of the data collected in advance was not reported accurately (for example, did not include Community Health Worker needs) or was not reported at all, some of the health facilities felt that they were not being supplied with a sufficient quantity (but the distribution teams helped explain the process of obtaining additional quantities based on monthly reports and product orders). Given the recurrent stock-outs in Guinea and the prevalence of the “push” system for malaria products to date, many health centers are not used to ordering ACTs so this will require significant coordination between the facilities, health district/regional authorities, PNLP, PCG and the regional warehouses.

- Additionally, since some of the data collected in advance was not reported accurately (for example, did not include Community Health Worker needs) or was not reported at all, some of the health facilities felt that they were not being supplied with a sufficient quantity (but the distribution teams helped explain the process of obtaining additional quantities based on monthly reports and product orders). Given the recurrent stock-outs in Guinea and the prevalence of the “push” system for malaria products to date, many health centers are not used to ordering ACTs so this will require significant coordination between the facilities, health district/regional authorities, PNLP, PCG and regional warehouses.
- Another challenge surrounding the emergency distribution involved timing (part of the activities overlapped with the National Vaccination Days which delayed the distribution in several provinces).

Deliverables: Sub-Objective 4.1

Orientation materials associated with the emergency distribution; the distribution plan; product delivery receipts; and individual team reports. A combined final report for the distribution, including immediate and longer-term actions, is currently being finalized by PNLP.

Lesotho

Year 1 Work Plan

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: To assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes

Overall Quarter Progress

Activities this quarter have focused on establishing baselines for indicators to be measured to assess progress with supply chain performance in the 5 districts SIAPS is focusing its supportive supervision and mentoring (SSM) program activities in, being Botha Bothe, Berea, Mafeteng, Mohale's Hoek and Maseru. Towards that end, visits were conducted to 92 facilities - 5 hospitals and 87 health centers. The critical baselines that were established were on inventory management and patient care indicators, and these included stock out status, adherence to drug supply management SOPs (LeSOPs).

The district logistics officers (DLOs) and supportive supervision and mentoring coordinators (SSMCs) were also deployed to their stations in the 5 districts we are focusing our SSM program in.

Follow up visits were conducted for the laboratory logistics management information system (LMIS) to provide supportive supervision to facility staff, and mentoring where required. A total of 7 hospital laboratories in 4 districts were visited and 18 health care workers (HCWs) were reached.

On-going support for pharmaceutical management information system (PMIS) continued. Paray hospital was visited and the importance of information management as one of the key processes in pharmaceutical management was reinforced. Support was also provided to HCWs in using the paper-based system or RxSolution as a means of collecting PMIS data.

The development process for new solutions for PMIS at health center (H/C) level continued. The goal of this activity is to optimize reporting rates and use of PMIS data for inventory management decisions. The ePMIS and mHealth solutions have been developed. These have been discussed with Ministry of Health (MOH), and they will be discussed with SIAPS head office for support in finalizing them during the next quarter.

Training in supply chain management was conducted for HCWs from 3 districts in Lesotho - Berea, Maseru and Leribe. A total of 23 HCWs were trained, and the participants included pharmacists, pharmacy technicians, nurses, laboratory technologists and counselors for HIV testing and counseling (HTC).

A mentoring visit was also conducted at National Drug Service Organisation (NDSO) to support the IT staff who was capacitated by SIAPS in 2012 to be a super user of the system. The outcome of that visit was that the super use is now capable of carrying out some important maintenance activities for RxSolution at NDSO, and can provide on-site support for other NDSO staff on use of the system.

The costing analysis study for NDSO was also finalized and report submitted to NDSO. This report will inform not only NDSO's operational and management decisions, but will also inform the broader supply chain options analysis, which is expected to be implemented in the coming quarter.

Key challenges faced during the quarter

The main challenge still remains competing priorities at the Ministry of Health that hinder progress in the implementation of certain activities. However, some activities have been halted by lack of support for those activities by the MOH department responsible for them. The national stakeholder validation meeting for finalizing the STGs and EML has still not been held, and this is largely due to lack of support for the process by the Directorate of Pharmaceuticals. SIAPS will continue to provide support to the MOH in this activity upon request from the MOH.

Implementation of the minilab activity is still being delayed by the expiry of the pharmaceutical standards for

the minilab and therefore no tests were conducted. During this past quarter, NDSO submitted the list of expired items and SIAPS is going to procure them for NDSO.

RxSolution is still not operational at some of the sites due to refurbishment of health facilities by MCA. Due to lack of pharmacy personnel and high work load at Botha-Bothe hospital, the staff is still not using RxSolution because of severe workload and they are using paper-based registers.

Key activities planned for next quarter

In the next quarter, SIAPS will continue to advocate with the MOH for finalization of the STGs and EML. Support will also be provided for implementation of quality assurance mechanisms for ARVs and other HIV-related commodities. SIAPS will provide technical assistance for in-service training in SCM. Implementation of the supply chain options analysis will also be done in the coming quarter. SIAPS will also support implementation of ART PMIS and Laboratory LMIS. SIAPS will also continue to provide support for implementation of the SSM program. SIAPS will also initiate the process of reviewing the pharmacy curriculum at the National health training College (NHTC). Coordination of SCM activities will continue through providing support to the SCM TWG.

Quarterly Progress for Objective 1: Strengthen pharmaceutical sector governance

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 and low levels of support for this activity by the department responsible (the Directorate of Pharmaceutical Services). However, SIAPS continues to advocate for finalization of this process among stakeholders within the MOH and outside. Stakeholder Validation workshop is yet to be approved by MOH. With regard to the Medicines Bill, the process is progressing slowly due to lack of direction for the process by the department responsible, being the Directorate of Pharmaceutical Services.

Quarterly Progress for Objective 2: Increase and enhance the capacity for pharmaceutical supply management and services

SIAPS continued to support the SSM program for both the ART and laboratory programs at the MOH. The baseline assessment for ART services was conducted, whose purpose is to inform the SSM program for the national ART services program. Data on ART pharmaceutical management was collected, and this included data on inventory, patient care and information management processes. Indicators for the SSM program are being reviewed as a result of the baseline assessment and the baseline report is currently being prepared. It will be shared with the MOH and other stakeholders once it is approved by the Disease Control Directorate (DCD), and it will inform the next SSM visits.

A training in SCM was conducted for 23 HCWs from Berea, Thaba Tseka and Maseru. This represents 19% of the set target of 120 HCWs trained in SCM during this year (year 2). Three more training workshops have been planned, from which 97 HCWs will be trained. These will be done over the coming 3 quarters.

SIAPS conducted a supportive supervision and mentoring (SSM) exercise with the laboratory directorate, through which 7 hospital laboratories were visited in the 4 districts of Mokhotlong, Botha Bothe, Berea and Thaba Tseka. 13 laboratory staff, 1 doctor, 2 nurses and 1 administrator were reached with these visits. The visits resulted in more commitment from the hospitals to implement LMIS and use the data from the system to inform inventory management decisions. An additional 2 DLOs were recruited during the quarter to support implementation of the SSM program and support implementation of the ART PMIS and laboratory LMIS.

The draft Capacity Needs Assessment for the ART Program report has been developed and work is ongoing to

finalize the report.

Quarterly Progress for Objective 3: Increase utilization of information for pharmaceutical and laboratory decision-making

SIAPS continues to support implementation of the ART PMIS at district hospital ART sites. Towards this end, SIAPS has, during this quarter, provided supportive supervision and mentoring to pharmacy staff at Paray hospital, which uses RxSolution. Development of electronic solutions that are meant to strengthen implementation of RxSolution at hospitals and management of information in general across all the levels of health care, continued. The ePMIS solution, meant to streamline reporting from district level to headquarters (HQ) level, was presented to the MOH and approved, pending incorporation of a few inputs. Work started on development of an mHealth solution that is intended to optimize capturing and reporting of ART data at H/C level. These solutions have been developed in an integrated manner with the already existing platform of RxSolution and are meant to maximize data capturing and reporting across the different levels of health care.

SIAPS has continued to provide support for implementation of the laboratory LMIS. Reports from facility laboratories continue to be analyzed, and the logistics coordinator at the laboratory directorate has been capacitated such that she is now leading the reporting and LMIS management activities. A consolidated report for the 6-month period starting from June 2012-December 2012 is being prepared and will be shared with all relevant stakeholders early next quarter. The purpose of this sharing activity is to sensitize all stakeholders on the importance of consistent LMIS data collection and its processing to get information for informed laboratory logistics decision-making.

Quarterly Progress for Objective 4: Strengthen financing strategies and mechanisms to improve access to medicines and laboratory products

The NDSO Costing Analysis Report has been submitted to NDSO. This report will inform the procurement, warehousing, logistics and general management decisions at NDSO. It will also inform the supply chain options analysis which will be conducted in the next quarter. Both these studies will inform development of the NDSO procurement plan, which is expected to be completed by the third quarter of year 2 of SIAPS program implementation.

Quarterly progress toward sub-objective 1.1: Improve medicines policies, legislation, regulations, norms, and standards

There has been no progress on finalization of the STGs and EML due to low support for this activity from the Directorate of Pharmaceutical Services. NDSO submitted a list of expired standards for the Minilab that SIAPS will procure for them in order to start implementation of quality assurance activities for ARVs, anti-TB medicines and medicines for opportunistic infections at NDSO.

Challenges in progress toward sub-objective 1.1

Low support for the activity from the Pharmaceuticals Directorate impeded finalization of the STGs and EML documents. Lack of funding at NDSO prevented purchasing of standards for the Minilab and thus delayed implementation of the QA for ARVs, anti-TBs and OI medicines.

In order to mitigate these challenges, SIAPS has continued to advocate within and outside the MOH for completion and adoption of the STGs and EML. SIAPS has approached the DCD to lead the process of completing these documents and the DCD has agreed. A plan for completing the process is being worked out with the DCD. SIAPS has also requested NDSO to provide a list of expired Minilab standards, which has been done, and SIAPS

will procure these standards for NDSO to initiate use of the Minilab.

Quarterly progress toward sub-objective 2.1: Strengthen pharmaceutical management capacity of individuals, institutions, organizations, and networks

SIAPS continued to support the SSM program for both the ART and laboratory programs at the MOH. The baseline assessment for ART services was conducted, whose purpose is to inform the SSM program for the national ART services program. Data on ART pharmaceutical management was collected, and this included data on inventory, patient care and information management processes. Indicators for the SSM program are being reviewed as a result of the baseline assessment and the baseline report is currently being prepared. It will be shared with the MOH and other stakeholders once it is approved by the Disease Control Directorate (DCD), and it will inform the next SSM visits.

A training in SCM was conducted for 23 HCWs from Berea, Thaba Tseka and Maseru. This represents 19% of the set target of 120 HCWs trained in SCM during this year (year 2). Three more training workshops have been planned, from which 97 HCWs will be trained. These will be done over the coming 3 quarters.

SIAPS conducted a supportive supervision and mentoring (SSM) exercise with the laboratory directorate, through which 7 hospital laboratories were visited in the 4 districts of Mokhotlong, Botha Bothe, Berea and Thaba Tseka. 13 laboratory staff, 1 doctor, 2 nurses and 1 administrator were reached with these visits. The visits resulted in more commitment from the hospitals to implement LMIS and use the data from the system to inform inventory management decisions. An additional 2 DLOs were recruited during the quarter to support implementation of the SSM program and support implementation of the ART PMIS and laboratory LMIS.

Challenges in progress toward sub-objective 2.1

Unreliable services by some transport hire providers resulted in visits not being conducted to H/Cs. This will be mitigated by procuring vehicles for the program.

Deliverables: Sub-Objective 2.1

- Draft SSM Baseline report; SCM training report - Berea; Trip Report - LMIS SSM Visits, November 2012.

Quarterly progress toward sub-objective 2.2: Adopt and implement innovative and proven approaches for human resource capacity building

The draft Capacity Needs Assessment for the ART Program report has been developed and work is on-going to finalize the report.

Challenges in progress toward sub-objective 2.2

The compilation of the draft report was delayed due to the STTA having competing priorities. The draft has been completed and submitted and work is now ongoing to finalize it. It is expected the report will be completed by early next quarter.

Deliverables: Sub-Objective 2.2

- Draft report - Capacity Needs Assessment for the ART Program in Lesotho

Quarterly progress toward sub-objective 3.1: Strengthen use of pharmaceutical management information

systems (PMIS) to support both inventory and patient management

SIAPS continues to support implementation of the ART PMIS at district hospital ART sites. Towards this end, SIAPS has, during this quarter, provided supportive supervision and mentoring to pharmacy staff at Paray hospital, which uses RxSolution. Development of electronic solutions that are meant to strengthen implementation of RxSolution at hospitals and management of information in general across all the levels of health care, continued. The ePMIS solution, meant to streamline reporting from district level to headquarters (HQ) level, was presented to the MOH and approved, pending incorporation of a few inputs. Work started on development of a mHealth solution that is intended to optimize capturing and reporting of ART data at H/C level. These solutions have been developed in an integrated manner with the already existing platform of RxSolution and are meant to maximize data capturing and reporting across the different levels of health care.

Challenges in progress toward sub-objective 3.1

Renovation of hospitals by MCA is delaying RxSolution implementation. There is nothing SIAPS can do about this except be ready to re-implement once renovations are complete.

Deliverables: Sub-Objective 3.1

- Trip Report - Supportive Supervision and Mentoring Visit for RxSolution- Paray Hospital

Quarterly progress toward sub-objective 3.2: Improve availability and use of strategic information for laboratory systems strengthening

SIAPS has continued to provide support for implementation for the laboratory LMIS. Reports from facility laboratories continue to be analyzed, and the logistics coordinator at the laboratory directorate has been capacitated such that she is now leading the reporting and LMIS management activities. A consolidated report for the 6-month period starting from June 2012-December 2012 is being prepared and will be shared with all relevant stakeholders early next quarter. The purpose of this sharing activity is to sensitize all stakeholders on the importance of consistent LMIS data collection and its processing to get information for informed laboratory logistics decision-making.

Challenges in progress toward sub-objective 3.2

The main challenge for this activity was that the reporting rates dipped again. The SSM visit conducted during this quarter will hopefully improve on the reporting rates again.

Deliverables: Sub-Objective 3.2

- Laboratory LMIS Supportive Supervision and Mentoring Trip Report - November 2012

Quarterly progress toward sub-objective 4.1: Strengthen NDSO and public sector supply chain system in Lesotho

The NDSO Costing Analysis Report has been submitted to NDSO. This report will inform the procurement, warehousing, logistics and general management decisions at NDSO. It will also inform the supply chain options analysis which will be conducted in the next quarter. Both these studies will inform development of the NDSO procurement plan, which is expected to be completed by the third quarter of year 2 of SIAPS program implementation.

Challenges in progress toward sub-objective 4.1

The slow response rate from NDSO delayed finalization of the report. It has however been finalized and will now be published and used to inform the SCOA in the next quarter.

Deliverables: Sub-Objective 4.1

- NDSO Costing Analysis Trip Report - September 2012; NDSO Costing Analysis Technical Report - December 2012.

Year 2 Work Plan

Goal: To assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes

Overall Quarter Progress

SIAPS year two work plan aims to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Objective one of the work plan was to ensure that pharmaceutical sector governance is strengthened. To achieve the objective, performance was to be measured through % of prescriptions that contain an antibiotic and % of prescriptions in compliance with STGs. The annual work plan targets for the indicators are 35% and 45% respectively. Performance measurements for these indicators are yet to be determined in order to conform to the set targets. Another objective is to ensure that capacity for pharmaceutical supply management and services is increased and enhanced. The first performance indicator for the objective is % of public sector personnel working in the pharmacy that know how to order according to LeSOP HOSP ORD 04 with the annual target of 40%. On the other hand, another performance indicator is % of public sector personnel working in pharmacy that order according to LeSOP HOSP ORD 04 with an annual target of 30%. Objective three of the work plan is to ensure increased utilization of information for pharmaceutical and laboratory decision-making across all levels of the Lesotho health system. For these objectives, a supportive supervision and mentoring template has been developed for acquisition of information at the health facilities. The document awaits approval from the Ministry of Health so that information can be collected from the health facilities through District Logistics Officers with supervisory support from SSMCs. The baseline and target information for objective four (financing and procurement mechanisms strengthened to improve access to health commodities) are yet to be determined.

Key challenges faced during the quarter

The general challenges that were experienced during the quarter were on slow progress in fast tracking implementation of activities as outlined in the annual activity monitoring matrix. These challenges emanated from delays in setting up of supportive supervision and mentoring program especially deployment of District Logistics Officers (DLOs) and Supportive Supervision and Mentoring Coordinators (SSMCs). However, SIAPS has engaged the services of two SSMCs to coordinate supportive supervision and mentoring at the district level. Currently these employees are working towards establishment of baselines for key activities planned for support at the district level. Other efforts made were also on deploying District Logistics Officers (DLOs) to support the health facilities in inventory management. The last quarter has been basically on setting up of these district structures to improve support in SSM program at the health facilities and the DHMTs. Another impediment was the resignation of one DLO who left a gap for the already initiated support at the health facilities. Nonetheless, two new hires were employed to assume responsibilities as DLOs. The expectation is that efforts will be doubled in the next quarter for the slow progress that was experienced during the quarter.

Key activities planned for next quarter

Below is a list of key activities planned to be done in the next quarter. These activities are a continuous implementation emanating from quarter one planned activities. These are:

- Provide technical assistance for implementation of STGs and EML
- Provide technical assistance for implementation of Quality Assurance mechanisms for ARVs and other HIV-related commodities
- Increase SCM HR capacity at all levels
- Provide technical assistance for pre and in-service training in SCM
- Support implementation of SSM program
- Support pharmacy curriculum review at NHTC
- Support implementation of ART PMIS
- Support implementation of laboratory LMIS
- Provide technical assistance for the development and implementation of a procurement and supply management system (at NDSO)

Quarterly Progress for Objective 1: Pharmaceutical sector governance strengthened

There are two objective level performance indicators that are supposed to be tracked for objective one of this workplan. These are on measuring % prescriptions that contain antibiotics and % prescriptions in compliance with STGs. At this level, there has not been any progress towards achieving the expected outcomes. These indicators are being tracked overtime and currently baseline information is still being collected at health facility level through SSMCs and DLOs in order to make sure that pharmaceutical sector governance is strengthened.

Quarterly Progress for Objective 2: Capacity for pharmaceutical supply management and services increased and enhanced

Objective two was working towards increasing and enhancing capacity for pharmaceutical supply management and services. Performance indicators for this objective are % of public sector personnel working in the pharmacy that know how to order according to LsSOP HOSP ORD 04 and % of public sector personnel working in the pharmacy that order according to LeSOP HOSP ORD 04. There has not been any progress on these indicators. The SSMCs and DLOs are currently compiling baseline data that will be used to define a notable change in achieving the set targets for the indicators.

Quarterly Progress for Objective 3: Utilization of information for pharmaceutical and laboratory decision-making increased across all levels of the Lesotho health system

Utilization of information for pharmaceutical and laboratory decision-making increased across all levels of Lesotho health system was to be measured by three performance indicators being:

- % of SIAPS-supported SDPs that experienced stock outs of ARVs, OIs, TB medicines and contraceptives of more than 28 days in the past 6 months,
- % of SIAPS-supported SDPs with stock-outs of ARVs, OIs, TB medicines and contraceptives for 3 days or more in the last 3 months and
- % availability of tracer medicines and commodities in SIAPS-supported SDPs reported in past 3 months.

The indicator targets have not been set yet because currently the Ministry of Health through SIAPS is going to introduce SSM program baseline. The document is currently being reviewed and will be implemented as soon as it has been approved by the Directorate of Disease Control Director.

Quarterly Progress for Objective 4: Financing and procurement mechanisms strengthened to improved access to health commodities

In order to strengthen financing and procurement mechanisms for improved access to health commodities, SIAPS has set up four objective level indicators to measure the performance of this objective. The baselines and targets for these indicators have not been determined as yet. However, costing analysis study has been conducted through technical assistance from HQ. A draft report on NDSO costing analysis has been sent out for comments. There is planned technical assistance for conducting Supply Chain Options Analysis study in the succeeding quarters. The results of these studies are going to be used on determination of baselines and targets and thereby strengthening financing and procurement mechanisms to improved access to health commodities.

Quarterly progress toward sub-objective 1.1: Improved medicines policies, legislation, regulations, norms, and standards

The specific activities on progress towards sub-objective 1.1 were to provide assistance for implementation of STGs and EML and also to provide technical assistance for implementation of quality assurance mechanisms for ARVs and other HIV-related commodities. Quarterly progress towards this sub-objective has seen the DCD Director working with SIAPS towards finalization of the documents. On the other hand, list of standards that had expired from NDSO have been given to SIAPS. The indicators in reference to progress towards sub-objective 1.1 are 1.1a, 1.1b and 1.1c of the work plan.

Challenges in progress toward sub-objective 1.1

The Directorate of Pharmaceuticals has not been supportive especially towards accomplishment of this sub-objective. The DCD Director has therefore agreed to assist so that the STGs and EML are completed. The standards for quality assurance at NDSO had expired and SIAPS is a position to procure standards for the minilab. It will further provide TA for testing and analysis of data and use the same information to guide the procurement plan.

Deliverables: Sub-Objective 1.1

There have not been any completed products under this sub-objective. However, expected pipeline documents are QA report, National STG and EML, Official launch report, trip report, one article in the SIAPS Lesotho Newsletter and one on SIAPS website.

Quarterly progress toward sub-objective 2.1: Technical medical products management capacity of individuals, institutions, organizations, and networks in Lesotho's supply chain strengthened

For this sub-objective, progress is reported with reference to indicators 2.1a, 2.1b, 2.1c, 2.1d and 2.1e as outlined in the performance monitoring matrix of the work plan. Baseline SSM visits have been conducted in the five districts that SIAPS is supporting and there has been identified need in inventory such as shelving and refrigerators in the health facilities. A baseline report has been compiled and will be disseminated in February. An in-service training was conducted using DSM manual for Lesotho and 23 health care workers from four districts of Maseru, Berea and Thaba-Tseka were trained during the quarter. 19% of planned target for the in-service training has been covered in the quarter. The training was co-funded by Irish AID.

Challenges in progress toward sub-objective 2.1

Transport reliability has been an issue for SSM baseline information collection. However, there is planned

procurement of three vehicles to support the implementation of the SSM program. The performance indicators for this sub-objective will be informed by the baseline information that is being collected through the SSM program. Cumulatively, only 19% of targeted in-service training has been conducted. However, there are more planned trainings in the following quarters. No SCM TWG meetings were held during the quarter due to competing priorities from relevant departments; however these meetings can be extended to the following quarters.

Deliverables: Sub-Objective 2.1

-Trip report for in-service training and SSM baseline data trip reports.

Quarterly progress toward sub-objective 3.1: Use of pharmaceutical management information systems (PMIS) supports both inventory and patient management

This sub-objective measures the use of pharmaceutical management information systems (PMIS) to support both inventory and patient management. A continued support is still extended to Ntsékhe and Maluti Adventist hospitals in Rx Solution. These sites have been identified as the best practice hospitals in terms of usage of the system in an effort to inform pharmaceutical activities. The mHealth and ePMIS development is complete and awaits comments and discussions with HQ before piloting.

Challenges in progress toward sub-objective 3.1

The SSM program activity monitoring template is awaiting approval from the DCD to standardize collection of information from the health facilities. This will inform the performance indicators that measure this sub-objective.

Deliverables: Sub-Objective 3.1

Deliverables for the ART PMIS are trip reports.

Quarterly progress toward sub-objective 3.2: Availability and use of strategic information to support laboratory logistics management system improved

This sub-objective measures improvement in the availability and use of strategic information to support laboratory logistics management system. The performance indicator for this sub-objective is to minimize stock outs of HIV test kits and it is measured by looking at the % of district laboratories that experienced stock out of HIV test kits for a period of 3 days in the past 3 months. The in-service training workshop in Berea also trained HTC counselors and lab technicians in SCM for laboratory. SSM visits were conducted in seven laboratories in the districts of Mokhotlong, Butha-Buthe, Mokhotlong and Thaba-Tseka.

Challenges in progress toward sub-objective 3.2

Data cards at some districts do not work due to limited access to internet. Thus reporting rates at those laboratories are low. SIAPS has held discussions with internet service provider to solve the problem. Another major challenge of low reporting rates is due to laboratory personnel not seeing the value of LMIS. SIAPS has planned to address these challenges by increasing SSM activities. National feedback workshop will be held for LMIS following analysis.

Deliverables: Sub-Objective 3.2

Deliverable for this sub-objective was a trip report on LMIS

Quarterly progress toward sub-objective 4.1: Efficient use of existing resources strengthened

The sub-objective works towards strengthening efficient use of existing resources. This sub-objective is measured by % of items received from medical stores as per facility order. A draft report on costing analysis has been shared for comments. This will inform on the baseline and target setting for measuring the performance of this sub-objective.

Challenges in progress toward sub-objective 4.1

The costing analysis has been done and draft report shared. However, there is still a further need for supply chain costing analysis (SCOA). Technical assistance will continue from HQ to complete the SCOA.

Deliverables: Sub-Objective 4.1

- Costing Analysis Report

Liberia

Year 2 Work Plan

Quarterly Report Background

Liberia's 2008 Census reported a total population of 3.4 million with a growth rate of 2.1%. Malaria is endemic in the country and is most common among children aged five years and younger. Liberia launched the Presidents Malaria Initiative (PMI) in 2008, and received support through different mechanisms including the Strengthening Pharmaceutical System (SPS) Program, predecessor to the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. In 2008, SPS, with PMI funding, undertook an assessment of the pharmaceutical management supply system in which major problems were identified including lack of skills and capacities to manage pharmaceuticals (ordering, quantification, storage, inventory management and use) including anti-malarials. To address these challenges, SPS and now SIAPS has been providing support to strengthen the pharmaceutical management systems focusing on capacity and skills building for service providers at the health facilities of the Ministry of Health and Social Welfare (MOHSW).

Since 2008, with US States Agency for International Development (USAID) funding, SPS/SIAPS collaborated with the MOHSW to conduct a quantification workshop for the National Malaria Control Program (NMCP) for malaria commodities and conduct pharmaceutical management training of trainers (TOT) to build pharmaceutical management capacities of county pharmacists. SPS trained over 400 service delivery point workers (Officers- in-Charge and Dispensers) in the Nimba, Bong and Lofa Counties; disseminated logistics management information systems (LMIS) tools to over 130 health facilities in three (3) the USAID focus regions, and revised the national curriculum of the Pharmacy Department of the University of Liberia. In collaboration with the NMCP SPS/SIAPS has undertaken several quarterly end use verification (EUV) tool implementation activities which identified poor storage conditions in a number of sites and recommendations to support the renovation of the Nimba medicine depot. . SPS supported the MOHSW to develop the Rational Use of Medicine (RUM) Program, by updating three policy documents: the National Therapeutic Guidelines (NTG), National Formulary (NF), and the Essential Medicine List (EML

Liberia's NMCP is working to improve access to appropriate case management to 80% of the population as data have shown that., 49.3 %% (Liberia Malaria Indicator Survey , 2011) of the country's population access antimalarial medications through the private sector where presumptive treatment for malaria based on fever and other symptoms is common and confirmatory blood tests are not utilized for diagnosis. The NMCP is presently working to expand access to malaria case management through private sector pharmacies and medicine stores.

To support the NMCP, SPS in 2010, conducted an assessment of private sector capacities in the Montserrado County which showed poor quality of services within the private sector medicine outlets, large variation in the type and cost of treating common ailments such as Malaria. Additionally, through the Sustainable Drug Seller Initiative (SDSI) funded by the Bill and Melinda Gates Foundation, MSH conducted a mapping of pharmacies and medicine stores in Montserrado County which showed that there out of a total of 750 retail outlets (113 pharmacies and 637 medicine stores) only 36% had valid registration permit from the Pharmacy Board of Liberia (PBL).

In fiscal year (FY) 12, SIAPS will roll out the revised private sector model in collaboration with the NMCP. SIAPS will also work closely with MoHSW to monitor the use of anti-malarials using tools such the EUV in the public sector.

Goal: Improve the supply, quality of pharmaceutical services, and use of malaria commodities and other key pharmaceuticals to achieve desired health outcomes.

Overall Quarter Progress

SIAPS Liberia remains committed to achieving its overall goal which is to improve the supply and quality of pharmaceutical services and the use of anti-malaria commodities to achieve desire health outcomes.
Progress towards the achievement of the above goal was made by the implementation of the below activities:

1. Completed renovation of the Nimba County Drug Depot (using the 2011-2012 funding).
2. Conducted the qualitative study on the feasibility of introducing ACT & malaria Rapid Diagnostic tests (mRDTs) for malaria case management in private pharmacies and medicines stores in Monsterrado county of Monrovia. The Preliminary report has been drafted and shared with stakeholder Work on the final report is ongoing and will be ready end Jan 2013.
3. SIAPS also worked with the NMCP to finalized plans for the EUV Round 6.
4. SIAPS Conducted a three day meeting to finalize IEC/BCC messages design to include RDT in collaboration with the NMCP IEC/BCC Unit, National Health Promotion Division MOH.
5. Participated in a one day training conducted by USAID Liberia Monitoring and Evaluation Program (USAID L-MEP) and cooperated with USAID L-MEP for the creation of an electronic data base account with USAID Liberia Indicators for which SIAPS is to report on periodic basis. (USAID L-MEP is responsible for monitoring and evaluation of all USAID funded project in Liberia using USAID indicators).
6. Participated in the annual national Malaria Control Program Review Conference and presented during panel discussion of the NMCP Private Sector ACT and RDT Distribution Project and the Monitoring and Evaluation of malaria commodities and case management using the End Use Verification Tools.
7. Finalized data management tools for the private sector ACT and RDT project in collaboration with the National Malaria Control Program.

Quarterly progress toward sub-objective 1.1: Enhanced individual, institutional and organizational capacity for malaria case and commodities management

To build up capacity of the proprietors for successful implementation of the private sector ACT and RDTs distribution, the first batch of 60 proprietors have been selected and presentations for the orientation and sensitization meeting have been developed.

Challenges in progress toward sub-objective 1.1

SIAPS Liberia work plan has not yet been approved by the USAID Liberia Mission, however SIAPS is working with in country partners and USAID to finalize a micro plan which clearly defines and shows what and how the private sector mRDTs and ACT roll out will be like

Quarterly progress toward sub-objective 2.1: Pharmaceutical management information systems (PMIS) available and strengthened

To achieve the required data for processing to make available logistic information for decision making, data collection tools have been designed, developed by SIAPS and partners and these tools have been adopted by the Private Sector ACT Technical Working Group and approved by the National Malaria Control Program. These tools include: 1. Commodity management ledger; 2.Client record/ledger; 3. Referral form; 4. Monthly reporting form; 5. Commodity distribution form

To monitor the availability and use of malaria commodities in the public sector facilities for decision making purposes, SIAPS in collaboration with the National Malaria Control Program has finalized the plans for the End

Use Verification data collection exercise: intervention sites selected, facilities for data collection identified and data collectors selected.

Challenges in progress toward sub-objective 2.1

SIAPS Liberia work plan 2012-2013 has not yet been approved by USAID Liberia, but spillover activities from Year 1 have been implemented and activities that have to do with reproduction/printing of the various tools have not been done. We continue to have series of meetings with NMCP and the USAID to strengthen the approach again the USAID has been leading discussions with MoHSW on the private sector.

Quarterly progress toward sub-objective 3.1: Availability of pharmaceuticals improved

To achieve desire health outcomes for pharmaceuticals services, SAIPS Liberia has defined and developed the distribution model for the antimalarial medications and accessories commodities and endorsed by the NMCP. Commodity management tools have also been developed by SIAPS and approved by the NMCP. ACT and RDT distribution has not yet began.

Challenges in progress toward sub-objective 3.1

Same as earlier stated.

Quarterly progress toward sub-objective 3.2: Patient Safety and therapeutic effectiveness assured

To enhance client safety, SIAPS in collaboration with the Montserrado County Health Team to incinerate waste that will be generated in the medicine stores and pharmacies during the implementation exercise. SIAPS has drafted the MoU and is currently undergoing review by the Montserrado county health team.

Challenges in progress toward sub-objective 3.2

- Same as mentioned earlier

Quarterly progress toward sub-objective 3.3: Medication use improved

To enhance the quality of services to be offered in the medicines store and pharmacy through routine supportive supervision that will help reinforce the skills and approaches thoughts during the training, SIAPS has designed and developed a supervision check List. This tool has been reviewed and endorsed by the National Malaria Control Program for the private sector. Information education and communication/behavior change communication strategy has been designed which forms the basis for IEC/BCC message development and roll out.

Challenges in progress toward sub-objective 3.3

SIAPS Liberia work plan has not been approved by the USAID Liberia Mission. The generic work plan was accepted and after series of meetings, the mission requested for a microplan. The microplan has been submitted and we have had series of meetings with the missions, and currently, the mission has promised to give us response.

Based on the above, distribution of commodity has not yet commenced to allow supervision visits and IEC BCC messages have not been developed.

Mali

Year 1 Work Plan

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 anti-malarials, 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 medicament, is unable to full carry out the functions conferred through its mandate.

Goal: Improved Access to pharmaceuticals and services

Overall Quarter Progress

The overall goal of SIAPS in Mali is to increase access to quality essential pharmaceuticals and optimal pharmaceutical services. During the first quarter of year 2, SIAPS continued working on its year 1 work plan but also start working on its year 2 work plan activities which was approved on December 2012. Progress was made on IR1 and IR2 to strengthen the pharmaceutical sector governance and also to make available pharmaceutical management information for decision-making. IR1: Pharmaceutical sector governance was strengthened to address the problem of inadequate collaboration and communication among key actors in Mali's pharmaceutical system.

SIAPS met the Directorate of Pharmacy and Medicines (DPM) on December, to explore the possibility of creating

an overarching mechanism for the coordination of health commodities in which the existing committees (hold by health program such as PNLP) will be folded into. During this meeting SIAPS shared with the DPM experiences from other countries. At the end of the meeting a draft of the SOW of this technical coordination committee was shared with the Directorate of DPM for review. Discussion with DPM will continue during the next quarter for the establishment this committee and to make it functional. In the meantime, SIAPS continues supporting the PNLP to coordinate key actors involving in Malaria commodities management.

During this quarter, SIAPS also contributed to strengthen the governance of the pharmaceutical sector by assisting the DPM to the dissemination at the central level of the "Schema Directeur des Approvisionnements et de la Distribution des Medicaments Essentiels (SDADME)" which is a key document guiding the functioning of Mali's pharmaceutical sector. IR3: Pharmaceutical management information available and used for decision making at different levels of the Malian health system. This intermediate result focuses on rendering the existing national medicines information system functional, so that it provides regular, useful logistical data on tracer health commodities that can be used for decision-making.

During this quarter, SIAPS continued to assist the MOH with the Malian's LMIS assessment. That activity started during Q4 with the quantitative assessment A qualitative assessment was conducted on October with the participation of key actors involved in the Malian's supply chain at all level. After this two parts assessment, a technical report with recommendations and next steps were made with the MOH. This will be shared and implemented to really make available logistical data for decision-making. During this quarter, SIAPS submitted, in October, a Procurement Planning and Monitoring Report (PPMRm). This report provides information from the central level of the health system on stocks level of malaria commodities. Data from lower levels of the health system was obtained through active data collection or specific surveys such as EUV. SIAPS assisted the NMCP to disseminate findings of last EUV carried out on September 2012 through a national workshop held at Bamako on November 2012.

Key activities planned for next quarter

SIAPS plans to implement the following activities during the next 3 months: • Proceed with the following work plan activities to contribute to the corresponding intermediate results: IR 1: Pharmaceutical sector governance strengthened - Improve the existing mechanisms for coordinating quantification, forecasting, distribution and corrective actions for the supply of health commodities. - Provide technical support to the PNLP to develop distribution plans for key commodities IR 2: Capacity for pharmaceutical supply management and services increased and enhanced o Train trainers in use of the new LMIS SOPs. o Support quantification exercises. IR 3: Pharmaceutical management information available and used for decision making at different levels of the Malian health system to Re-design the LMIS based on the consensus reached during the LIAT and LSAT assessments (develop new LMIS SOPs). 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).

Quarterly Progress for Objective 1: Pharmaceutical sector governance strengthened

SIAPS provided technical assistance to the DPM for the dissemination of the revised SDADME and for the revision of the tracer drugs list through a national workshop held on November 21, 2012. This workshop aimed to provide extensive information to health authorities based at the central and regional level about the content of the revised SDADME. The new SDADME was distributed during this workshop. During this workshop, a new list of tracer drugs has been proposed discussed and validated. During this quarter, SIAPS contributed to this objective by assisting the NMCP team to organize a coordination meeting on November 1, 2012, to share information regarding Malaria commodities level of stock, malaria commodities quantification results made with SIAPS technical assistance. The purpose of this meeting was to bring around a table all partners involved in malaria commodities

supply plan to discuss the stock level, the status of orders and to make decision. The team also assisted the NMCP to develop a distribution plan of malaria commodities received by September 2012. The distribution was made based on the burden of malaria in each region and district in reference to the 2011 Statistical Yearbook and displaced populations. The amounts were adjusted based on data collected into the field during the EUV and the LMIS assessment surveys. Discussion also started with the DPM regarding the possibility of creating an overarching mechanism for the coordination of health commodities in which the existing committees (hold by health program such as PNLP) will be folded. Draft of SOW of this committee was proposed.

Quarterly Progress for Objective 3: Pharmaceutical management information is available and used for decision-making

Technical assistance was provided to the NMCP to organize the restitution of the End User Verification survey carried out in September. All the Regional Directorates of Health were present. The Findings of the survey were shared and at the end of the workshop the following recommendations were made: • Take into account the integration of key logistic indicators malaria in the next revision of the tools • Ensure the establishment of a functional LMIS • Make available the revised SDADME at all levels of the health pyramid. • Conduct regular supervision of the implementation of the revised SDADME • Make effective availability of reference guidelines for malaria case management • Monitoring the supply and distribution of donated commodities especially between the regional level and the community level • Conduct formative supervision visits.

SIAPS also provided technical assistance to the DPM for the qualitative assessment of essential medicines logistics system (LMIS). The objective of the evaluation was to identify the strengths and weaknesses of the existing system and propose corrective measures to define standard operational procedures for logistic management especially for the peripheral and community level. An Action Plan was developed. Following this assessment, a workshop with representatives of organizations involved in the management of essential drugs in Mali was conducted in Sélingué from 15 to 17 October. SIAPS also submitted during this quarter a PPMRm report.

Quarterly progress toward sub-objective 1.1: Improved capacity of the DPM to promote and instill good governance in the Malian pharmaceutical sector

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. In November 21, 2012, a national workshop involving the central and regional level was organized by the DPM with SIAPS technical, logistical and financial assistance. During this workshop, the revised SDADME was presented to the participants and distributed to the participants. The tracer drug list was also revised in accordance to the new list of essential drugs and guidelines revised in 2012 during this workshop.

Deliverables: Sub-Objective 1.1

- 1 report of the National workshop for the dissemination of the SDADME. 1 revised tracer drug list.

Quarterly progress toward sub-objective 1.2: Mechanisms for national forecasting, quantification and

supply planning of key pharmaceuticals are consolidated and made more efficient

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 personals and in-country various implementing partners' representatives for key MoH national programs. SIAPS assisted the PNLP to organize a technical coordination meeting on November 1st, 2012. During this meeting, the malaria commodities quantification exercise was presented to all the partners involved in Malaria commodities supply chain. Malaria commodities stock level was also shared during this meeting and decision was taken regarding next orders.

During this quarter, several meetings and discussions occurred with the DPM, and the PNLP to discuss the necessity for having only one commodities coordination committee with subcommittees coordinated by the DPM. This type of structure was also recommended by the Global Fund). On December 21, 2012 SIAPS met the DPM to share with them experiences from others countries regarding commodities technical and coordination committee. At the end of the meeting, SIAPS team shared with DPM a draft of SOW for Mali's technical coordination committee for discussion. Work remains to be done to make this coordination mechanism functional 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. SIAPS assisted the PNLP and the PPM on October and December 2012 with the reception of malaria commodities and with their distributions plans.

Deliverables: Sub-Objective 1.2

- 1 coordination meeting report (November 1, 2012). - 1 distribution plan for Malaria commodities.

Challenges in progress toward sub-objective 2.1

For this objective SIAPS have to monitor the reception and the distribution made by the PPM for all health commodities purchased by PMI and delivered to Mali, and to provide written feedback to JSI/DELIVER once the items are received and distributed. On October 2012, a new PDG (President Director General) of the PPM was nominated. During all this quarter (October 2012 to December 2012), the PPM was in a transition process and it was not possible to work with them on the distribution they made regarding JSI/PMI products in the country. But, SIAPS team requested a meeting with the new director of the PPM to discuss collaboration. Information related to PMI commodities distribution will be available in next quarter.

Quarterly progress toward sub-objective 3.1: Pharmaceutical management systems support both patients and products

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 Q1 year 2 (on October 2012) • These data collected through PPMRm were shared with decision makers to facilitate procurement decisions for malaria commodities and also helped the NMCP to make distributions plans for Malaria commodities received on September 2012. EUVS: A national workshop was organized by the NMCP with SIAPS technical and financial assistance to disseminate the EUV results. During this workshop, the findings of the last EUV were shared with all the attendees from the central and the regional level of the health system. Decision was taken and recommendations were made to improve malaria commodities management in facilities based on EUV findings • LMIS Assessment: During the first quarter of its second year activities, SIAPS continued with the LMIS

assessment that started during the last quarter. The technical report was also shared with the DPM. As a follow up, of these activities, the LMIS SOPs will be revised taking in consideration the recommendations made during the assessment.

Deliverables: Sub-Objective 3.1

-1 PPMRm report submitted by October 2012
- 1 EUV dissemination workshop report.
- 1 LMIS assessment report.

Mozambique

Year 1 Work Plan

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

Overall Quarter Progress

During the first quarter of Year 2 SIAPS implementation, the SIAPS Team in Mozambique continued to work toward the goal of improving access to safe, efficacious and quality pharmaceutical products and effective pharmaceutical services that will contribute to the achievement of desired health outcomes. The SIAPS team worked closely with the pharmaceutical sector of the Ministry of Health, particularly the Pharmacy Department and the Pharmaceutical Unit of the National Directorate for Medical Assistance to improve governance, human resource capacity, use of strategic information for decision-making and the delivery of services at the facility level.

Highlights of the SIAPS program's work in Mozambique this quarter, October 2012 through December 2012, included:

- The promotion of the Senior Technical Advisor to Country Project Director (CPD). The CPD attended a two week intensive training at MSH HQ in early December 2012.
- The development of the Year 2 work plan which was submitted to USAID for approval. The SIAPS Mozambique Team worked with partners to revise activities to produce a more realistic and attainable plan for Year 2. As a result, some objectives and activities were not carried over from the Year 1 work plan and this will be discussed in the next quarterly report once we have approval of the new work plan.
- Provision of regular, in-house technical support to the Pharmacy Department and the Hospital Pharmacy Department.
- Provision of continued support and technical assistance for the registration team at the Pharmacy Department in the development and finalizing of SOPS, job descriptions and guidelines of essential tools to guide the evaluation of products for registration.
- Frequent training provided to the registration staff in the evaluation of medicine dossiers and the appropriate use of registration tools.
- A stakeholder meeting was held in October 2012 to build consensus on the framework for the national pharmacovigilance system.

- The provision of pharmacovigilance support to scale-up active surveillance system.
- The planning and development of SOWs for technical assistance for the assessment and revision of drug pricing system. This work should begin in late February 2013.
- The planning and development of SOWs for technical assistance for the assessment and development of a framework and work plan to support the implementation of an M&E and electronic information system for the pharmacy department. This work should begin mid-February 2013.
- The planning and development of TORs for the piloting of a Drug Therapeutic Committee (DTC) at the hospital level in one pilot hospital,
- The SIAPS Mozambique Team has also hired a Technical Advisor for Pharmaceutical Services to start February 2013.

Key challenges faced during the quarter

The SIAPS Team has encountered a number of challenges during this quarter. A primary challenge is the level of initiative, motivation and dedication of some of the current staff and the current leadership at the Pharmaceutical Department is the biggest challenge to achieving significant improvements within the Department in the short-term. The SIAPS Team will continue to work towards improving this dynamic in the coming quarter. SIAPS has hired a Mozambican Pharmacist to become the Technical Advisor for Pharmaceutical Services which we believe will help balance the work load and help provide more insight into improving the motivation of some staff and leadership at the PD. Further, due to competing priorities, heavy workload, and the holidays it was difficult for some staff to participate in training sessions or fully benefit from some of the technical assistance activities.

Key activities planned for next quarter

The SIAPS Team for Mozambique has been planning for an increase in activity over the next two quarters. With the approval of the Year 2 work plan and revision of sub-objectives and activities, SIAPS will be able to continue follow-up of activities from this quarter and move ahead with a number of initiatives which have been agreed upon by partners for Year 2.

As noted in the summary, SIAPS will have in place a Technical Advisor for Pharmaceutical Services. The pharmaceutical sector in Mozambique needs an updated essential medicines list (EML) to streamline procurement activities, minimize institutional costs and optimize patient care. SIAPS will begin providing technical assistance to the PD to select an appropriate committee, define standardized and evidence-based criteria for the selection of medicines for the EML, coordinate the selection process and then disseminate the list to stakeholders.

SIAPS has been planning for provision of technical assistance to assist the PD to develop an M&E system. The PD does not currently have a formalized and comprehensive plan to monitor and evaluate the effectiveness of its activities, and of the regulatory system as a whole. This activity will be elaborated in conjunction with the development of the department's strategic and annual work plans.

The SIAPS Team for Mozambique has also planned for and developed activity plans for assessing the information system and related technical assistance needs of the PD. The existing information system in-use at the PD for medicine registration, WHO-supported SIAMED, is in need of updating, so that the PD can more efficiently and effectively manage the information they use to regulate medicines. The SIAPS team will also analyze the different system options in close collaboration with the Department to define data elements and identify an appropriate tool that is compatible with local technology and capacity.

In addition, plans have been developed for provision of technical assistance to work with the Pharmacy Department to review the current medicine pricing regulatory framework and enforcement capabilities and begin

developing a sustainable and transparent regulatory system. As a first step SIAPS will provide support to assess the extent of medicine price transparency, variation, and affordability from the perspective of patients, as well as build capacity in the PD to monitor medicine prices.

Further in the next quarter the licensing system in particular will be reviewed and the required JDs, SOPS and guidelines will be developed in coordination with the PD licensing department. Review and recommendations of the automated licensing database and system will be carried out in Q2 and Q3 2013.

Quarterly progress toward sub-objective 1.1: Improved medicines policies, legislations, regulations, norms and standards

To contribute to the overall Objective 1 Governance in the pharmaceutical sector strengthened, the SIAPS Team in Mozambique continued working through activities associated under Sub-objective 1.1 Improved medicines policies, legislations, regulations, norms and standards.

Much of the work in this quarter, focused on Activity 1.1.2 and the SIAPS team continued to provide technical assistance to the registration unit at the PD to implement the new tools and guidelines, including revised forms, checklists, job descriptions and standard operating procedures to assure the quality and efficiency of the tools' application. Support was provided in the form of monitoring the efficiency of the new tools (e.g. registration dossier review time), conducting additional trainings in response to observed areas of weakness, streamlining the manual/non-automated and automated steps of the process, and modifying the system as needed. World Health Organization (WHO) and Southern African Development Community (SADC) standards and guidelines are being adapted to the Mozambique context. Additional support will be provided to ensure that the registration team has the technical capacity to follow the guidelines and employ the tools effectively. Upon completion, the registration team and SIAPS will share the tools with stakeholders, including the Therapeutics and Pharmacy Technical Committee, Commissão Técnica de Terapêutica e Farmácia CTTF), the central Medical Store, Central de Medicamentos e Artigos Medicos (CMAM) and applicants, to solicit input and build consensus. The intended outcome of the activity will include a more streamlined, efficient and accountable registration process that effectively ensures timely access to safe, efficacious and quality pharmaceutical products as measured by regular monitoring and evaluation.

SIAPS will continue to provide the necessary support to ensure the guidelines and tools are technically sound, consistent with SADC and WHO standards, finalized, and then submitted for approval to the Ministry. SIAPS will also assist the PD with planning a stakeholder meeting to share the completed tools once the approval process was finalized.

Further training of the registration department staff will be carried out in Mar, 2013 mainly in dossier evaluation and to ensure compliances with the developed and approved SOPs and Guidelines.

Challenges in progress toward sub-objective 1.1

During this quarter, competing priorities, heavy workload, and the holidays often made it difficult for the registration team to be able to participate fully 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

SIAPS has provided on-going technical support to the registration team at the Pharmacy Department to develop new guidelines and tools based trainings they received in previous quarters of the evaluation of medicine dossiers.

The CPD worked closely with the registration department staff in working towards finalization of the job descriptions, SOPs and flow chart of process needed for reception and evaluations of the registration applications.

During this quarter, October 2012 to December 2012, the SIAPS team assisted with the 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.

Quarterly progress toward sub-objective 1.2: Transparent and accountable pharmaceutical management systems

Activities associated under Sub-objective 1.2 Transparent and accountable pharmaceutical management systems, were mostly associated with Activity 1.2.1 Conduct a stakeholder meeting to build consensus. The SIAPS team also worked this quarter on developing SOWs for Activity 1.2.2 Assist the PD with the development of an M&E plan. This activity will be rolled out with finalization of the RSAT report and in conjunction with strategic planning with the PD.

A consensus meeting on the Pharmaceutical Department's vision of the national pharmacovigilance system for medicines and vaccines was held on 31 October 2012. It included participation of 66 health professionals from MoH central departments, programs, and provincial health authorities, and representatives from academic and research institutions. The MoH Permanent Secretary opened the meeting and the Minister of Health attended the closing. The meeting agreed that medicines safety is a shared responsibility and that development and strengthening of the pharmacovigilance system should include active surveillance activities as well as voluntary reporting of suspected adverse events. Key recommendations included improve analysis and reporting of received adverse event reports; increase stakeholder communications and coordination; develop active surveillance during introduction of new pneumococcal vaccine; and development and implementation of pharmacovigilance pre-service training modules, among others.

A training workshop on pharmacovigilance, conducted 3-5 September for more than 40 participants, complemented the consensus meeting. The output of this consensus meeting lays the basis for improving pharmaceutical sector governance through (1) increased accountability and transparency of the Pharmaceutical Department and (2) improved communication and coordination between the PD and other key stakeholders, including academic and training institutions. Academic institutions have agreed on their role in (a) pre-service training and (b) in generating and analyzing medicines safety signals.

The upcoming introduction of the pneumococcal vaccine and the interest of the Universidade Lurio in Nampula to establish a pharmacovigilance program may provide opportunities to continue SIAPS support to strengthen the pharmacovigilance system, through increased Pharmaceutical Department coordination, collaboration, and engagement with other stakeholders.

Challenges in progress toward sub-objective 1.2

The level of initiative, motivation and dedication of the current human resources and the personality and capability of current leadership at the Pharmaceutical Department is the biggest challenge to achieving significant

improvements within the Department in the short-term. Strengthening non-Pharmaceutical Department dependent components of the proposed pharmacovigilance may be a more plausible approach, if leadership change is not anticipated.

Another significant barrier to be overcome is SIAPS ineffectiveness in recruiting a Portuguese-speaking regulatory/pharmacovigilance specialist to be inserted into the Pharmaceutical Department to provide day-to-day (continuous) practical technical assistance (hand-holding) over a prolonged period of time. Moving forward will require this level of practical support and successful working relationship.

Quarterly progress toward sub-objective 1.3: National pharmaceutical sector development plans are strategic and evidence-based

During this quarter under Sub-objective 1.3 National pharmaceutical sector development plans are strategic and evidence-based, the SIAPS Team followed up on work which started the previous quarter.

Under Activity 1.3.1 Conduct a baseline assessment of the regulatory system using the Regulatory Assessment Tool (RSAT), the SIAPS Team has completed a draft RSAT report which is being reviewed by SIAPS global technical leads before being shared with the Pharmacy Department, which is expected early in the next quarter.

Under Activity 1.3.2 Provide technical support to the PD to develop a 5-year strategic plan and annual work plans, the SIAPS team in Mozambique continued to provide technical support to the PD to develop and expand on its draft goals, objectives and priorities defined in the 5-year strategic plan for the regulatory system. The work plan will define relevant technical activities to maintain and strengthen the PD's key functions in registration, inspection and pharmacovigilance, including realistic allocations of the financial and human resources (HR) required for the implementation and appropriate performance metrics to monitor and evaluate the activities. Technical assistance needs and the appropriate TA providers will also be identified as we move forward and finalize the RSAT. The work plan will provide a roadmap for activity implementation and promote effective coordination and collaboration between the PD and its partners to ensure that the department can fulfill its mandate to ensure timely access to safe, quality, and efficacious health products in Mozambique.

Deliverables: Sub-Objective 1.3

To now 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 have not been developed with a clear and consistent vision of its immediate and long-term goals and objectives. SIAPS is providing technical support to the PD to use existing information—including initial findings of 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.

The development of strategic pharmacy department plan started in this year Q1. This strategy plan was developed as part of the overall MISAU strategic plan which requires only developing objectives and sub-objectives. Once this is finalized, the related activities will be developed and finalized by the pharmacy department. It is expected that this strategy plan will be finalized by Mar-April 2013.

Namibia

Year 2 Work Plan

Quarterly Report Background

Namibia faces a high human immunodeficiency virus (HIV) and tuberculosis (TB) burden, with a TB/HIV co-infection rate of over 50%. The country's antiretroviral therapy (ART) and TB programs are well-resourced and have achieved universal access, but continue to suffer from program implementation challenges, such as ensuring long-term adherence to ART, patient retention in care, minimization of loss to follow-up (LTFU) and the growing threat of HIV-drug resistance (DR) and multi-drug resistant (MDR)-TB.

The major health system challenges are:- the persistent shortage of skilled pharmaceutical human resources and an enormous dependency on donor-funded seconded staff, majority of whom are non-Namibian; overstretched public sector capacity for antiretroviral (ARV) dispensing and pharmaceutical service provision; challenges in accessing pharmaceutical services by the difficult-to-reach remote/rural communities; and low involvement or utilization of private or community pharmacies for ARV dispensing. In addition, there is variable quality of pharmaceutical services data across all levels of the public sector health system; inefficient regulation of pharmaceutical products and personnel, and a general lack of use of local evidence on anti-microbial resistance (AMR) to inform medicine selection and development of treatment guidelines. Although Namibia is considered an upper middle-income economy, disparities in the utilization of health services exist between populations. Poverty, distance to facilities, limited coordination and organization of services and weak referral systems impede access to, and timely utilization of, health services.

Namibia's Gini coefficient of 0.63 reflects a large income disparity. In the more remote northern areas where 60% of the population lives, health services often remain out of reach to residents in sparsely settled rural areas. The health of women and children in these underserved areas is particularly impacted. These access issues have continually affected the goal of reaching health impact targets. SIAPS will therefore use a multi-pronged approach to address the challenges facing pharmaceutical service delivery to ensure that the achievements of TB and HIV/AIDS programs and USAID objectives in Namibia are sustained while increasing access to ART for PLWHAs.

In FY13, the SIAPS will continue to contribute to the GHI strategy, USG/GRN Partnership Framework (PF), the National Strategic Framework (NSF) for HIV/AIDS and the National Pharmaceutical Master Plan (NPMP) as guiding documents. SIAPS will focus on the following two main strategic areas of the PF: (1) Improving governance and strengthening management systems in the pharmaceutical sector, under the Governance and Health Systems strategic area; and (2) containing antimicrobial resistance, enhancing access to medicines, and ensuring appropriate use of medicines, under the Care and Treatment strategic areas. SIAPS will work with all major stakeholders focusing on strengthening MoHSS capacity to effectively manage pharmaceutical services delivery to ensure sustainable availability of HIV/AIDS commodities in all the 13 regions of Namibia. The activities are funded under HIV Adult Treatment (HTXS), Pediatric HIV Treatment (PDXTS), and System Strengthening (OHSS) and HIV Strategic Information (HVSI) PEPFAR program areas.

SIAPS will continue to advocate for the GRN/MoHSS absorption of the seconded staff and transition from short-term HR support to the GRN to more long-term interventions and technical assistance. Program delivery costs will also be reduced through sharing overhead/operational costs and leveraging synergies of other projects managed by MSH in Namibia (SCMS and BLC). Additionally, the MoHSS will be encouraged to co-fund selected interventions as a key strategy for improving its ownership of activities. SIAPS has developed clear, measurable indicators, which will be used to track the progress of the projects.

Goal: Assure the availability of quality pharmaceutical products and effective pharmaceutical services to

achieve desired health outcomes

Overall Quarter Progress

In Q1, 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 (SIAPS IR.1), SIAPS contributed towards strengthening of the regulation of antiretroviral and other essential medicines in Namibia by the Namibia Medicines Regulatory Council (NMRC) and its secretariat, the Pharmaceutical Control and Inspection (PC&I) sub-Division of MoHSS. Through SIAPS support, a framework for guiding the PC&I in conducting of its surveillance of the quality of ARVs and other pharmaceutical products used in Namibia was drafted. In addition, the continuing technical assistance by SIAPS to National Medicines Policy Coordination (NMPC) sub-Division of MoHSS contributed to a better coordination and technical oversight of the delivery of pharmaceutical services, particularly in the public sector facilities in Namibia by the NMPC. SIAPS support enabled the NMPC to rapidly update the draft National Medicines Policy (NMP) to incorporate feedback from the MoHSS Policy Management, Development and Review Committee (PMDRC). Once approved, the updated NMP will become the official guiding document on pharmaceutical policy in Namibia.

In objective 2 (SIAPS IR.2), SIAPS made progress towards strengthening the capacity of pharmaceutical human resources and local Institutions in managing the pharmaceutical system and supply chain in delivery of sustainable ART and other pharmaceutical services in Namibia. In collaboration with SCMS, SIAPS continued supporting the University of Namibia in adapting SCMS course modules for the pre-service teaching of supply-chain related topics to the Bachelor of pharmacy students at UNAM, and 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. Towards transition, country ownership and sustainability, SIAPS continued advocating for the absorption of SIAPS-funded seconded staff to the Ministry of Health and Social Services payroll.

Under objective 3 (SIAPS IR.3), the activities supported by SIAPS contributed towards improving Ministry's patient management and pharmaceutical data capture tools, the pharmaceutical management information system and basic skills of pharmaceutical personnel in data manipulation, analysis and reporting so as to improve the availability of data for making evidence-based management and strategic decisions in pharmaceutical management and pharmaceutical service delivery.

For Objective 4 (SIAPS IR.4), little progress was made towards reaching this objective during the first quarter. Apart from few conceptual discussions that were conducted in Quarter 1, the activities planned under sub-objective 4.1 on improving the Ministry of Health and Social Services' efficiency in the management of Drug Resistant TB medicines and ARVs, will commence Quarter 2.

For Objective 5 (SIAPS IR.5), SIAPS contributed towards strengthening the Ministry's approaches for the effective delivery of pharmaceutical services in order to improve adherence to HIV/TB treatment, enhance achievement of health outcomes contain Antimicrobial Resistance (AMR) and strengthen pharmacovigilance and therapeutics information activities. SIAPS initiated stakeholder consultations with USAID and IntraHealth to conceptualize on how best to deploy mHealth technologies and the EDT in supporting patients having ART adherence problems to adhere to their prescribed treatment. Furthermore, SIAPS provided technical assistance to the TIPC on the analysis of antimicrobial sensitivity data, and in strengthening the passive and active pharmacovigilance surveillance activities of the TIPC, including monitoring of the safety of ARV and anti-TB medications in the community.

Key challenges faced during the quarter

The SIAPS software programmer assigned to work on Pharmadex resigned and this caused a delay in the pace of implementation of the Pharmadex upgrade. In addition, there were staff changes within the sub-Division: Pharmaceutical Control and Inspection (PC&I) of the MoHSS, which required a slow-down in the finalization of documentation of the revised NMRC registration processes. The SIAPS Namibia office will continue following up with the Head Office to identify a new software programmer to complete the Pharmadex updated and work with PC&I to continue training new users on the current version of Pharmadex

Some of the seconded staff earmarked for absorption have not yet received their letters of offer from the MoHSS. SIAPS will continue leveraging its membership of the multi stakeholder HRH-TWG of the MoHSS to follow up and resolve this issue.

There was no progress on DQA site visits which were to be conducted jointly with the MoHSS/ RM&E sub-Division because of unavailability of key RM&E staff. SIAPS will continue engaging with MoHSS/RM&E staff to conduct this activity in Q2. Severe staff constraints at the MoHSS continue hamper implementation of planned activities.

Key activities planned for next quarter

In Quarter 2, SIAPS will support the MoHSS to conduct the 2013 national pharmaceutical support supervision visits; initiate data collection for the new PMIS indicators covering the central and regional medical stores and medicines regulation. SIAPS will support UNAM towards development of a strategic plan for the newly established School of Pharmacy. Additionally, activities planned under sub-objective 4.1 on improving the Ministry of Health and Social Services' efficiency in the management of Drug Resistant TB medicines and ARVs, will commence Quarter 2.

Quarterly Progress for Objective 1: Pharmaceutical system governance strengthened

In Q1, SIAPS continued providing technical assistance to the Pharmaceutical Control and Inspection (PC&I) sub-division of MoHSS, which also serves as the secretariat for the Namibia Medicines Regulatory Council (NMRC) in strengthening the regulation of antiretroviral and other essential medicines in Namibia. SIAPS provided technical assistance in the updating of the Pharmadex user-requirements document that was developed in FY12, to harmonize it with the new NMRC registration SOPs and supported capacity building of a new pharmacist seconded to the PC&I on the use of the Pharmadex tool for registration of medicines. A framework for guiding the PC&I in conducting of its surveillance of the quality of ARVs and other pharmaceutical products used in Namibia was drafted. Additionally, through technical assistance from SIAPS, the MoHSS sub-Division: National Medicines Policy Coordination (NMPC) was able to rapidly update the draft National Medicines Policy (NMP) to incorporate feedback from the MoHSS Policy Management, Development and Review Committee (PMDRC). Once approved, the NMP is the main guiding document on pharmaceutical policy in Namibia.

Quarterly Progress for Objective 2: The Capacity of pharmaceutical human resources and local Institutions in managing the pharmaceutical system and supply chain in delivery of sustainable ART and other pharmaceutical services strengthened

During the first quarter, SIAPS made progress towards strengthening the capacity of pharmaceutical human resources and local Institutions in managing the pharmaceutical system and supply chain in delivery of sustainable ART and other pharmaceutical services in Namibia. In particular, 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 National Health Training Center (NHTC) of the Ministry of Health and Social Services towards strengthening NHTC's capacity for training of pharmacy assistants. Towards transition, country ownership and sustainability, SIAPS continued advocating for the absorption of SIAPS-funded seconded staff to the Ministry of Health and Social Services payroll.

Quarterly Progress for Objective 3: Pharmaceutical metrics developed and the availability and use of data for making strategic evidence based decisions improved.

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 management and pharmaceutical service delivery.

In Quarter 1, the support included several planning and stakeholder consultative meetings to discuss technical strategies for enhancing the interoperability between the Electronic Dispensing Tool (EDT) that is supported by SIAPS and the electronic Patient Management System (ePMS) that is supported by IntraHealth, with the overall aim of improving ART data quality for supporting evidence-based programmatic decision- making. In conjunction with the National Tuberculosis and Leprosy Control Program (NTLP), SIAPS commenced the evaluation of the eTB manager, which will be completed in Q2.

Additionally, SIAPS continued to provide TA for the implementation of Data Quality Assurance activities as well as providing TA to the MoHSS in developing the Pharmaceutical Management Information System (PMIS) data collection and reporting templates for the Central Medical Stores (CMS), Regional Medical Stores (RMS) and the MoHSS sub-division of Pharmaceutical Control and Inspection (PC&I), in preparation for the commencement of PMIS reporting in Quarter 2.

Quarterly Progress for Objective 4: Financing strategies and mechanisms to increase access to medicines strengthened.

Little progress was made towards reaching this objective during the first quarter. Apart from few conceptual discussions that were conducted in Quarter 1, the activities planned under sub-objective 4.1 on improving the Ministry of Health and Social Services' efficiency in the management of Drug Resistant TB medicines and ARVs, will commence in the second quarter.

Quarterly Progress for Objective 5: To strengthen pharmaceutical services delivery to improve adherence to HIV/TB treatment, enhance achievement of health outcomes, and contain Antimicrobial Resistance (AMR).

This objective covers the SIAPS-supported activities that strengthen approaches for the effective delivery of pharmaceutical services by the Ministry of Health and Social Services, to improve adherence to HIV/TB treatment, enhance achievement of health outcomes, contain Antimicrobial Resistance (AMR) and strengthen pharmacovigilance and therapeutics information activities of the Therapeutics Information and Pharmacovigilance Center (TIPC).

The activities planned under the sub-objective 5.1: Pharmaceutical services delivery at hospitals and health centers improved will be implemented from Quarter 2 onwards. Under the sub-objective 5.2: Promote safe and rational use of ARVs and other antimicrobials to contain emergence of antimicrobial resistance (AMR) in Namibia, SIAPS initiated consultations with USAID and IntraHealth to conceptualize on how best to deploy mHealth technologies and the EDT in supporting patients with ART adherence problems to adhere to their prescribed treatment. SIAPS

provided technical assistance to the TIPC on the methodological approach to be used in the analysis of the data as well as in the interpretation of the findings; in reviewing and refining a manuscript based on the report of the analysis of the NIP antimicrobial sensitivity data, for journal publication.

SIAPS provided TA to the Windhoek Central Hospital in reviewing its draft antibiotic use policy aimed at promoting the rational antibiotic use to reduce risk of generating antibiotic resistance, for adoption by the Namibians Against Antibiotic Resistance (NAAR), whose membership includes the public and private sector medical practitioners. Lastly, SIAPS continued to provide technical assistance to the TIPC in strengthening its passive and active pharmacovigilance surveillance activities, including monitoring of the safety of ARV and anti-TB medications in the community.

Quarterly progress toward sub-objective 1.1: Efficiency of pharmaceutical regulation strengthened.

The Pharmadex user-requirements document that was developed in FY12 was further updated and harmonized with the new NMRC registration SOPs. A new pharmacist was trained on how to use the current version of Pharmadex for medicines registration processes.

With SIAPS support, the drafting of the MoHSS post-marketing surveillance framework for the quality of pharmaceutical products was completed and the document is currently being reviewed by the sub-division: Pharmaceutical Control & Inspection (PC&I) and the Registrar of Medicines. This framework will guide key Inspection and Quality Control/Assurance activities of the PC&I.

A meeting was held with the Pharmacy Council to agree on the areas of focus for SIAPS' technical support.

Challenges in progress toward sub-objective 1.1

There has been a delay to upgrade Pharmadex and in addition, there were staff changes within the sub-Division: Pharmaceutical Control and Inspection (PC&I) of the MoHSS, which required a slow-down in the finalization of documentation of the revised NMRC registration processes.

Deliverables: Sub-Objective 1.1

- Final draft post-marketing framework for the quality of pharmaceutical products

Quarterly progress toward sub-objective 1.2: Implementation, monitoring, and evaluation of the NMP and NPMP strengthened.

SIAPS provided technical assistance to the MoHSS sub-Division: National Medicines Policy Coordination (NMPC) in updating templates for the 2013 edition of national pharmaceutical support supervisory visits, and planning for the visits.

In addition, SIAPS provided technical input in addressing questions and comments that were raised by the MoHSS Policy Management, Development and Review Committee (PMDRC) on the draft National Medicines Policy (NMP). The PMDRC raised concerns and comments on SADC procurements (country autonomy), registration of pharmaceutical facilities and infrastructure, research on humans and clinical trials and requested a donation policy to be part of the NMP document. All the issues raised by the committee needed to be addressed before submission of the NMP to the Cabinet of Ministers for approval.

Challenges in progress toward sub-objective 1.2

There were no major challenges to report. The MoHSS process of approving the draft National Medicines Policy document is slow but moving.

Quarterly progress toward sub-objective 2.1: HIV and TB related pharmaceutical management training and operational research capacity of institutions, organizations and networks enhanced

SIAPS held preliminary meetings with the UNAM School of Pharmacy to prepare for a short-term consultancy for on the development of the strategic plan for the Pharmacy School. In collaboration with SCMS, SIAPS provided technical assistance in compiling teaching materials focusing on supply chain management for the Pharmacy practice module of the Bachelors of Pharmacy curriculum.

Deliverables: Sub-Objective 2.1

Draft lecture guides, presentations and student work book on supply chain management for the UNAM Bachelor of Pharmacy course

Quarterly progress toward sub-objective 2.2: Pharmaceutical system human resource capacity strengthened

Leveraging its membership of the multi stakeholder HRH-TWG of the MoHSS, SIAPS continued advocating for the absorption of all seconded staff from the SIAPS budget to the MoHSS payroll. The MoHSS has recently approved the absorption of some pharmacists and pharmacy assistants. During Q1, one seconded staff was absorbed by the MoHSS. Two more are expected to be absorbed in Q2.

Challenges in progress toward sub-objective 2.2

Some of the seconded staff earmarked for absorption have not yet received their letters of offer from the MoHSS. SIAPS will continue leveraging its membership of the multi stakeholder HRH-TWG of the MoHSS to follow up and resolve this issue.

Deliverables: Sub-Objective 2.2

Report of the MoHSS HRH-TWG indicating that one of the three (1/3) SIAPS seconded staff was absorbed by MoHSS

Quarterly progress toward sub-objective 3.1: Pharmaceutical management information systems strengthened.

During this quarter, SIAPS and IntraHealth technical staff held consultative meetings to discuss ways of enhancing the interoperability between the Electronic Dispensing Tool (EDT) supported by SIAPS and the electronic Patient Management System (ePMS) supported by IntraHealth with the overall aim of improving ART data quality and support evidence-based programmatic decision- making. In addition, SIAPS technical staff started working on standardization and harmonization of EDT reference data to support interoperability with other systems. This work will continue in Q2. SIAPS supported the National Medicines Policy Coordination (NMPC) sub-Division of MoHSS to develop data collection and reporting templates for CMS, RMS and PC&I in preparation for the commencement of PMIS reporting in Q2.

Challenges in progress toward sub-objective 3.1

There was no progress on DQA site visits which were to be conducted jointly with the MoHSS/ RM&E sub-Division because of unavailability of key RM&E staff. SIAPS will continue engaging with MoHSS/RM&E staff to

conduct this activity in Q2. Severe staff constraints at the MoHSS continue hamper implementation of planned activities.

Deliverables: Sub-Objective 3.1

- 3 Data collection templates for CMS, RMS and PC&I were developed.

Quarterly progress toward sub-objective 4.2: Support public-private partnerships for enhanced pharmaceutical service delivery

There was no progress on this sub-objective because of serious concerns about its feasibility and has therefore been dropped-off the FY13 SIAPS work plan.

Quarterly progress toward sub-objective 5.2: Promote safe and rational use of ARVs and other antimicrobials to contain emergence of antimicrobial resistance (AMR) in Namibia

During Quarter 1, consultations were initiated with USAID and IntraHealth to conceptualize how best to support the MoHSS in deploying innovative approaches such as integrating the use of mHealth technologies with the EDT to send targeted SMS reminders to support patients to adhere to ART. Further consultations with the MoHSS will continue in Q2 so that strategies can be finalized and concrete steps be taken in implementing such interventions.

The Therapeutics Information and Pharmacovigilance Center (TIPC) of the Ministry of Health and Social Services obtained data from the Namibia Institute for Pathology (NIP) on culture and sensitivity patterns of pathogens to different antimicrobials. SIAPS provided technical assistance to the TIPC on the methodological approach to be used in the analysis of the data as well as in the interpretation of the preliminary findings. TIPC subsequently compiled and shared with the NIP a draft report of the findings for their comments and input, before finalizing it for dissemination.

Additionally, SIAPS provided further technical assistance to the TIPC in reviewing and refining a manuscript based on the report of the analysis of the NIP antimicrobial sensitivity data, which was subsequently submitted to the Southern Medical Review for consideration for publication.

SIAPS held a preliminary meeting with the head of the Windhoek Central Hospital's antimicrobial stewardship committee to identify potential areas of collaboration. Later, SIAPS provide technical input in the review of the WCH's draft antibiotic use policy aimed at promoting the rational antibiotic use to reduce risk of generating antibiotic resistance. These guidelines were later adopted by the Namibians Against Antibiotic Resistance (NAAR), whose membership includes the public and private sector medical practitioners.

Challenges in progress toward sub-objective 5.2

HIVDR EWI: No progress was made by RM&E on the data validation process as the staff were reportedly busy preparing the submission for Round 10 Global Fund grant. SIAPS is discussing with RM&E management so that progress on this activity is made in Q2

Deliverables: Sub-Objective 5.2

- Semi-final Draft ART Adherence Baseline Survey report.
-Technical report and Manuscript on the AMR patterns based on data from the NIP.

Quarterly progress toward sub-objective 5.3: Pharmacovigilance and therapeutics information activities strengthened.

Through technical assistance from SIAPS and the University of Washington, 278 patients out of a target of 600 (46%) were recruited into the ARV safety active surveillance program of the MoHSS/TIPC to assess the safety of commonly used first line ARV medicines in the public sector in Namibia.

In addition, through SIAPS ongoing technical assistance, 41 adverse event reports received and processed, 75.6% (31/41) of which were related to treatment with antiretroviral medicines

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, by Project Hope's Field based promoters. The first TB and HIV medication safety training was conducted from the 15-16th November in Ongwediva, where 34 field-based TB DOTS promoters were trained. Participants were trained in basic Pharmacovigilance techniques and also in data collection and reporting of adverse medication reactions experienced by the patients who they take care of at community level. The next training is scheduled for mid-February 2013 in the Kavango region.

Challenges in progress toward sub-objective 5.3

The challenge previously faced in getting the forms filled by the health care workers has reduced as a result of implementing two weekly supportive visits by TIPC staff to the sites. There was no recruitment of new patients at the two sites in the month of December due to the holiday season and the frequent movement of patients. Recruitment of new patients will re-commence in Q2 (January 2013.

Deliverables: Sub-Objective 5.3

Training report on Community-based pharmacovigilance for Project Hope's Field-based promoters

Philippines

Year 2 Work Plan

Quarterly Report Background

Tuberculosis (TB) is the 6th leading cause of morbidity in the Philippines. The National Tuberculosis Control Program (NTP) under the Department of Health (DOH) provides and formulates strategic, technical standards and guidelines to the program and the National TB Reference Laboratory (NTRL) provides overall direction and leadership to laboratory network. Since 2010, at the request of USAID, SPS worked closely with the DOH/ NTP, NTRL and the Lung Center of the Philippines (LCP) and other stakeholders to strengthen capacity of pharmaceutical and laboratory management of MDR-TB. Barriers in the health system continue to hamper the efficient and effective delivery of TB control services. Inadequate human resources management and staffing, weak capacity of staff to manage pharmaceutical and laboratory services at peripheral service delivery points, uncoordinated information management systems, and gaps in program financing are some of the key problems facing the national TB program.

The goal of SIAPS is to assure the availability of quality pharmaceutical products and services to achieve desired health outcomes. Through the application of a systems approach in strengthening medicines and laboratory diagnostic management, the SIAPS work plan for 2013 aims to contribute to reducing TB disease burden and reduce transmission morbidity and mortality and ultimately assist the control TB. SIAPS will continue supporting USAID to achieve its strategic objectives and intermediate results in TB. The activities and outputs of the SIAPS work plan to the pharmaceutical and laboratory system improvements also reflect the strategic objectives of PhilPACT for the National TB Program. The SIAPS PH goal is to: Strengthen key institutions in reducing the TB burden through increased access to quality and effective pharmaceutical and laboratory services. SIAPS PH has three objectives under this work plan. The activities and inputs to objective 1 looks at improving capacity of pharmaceutical and laboratory supply services, objective 2 focuses on increasing capacity for better use of evidence-based information for decision making and activities under objective 3 focus on improving pharmaceutical management for better TB case management outcomes.

Goal: To improve systems for increased access to quality health technologies and effective services to reduce the burden of TB in the Philippines

Overall Quarter Progress

SPS PH activities closed in December 2012. This quarterly report of SIAPS PH follow on program represents one month of SIAPS activities under the SIAPS PH 2013 work plan. During this short reporting period, SIAPS PH made progress in the following areas:

- Drafted a scope of work for phase 2 human resource system improvement activities
- Participated in several TWGs meetings to prepare for the consolidation of information working groups
- Assisted in completing the migration of data from eTB Manager to Department of Health's ITIS (Integrated TB Information System) and participated in meetings and workshop at Information Management Services (IMS)
- Assisted the Drug Supply Management (DSM) team at the Lung Center of the Philippines in reviewing the latest pharmacy data for second line drugs
- Mentored new staff at DSM in quantification for second-line drugs
- At the request of USAID, assisted the US Embassy Medical Unit to enhance its TB services for national embassy employees and provided technical notes for TB screening procedures

Key challenges faced during the quarter

Due to the end of year holidays the key challenge the program faced during the month of December there was reluctance from counterparts to initiate activities at the end of year.

Key activities planned for next quarter

- Prepare a report on the Quezon City -LMDP team Community Health Management Team (CHMT) initiative in Payatas
- Present results of LMDP initiative in Payatas to Quezon City Health Department executive committee and other stakeholders in the community
- Package the processing for establishing CHMT into a usable tool for Quezon City health staff
- Submit edited Phase one human resources report to USAID
- Invite RITM, LCP/PMDT and NTP to discuss the scope of work for human resources (HR) systems improvement.
- Submit the final scope of work for human resources assessment and start implementation of activities
- Submit a draft medium term plan to strengthen TB information management to NTP
- Continue providing technical support to the TWG and programmatic management of drug-resistant TB(PMDT) working group
- Receive concurrence from NTP on the Practical Guide on Pharmaceutical Management, receive concurrence from NTRL
- Train new PMDT drug assistant officers and continue supporting and mentoring DSM staff.
- Meet MMD (central warehouse) managers to identify areas of technical support
- Monitor and report of distribution and / allocation plan for second line drugs to all treatment centers and satellite treatment centers ensuring FEFO is followed
- Develop a tool to monitor distribution and consumption of vital TB medicines and supplies
- Start pharmacovigilance activities on adverse drug reactions (ADR) in TB with the national program and NTP.
- Plan the final phase of data migration from eTB Manager to ITIS

Quarterly progress for objective 1: Capacity of pharmaceutical and laboratory supply management improved

SIAPS PH is at the early stages of implementation, having recently transitioned from the prior SPS program during this quarter. Activities under current work plan started in December 2012

- Key stakeholders such as NTP, LCP, FDA, and the Materials Management Division's (MMD) Central Warehouse were contacted to discuss future collaborative efforts under SIAPS
- Under the current work plan, SIAPS can provide technical assistance for first and second line TB medicines. The previous SPS program was limited to MDR TB.
- Senior staff at SIAPS made contact with managers of MMD (central warehouse) to discuss areas needing collaboration to support supply chain management of TB medicines and related supplies.
- SIAPS is in touch with Quezon City health workers who received the LMDP training. Community Health teams were established and follow up reviews are expected to occur during the new quarter.

Quarterly progress for objective 2: Capacity for transparent and evidence based decision making increased

Under this objective, SIAPS works with key stakeholders to equip national partners with the data and capacity to become more effective decision makers. SIAPS started working with several technical working groups to promote a better understanding of the information needs of the program. SIAPS continues to support the transition of quality data from eTB Manager to the national ITIS system.

Quarterly progress for objective 3: Pharmaceutical services strengthened for improved outcome in TB case management

Activities under objective 3 will begin in the upcoming quarter. Pharmacovigilance activities, plans, and approaches will be discussed with counterparts during an upcoming visit of David Lee in February 2013.

Quarterly progress toward sub-objective 1.1: Capacity of human resources system for laboratories and pharmaceutical services in programmatic management of drug-resistant TB (PMDT) improved

- Planning for the second phase of support to improve laboratory human resources systems has begun
- HR consultant identified and SOW is being finalized
- During the month of December, several meetings and discussions were held with consultant and team to map approach for the next phase of technical assistance

Quarterly progress toward sub-objective 1.2: Capacity of laboratory and clinic health workers to lead and manage pharmaceuticals services for MDR-TB treatment improved

The team assisted Quezon City-LMDP team to establish additional Community Health Management Teams (CHMTs) in other areas of the city to improve community level health program leadership and management.

SIAPS PH also helped Quezon City –LMDP Team to develop a process for engaging community partners and other stakeholders to establish CHMT. As a result, two CHMTs were established in two additional barangays, using SIAPS technical tools and AUSAID financial aid.

Challenges in progress toward sub-objective 1.2

- Sustainability of technical support to Quezon Cotu LMDP given SIAPS limited staff. To address this challenge, SIAPS will discuss with senior Quezon City Health staff how to sustainably expand the number of CHMTs.

Quarterly progress toward sub-objective 1.3: Capacity of supply chain management improved

- Finalized the draft of the Practical Guide on Pharmaceutical Management
- Discussed above draft with key stakeholders to integrate comments. Concurrence from NTRL is needed to complete the task.
- Mentored LCP DSM and Philippines Business for Social Progress (PBSP) staff on the forecasting and procurement of second line drugs.
- Worked with LCP DSM to improve inventory management of supplies (practice of FEFO)
- Discussed with LCP to develop plans to monitor distribution and consumption of TB medicines

Challenges in progress toward sub-objective 1.3

- NTRL concurrence to include laboratory supplies in the Practical Guide. SIAPS will set a meeting to discuss the issue.

Deliverables: Sub-Objective 1.3

- Drafting of guide is ongoing.

Quarterly progress toward sub-objective 2.1: TB information management system enhanced to support

both products and patients.

SIAPS PH supported the National TB Program's (NTP's) programmatic management of drug-resistant TB (PMDT) working group to improve management of TB information, coordination between diagnostic and treatment services, and between program managers and policy makers.

- Participated as a technical resource in two workshops for the revision of the TB recording system, PMDT strategic planning workshop and a yearend regional consultative workshop
- Assisted NTP in the analysis and interpretation of TB surveillance data
- Assisted NTP in writing the above mentioned report; the report was submitted to WHO
- Provided advice in the interpretation of DRS results in preparation for the writing of the DRS report
- Participated in the strategic planning workshop and assisted NTP in collaboration with other technical partners to develop and implement the plan for enhancing TB information System

Deliverables: Sub-Objective 2.1

- NTP report to WHO and Strategic planning report.

Quarterly progress toward sub-objective 2.2: Availability of quality TB data increased and used for decision making

SIAPS PH supported DOH's Information Management Services (IMS) in the final phase of MDR TB patient data migration from eTB Manager to the DOH's ITIS system.

- The data migration plan is on track, with 100% transfer of all data completed
- Assisted IMS with ongoing transition activities
- Supported IMS staff to develop SOPs, specifically to monitor data quality, validate eTB Manager during the transition, and confirm with ongoing new ITIS system
- Performed spot test on actual migrated data

South Africa

Year 1 Work Plan

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: Strengthen the capacity of pharmaceutical systems at all levels to support the SAG priority health programs and initiatives to improve health outcomes

Overall Quarter Progress

On World AIDS day, the Minister of Health (MoH), announced a R2.2 billion (27%) saving on the ARV tender effective 1 Jan 2013. The saving was attributed to introduction of fixed dose combinations & price negotiation with suppliers. This was the 13th pharmaceutical contract taken over by National Department of Health (NDoH) from National Treasury with technical support from SIAPS. SIAPS also supported quantification for the tender.

The MoH launched the Tertiary & Quaternary Level Essential Medicines Recommendations that were completed with TA from SIAPS. The National Pharmacoeconomic guidelines were approved for publication by NDoH. The EML & pharmacoeconomics guidelines had been developed with TA from SIAPS.

The 1st edition of the Mpumalanga (MP) medicines formulary was printed & is ready for implementation. SIAPS supported the development, printing & shipment of 4000 copies of the formulary.

SIAPS continued to implement the Pharmaceutical Leadership Development Program (PLDP) for pharmacists in North West (NW) & KwaZulu-Natal (KZN). Follow up visits in Northern Cape (NC) & Eastern Cape (EC) highlighted progress made by teams since completing the PLDP. One team in NC had worked to improve reporting of adverse drug events (ADEs) in Frances Baard district. By the end of the PLDP 25.8% of facilities in the district were reporting ADEs. The level of reporting increased to 45.2% in the 8 months leading up to the follow up visit. SIAPS continued to conduct the PLDP for 12 teams in the Western Cape (WC). The PLDP in WC is a cost share arrangement with the counterpart.

The service level agreement (SLA) between the Medical Depot, Pharmaceutical Services & demanders in Free State (FS) was finalized & is awaiting final sign off by the Legal Unit. During this quarter work continued on a similar SLA between Depots in the Eastern Cape (EC) & demanders served by these Depots.

Consultants contracted to develop qualifications for Medical Representatives as well as the curriculum for General Pharmacy Assistants submitted their reports & outputs to the South African Pharmacy Council.

RxSolution won a National Award for Innovative use of Information Technology for Effective Service Delivery by the Centre for Public Service Innovation. RxSolution was nominated by pharmacists at the Dihlabeng hospital & went on to win first prize in the ICT category. RxSolution also won overall 3rd prize out of 150 entries for the awards. SIAPS continues to support 219 health facilities actively using RxSolution across South Africa.

In the WC, TA continued to be provided on the policy framework outlining guidelines for the provision of medicines to private, non-governmental & other organizations providing health care on behalf of the provincial Department of Health. Call for service documentation was published in the local press & placed on the provincial website. A successful stakeholders meeting was held in the province in December.

SIAPS continued to work with other PEPFAR partners & NDoH in strengthening the pharmaceutical supply chain in Limpopo (LP) where the provincial Department of Health is under administration. TA was provided for the evaluation of bids for distribution of medicines & supplies to health facilities as well as for the preparation of monthly stock availability & expenditure reports.

A National Assessment of the Pharmaceutical Management of Tuberculosis in South Africa (PMTB) was completed by a consultant during this quarter. The assessment was finalized & presented to SIAPS for review.

SIAPS completed data collection & initial data analysis for the study entitled “What are the reasons for switching

patients, adults & adolescents, to 2nd line ART regimen in public health care facilities in GP".

SIAPS provided TA in conducting an ABC analysis of depot items to determine the top 10 items that will be the starting point for the revision of the Gauteng provincial formulary.

Key challenges faced during the quarter

- The post of Senior Technical Advisor for Pharmacovigilance under SIAPS is still vacant despite extensive recruitment efforts

Key activities planned for next quarter

SIAPS will continue to work with other PEPFAR partners and the National Department of Health in stabilizing the pharmaceutical supply chain in Limpopo Province (LP). SIAPS will also continue working with the National Department of Health (NDoH) to strengthen medicine supply management and improve compliance with the National Core Standards of ten facilities in Mangaung district, in the Free State.

SIAPS will continue to provide support to the NDoH in the awarding and management of tenders. Monitoring of supplier performance as well as off take vs. forecasted quantities will be of key concern in the upcoming quarter. Technical assistance will also be provided in quantification for medicines other than ARVs .It is expected that two service level agreements between depots and demanders will be completed during the next quarter.

SIAPS will continue to provide technical support to the Gauteng province to draft the Pharmaceutical and Therapeutics Committee policy and guidelines. Technical support will also be provided for the revitalization of PTCs in KwaZulu-Natal (KZN) and for the implementation of Rational Medicine Utilization interventions designed for facilities in Gauteng.

Workshops and coaching visits for the Pharmaceutical Leadership Development Program will be conducted in North West, KwaZulu-Natal and Western Cape provinces. The teams in North West are expected to complete and present their achievements to senior management in the upcoming quarter. Follow up of the teams who completed the pilot in Gauteng will also take place in the next quarter.

Support will continue to be provided to facilities currently using RxSolution®. SIAPS will also continue to work with counterparts in implementing RxSolution in NHI pilot sites in KwaZulu-Natal and Eastern Cape. The collaboration with CSIR in evaluating software standards to ensure interoperability will continue.

Quarterly progress for objective 1: Pharmaceutical sector governance strengthened

On World AIDS day, the Minister of Health, announced a R2.2 billion (27%) saving on the ARV tender for the period 1 January 2013 to 31 December 2014. The massive cost saving was attributed to the introduction of fixed dose combination (FDC) therapy and price negotiation with suppliers. The ARV tender was awarded within four weeks after closure of the bid. The ARV tender was the 13th pharmaceutical contract taken over by the National Department of Health (NDoH) from National Treasury with active technical support from SIAPS.

During this quarter, the Minister of Health, Dr Aaron Motsoaledi officially launched the Tertiary and Quaternary Level Essential Medicines Recommendations that were completed with technical assistance from SIAPS. The recommended list of medicines is expected to support an informed, unbiased and transparent decision making process regarding interventions for a given disease at tertiary facilities. SIAPS also made progress towards supporting the implementation of the Adult Hospital level EML 2012 with the development of academic detailing materials.

SIAPS provided comprehensive support to the Gauteng Provincial Pharmaceutical and Therapeutics Committee with the revision of the provincial formulary. The publication of the Adult Hospital level EML 2012 has necessitated the revision of the list of items to be considered for removal from the formulary in order to achieve 80% compliance with the National Essential Medicine List. SIAPS provided technical assistance in conducting an ABC analysis of depot items to determine the top ten items that will be the starting point for the revision of the formulary.

The first edition of the Mpumalanga Medicines formulary was printed and is ready for implementation in the province. SIAPS provided support in the development, editing, formatting, printing and shipment of 4000 copies of the formulary to the province.

The National Pharmacoeconomic guidelines were approved for publication by the NDoH. The guidelines had been developed with technical assistance from SIAPS.

SIAPS also worked in collaboration with pharmacoeconomists and academics from the University of KwaZulu-Natal Pharmacy School to develop a proposal for the review of the National Drug Policy (NDP) which was submitted to the NDoH. A response is awaited from the Department.

The service level agreement (SLA) between the Medical Depot, Pharmaceutical Services & demanders in the Free State (FS) was finalized and is awaiting final sign off by the Legal Unit. During this quarter work continued on a similar SLA between Depots in the Eastern Cape (EC) & demanders served by these Depots.

Support and TA was provided for a National workshop held at the end of October. The workshop was attended by representatives of the NDoH, Heads of Pharmaceutical Services of the provinces and Metros as well as representatives of the provincial Pharmaceutical Depots. Items discussed included financial management of pharmaceutical services, models of procurement, distribution and service delivery, service level agreements between depots and demanders, the management of stock shortages and stock outs and the role of ARV Monitors. TA was provided in the preparation of the report of the workshop. Key recommendations from the workshop will be tabled at the National Health Council.

In the FS, an assessment was conducted at ten primary health care facilities that had obtained the lowest score in the National Core Standards (NCS) baseline assessments conducted in the Mangaung Health District in July 2011. The objective of the assessment was to obtain an in-depth understanding of shortcomings relating to medicine availability. The findings of this assessment will be used to inform the facility improvement plan initiated by NDoH in collaboration with the province and the Mangaung Metropolitan District.

Quarterly progress for objective 2: Capacity for pharmaceutical supply management and services enhanced

The Pharmaceutical Leadership Development Program (PLDP) continued to provide a platform for pharmacists to use a systematic process to address challenges in their work environments. Workshops and coaching visits were conducted for teams of pharmacists in North West (NW), and KwaZulu-Natal (KZN). Follow up visits in the NC and EC highlighted considerable progress made by some of the teams since completing the PLDP. One team in NC had identified insufficient reporting of adverse drug events (ADEs) at facilities within Frances Baard district as a key challenge. Their measurable result was to have 20% of facilities in the district report ADEs by the end January 2012. By the end of the PLDP program 25.8% of the facilities in the district were reporting ADEs. The level of reporting increased to 45.2% in the 8 months prior to the follow up visit.

Another team had identified the need for a referral system to enable clients to access chronic level 1 – 3 medication at four primary health care (PHC) facilities surrounding Midlands District Hospital in the Camdeboo sub-district.

The team successfully established a system which facilitated the delivery of medicines supplied by Midlands Hospital, to the feeder clinics. Of the 168 stable clients identified, 30% and 48% were able to collect their chronic level 1 – 3 medication from a feeder PHC clinic of their choice in June and October 2012 respectively.

SIAPS also continued to conduct a condensed version of the PLDP for 12 teams in the Western Cape Province (WC) Northern Tygerberg Suburbs Sub-structure (NTSS). The teams, each comprising of a facility manager and a pharmacy manager, identified a key challenge within their facility and set about developing their desired measurable result during the first workshop. The PLDP in WC is a cost share arrangement with the counterpart paying for all expenses with the exception of accommodation and travel for the facilitators. A TDS on the PLDP in South Africa was hosted in December to share lessons learnt during the development and implementation of this program. Consultants contracted to develop the qualification for medical representatives as well as the curriculum for the General Pharmacy Assistants both submitted their reports and outputs to the South African Pharmacy Council during this quarter. This work is being reviewed currently.

Quarterly progress for objective 3: Use of information for decision making in pharmaceutical services improved

RxSolution won a National Award for Innovative use of Information Technology for Effective Service Delivery (http://www.cpsi.co.za/awards.php). The award was made at the National Public Sector Innovation Awards ceremony hosted by the Centre for Public Service Innovation (CPSI). The accolade was awarded for work done at Dihlabeng Regional Hospital in Bethlehem, rural FS which recently moved from a paper-based system to using RxSolution for dispensing prescriptions for patients on ARVs. The RxSolution system was nominated by pharmacists at the hospital and went on to win first prize in the ICT category. RxSolution also won overall 3rd prize out of 150 entries for the awards.

RxSolution continued to be used at 219 sites across South Africa. A report showcasing RxSolution's capabilities was submitted to the Council for Scientific and Industrial Research (CSIR) as a step towards getting the system certified as a government approved software solution. SIAPS is also working with CSIR contributing to the task team which is evaluating a set of national software standards to enhance interoperability.

SIAPS is working with counterparts in KZN and EC provinces to pilot RxSolution in National Health Insurance pilot sites. Work is also on-going for the pilot of the dispensing module within 28 sites in Tshwane Metro.

Quarterly progress for objective 4: Access to medicine improved by implementing new strategies

In the WC, TA continued to be 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. Input was provided on the call for service documentation which was subsequently published in the local press and placed on the provincial website. TA was also provided to both the WC Department of Health and the NDoH on the legislative requirements. A meeting took place with the Directorate: Affordable Medicine and the NDoH Legal Unit adviser to address the challenges. Communication subsequently took place between the NDoH and the province to outline agreements reached and the process to be followed. A successful stakeholders meeting was held in the province in December.

Quarterly progress for objective 5:Improved medicine availability

SIAPS was actively involved in quantifying for the R6 billion ARV tender awarded during the quarter. SIAPS, in partnership with the Clinton Health Access Initiative (CHAI), provided technical assistance to all nine provinces as well as the NDoH in determining quantities required for this tender. Usages monitoring reports, supplier performance reports as well as program patient numbers were used to determine these estimates using the ARV

quantification tool. SIAPS will continue to provide support in monitoring off take vs. forecasted figures in partnership with provincial role players and suppliers.

SIAPS continued to collaborate with other PEPFAR partners and NDoH in strengthening the pharmaceutical supply chain in Limpopo Province (LP) where the provincial Department of Health is under administration. During the quarter, technical assistance (TA) was provided for the evaluation of bids for distribution of medicines and supplies to health facilities as well as for the preparation of monthly stock availability and expenditures reports.

A National Assessment of the Pharmaceutical Management of Tuberculosis in South Africa (PMTB) was completed by a consultant during this quarter. Strategic interviews were conducted with key respondents at selected facilities in NHI pilot districts in the EC, FS, Gauteng (GP), LP, Mpumalanga (MP), NW and WC provinces. Interviews were also conducted with respondents from the National Health Laboratory Service, the HIV Directorate at NDoH, pharmacists at NDoH who are responsible for medicine tenders and suppliers. The assessment was finalized and presented to SIAPS during this quarter.

Quarterly progress for objective 6: Improved rational use of medicine and patient safety

SIAPS completed data collection and the first part of data analysis for the study entitled "What are the reasons for switching patients, adults and adolescents, to second line ART regimen in public Health care facilities in GP". The first draft is expected to be completed in the following quarter.

SIAPS developed a set of generic tools for governing PTCs. KZN and Ekurhuleni district in Gauteng were provided with these tools to be used as a basis for revitalizing functionality and governance of their committees. SIAPS is also working with the Gauteng province to develop a policy and guidelines for implementing PTCs.

SIAPS provided TA to the Rational Medicine Utilization sub-committee of the Gauteng PTC to develop medicine utilization data collection tools to review the usage of Polyvalent human immunoglobulin and Factor VIIII and Factor IX in the province. Further TA was provided in designing interventions to promote the rational use of insulin prefilled syringes and Phenytoin IV in the province. These tools are awaiting approval from the provincial PTC.

Quarterly progress toward 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.

SIAPS worked in collaboration with a consultant, a pharmacoeconomist with the Council for Medical Schemes and two academics from the University of KwaZulu-Natal Pharmacy School to develop a proposal for the review of the National Drug Policy (NDP). The proposal was submitted to the National Department of Health (NDoH). A response is still pending from the Department.

A consultant was identified to provide technical assistance with the review of the Pharmacy Act 53 of 1974 as agreed upon with the South Africa Pharmacy Council (SAPC). The consultant's particulars were submitted to the MSH Contracts Unit for onward submission to USAID.

SIAPS continued to provide TA for the review of clinical trials to the Clinical Trials Committee (CTC) of the Medicines Control Council (MCC).

In the Western Cape (WC) TA was provided in the drafting of terms of reference for the Pharmacy Management Forum which is the coordinating structure for Pharmacy Services in the province. The draft document was submitted to stakeholders for comment.

Challenges in progress toward sub-objective 1.1

While nothing stops SIAPS from conducting an informal assessment of the impact of the NDP, the outcome would be meaningless without the support and participation of NDoH, which has been forthcoming but which has meant that progress has been slower than anticipated

There have been some delays in the award of a contract for the consultant to work on the review of the Pharmacy Act, and the local team has endeavored to become more familiar with the contractual requirements for engaging consultants. In additional, recruitment is underway for a Regional Contracts Officer who will be based in the Pretoria office to expedite awarding of future contracts.

Deliverables: Sub-Objective 1.1

- Academic detailing chapters of the Adult Hospital level EML and Standard treatment guidelines
- National Pharmacoeconomic guidelines
- Proposed action plan for the rationalization of the Gauteng formulary

Quarterly progress toward sub-objective 1.2: SIAPS will be represented on the National EML committee and on three technical committees (PHC, Hospital/Adult and Tertiary Hospital).

During this reporting period, the Minister of Health, Dr Aaron Motsoaledi officially launched the Tertiary and Quaternary Level Essential Medicines Recommendations that were completed with technical assistance from SIAPS. The recommended list of medicines is expected to support an informed, unbiased and transparent decision-making process regarding interventions for a given disease at tertiary facilities throughout the country.

SIAPS provided technical assistance (TA) to the NDoH in developing the academic detailing materials for the Adult Hospital level Essential Medicines List (EML) and Standard Treatment Guidelines (STGs). These materials will form an integral part of the implementation of the Adult Hospital Level EML which was published in the previous quarter. SIAPS developed a scope of work for a consultant who has been contracted to develop an electronic version of the new Adult Hospital EML.

The first edition of the Mpumalanga medicines formulary was printed and is ready for implementation in the province. SIAPS provided support in the development, editing, formatting, printing and shipment of 4000 copies of the formulary to the province.

The Formulary sub-committee of the Gauteng Provincial Pharmaceutical and Therapeutics Committee (GPPTC) was tasked to revise the provincial formulary to increase its compliance with the National EML. With the publication of the 2012 Adult Hospital EML and the Tertiary EML, the list of items considered for removal from the Gauteng Provincial Formulary has to be revised.

As a starting point to identify items for removal from the Gauteng formulary, SIAPS provided TA in conducting an ABC analysis of items issued by the provincial depot over the period January to July 2012. The list of items being considered for removal was compared with the ABC analysis to identify the top 10 cost drivers among the list. The results of the analysis and the identified top 10 items were communicated to the Formulary sub-committee through the chairperson of the GPPTC. An evidence based review process will be undertaken by the formulary sub-committee to determine if these items should remain on the formulary. SIAPS will continue to support the PTC in implementing a strategy to revise the formulary.

The acting Chief Director for Clinical Support Services, in Gauteng, established a task team mandated to improve medicines availability through the reduction of pharmaceutical expenditure. The Medicine Availability Committee (MAC) is a multidisciplinary team composed of senior officials from the provincial DoH. SIAPS

provided technical assistance in conducting the following analyses in preparation for the first meeting of the newly formed MAC: Classification of provincial depot items as either non-pharmaceutical, EML or non EML; ABC analyses for each category, (non-pharmaceuticals, EML and non EML items) as well as a calculation of percentage expenditure per category. The percentage of expenditure due to non EML items was found to be well under 20%.

The National Pharmacoeconomic guidelines were approved for publication by the National Department of Health. The guidelines had been developed with technical assistance from SIAPS. SIAPS provided technical assistance to members of the EML secretariat in conducting Pharmacoeconomic evaluations which were completed and presented for review.

SIAPS provided technical assistance too on developing the Pharmacovigilance guidelines for the premarketing phase through the Medicines Control Council. The guidelines were circulated in the NDoH for internal comment. SIAPS also made a presentation to the South African National AIDS Commission on the lessons learnt relating to governance of the Essential Medicine List.

Challenges in progress toward sub-objective 1.2

The process of categorizing items issues by the Gauteng depot as either complying with the NEML or not is manual and thus time consuming with a risk of errors.

Steps taken to address challenges: The list of items issued by the Gauteng depot, complying or not with the NEML, as well as their allocation, will be captured in a database to facilitate future analysis

Quarterly progress toward 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.

Building on work initiated under the SPS program, SIAPS continued to provide technical assistance to the National Department of Health (NDoH) with the awarding and management of pharmaceutical tenders. On World AIDS Day, the Minister of Health, announced a R2.2 billion (27%) saving for the ARV tender for the period 1 January 2013 to 31 December 2014. The massive cost saving was attributed mostly to the introduction of fixed dose combination (FDC) therapy and price negotiation with suppliers. The ARV tender was awarded within four weeks of the closure of the bid. Prices obtained were lower than the reference prices advertised, and contracts for a 3-in-one fixed dose combination were awarded to three contractors at very competitive prices.

The ARV tender was the 13th pharmaceutical contract taken over by the NDoH from National Treasury with active technical support from SIAPS. All aspects of the tender process, including the development of specifications, bidding and the final award, were managed successfully by NDoH. SPS/SIAPS has to date provided support for the management of 27 tenders by the NDoH. The management of tenders by NDoH staff is the first phase for the establishment of a Central Procurement Unit for pharmaceutical services in South Africa.

SIAPS continued to support quarterly and semi-annual pricing reviews for awarded contracts as required. Technical assistance was provided to the NDoH for the implementation of tools (a: Electronic price adjustment calculator and b: Calculator for contract dates) and standard operating procedures to manage applications by suppliers for price adjustments. SIAPS provided technical assistance in the preparation of monthly budget and expenditure review reports for the NDoH and provincial counterparts.

SIAPS also worked with the NDoH to develop an electronic tender management tool which will be used to support

the contract management process. The tool was tested using data from the ARV tender. Further review of the tool is underway.

In the Free State (FS) comments on the draft service level agreement (SLA) between the Medical Depot, Pharmaceutical Services & demanders were received from the Legal Department of the province. The SLA was revised as suggested and resubmitted to stakeholders for review. Further comment from stakeholders was incorporated and the document was sent back to the Legal Unit. Final sign off of the document by the Legal Unit is awaited. During this quarter work continued on a similar SLA between the Port Elizabeth Pharmaceutical Depot in the Eastern Cape (EC) & demanders served by this Depot. A stakeholders meeting was held in October at the PE Depot. A decision was subsequently taken to expand this SLA to incorporate both depots in the province. Following the positive reception of the FS SLA at the National Workshop of Heads of Pharmaceutical Services held at the end of October, it was also decided to use the FS SLA as a template. Work on the EC SLA is underway.

Support and TA was provided for a National workshop held at the end of October. The workshop was attended by representatives of the NDoH, Heads of Pharmaceutical Services of the provinces and Metros as well as representatives of the provincial Pharmaceutical Depots. Items discussed included financial management of pharmaceutical services, models of procurement, distribution and service delivery, service level agreements between depots and demanders, the management of stock shortages and stock outs and the role of ARV Monitors. TA was provided in the preparation of the report of the workshop. Key recommendations from the workshop will be tabled at the National Health Council.

Challenges in progress toward sub-objective 1.3

Consultation process on SLAs is lengthy. Resistance to change is affecting implementation of the electronic tool for tender management.

Deliverables: Sub-Objective 1.3

- Database tool for contract management
- Heads Of Pharmaceutical Services workshop report

Quarterly progress toward 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".

In the Free State (FS), an assessment of the delivery of pharmaceutical services was conducted at ten primary health care facilities that had obtained the lowest score in the National Core Standards (NCS) baseline assessments conducted in the Mangaung Health District in July 2011. The objective of the assessment was to obtain an in-depth understanding of shortcomings relating to medicine availability. The finding of this assessment will be used to inform the facility improvement plan initiated by NDoH in collaboration with the province and the Mangaung Metropolitan District.

Deliverables: Sub-Objective 1.4

- Report on assessment of ten facilities in Mangaung district

Quarterly progress toward 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.

At Nelson Mandela Metropolitan University (NMMU) in the Eastern Cape (EC), support was provided in the lectures and practical sessions for Pharmacy Law and Ethics for final year BPharm students. Training on Medicine Supply Management (MSM) was also conducted for second year BPharm students at the university. SIAPS provided support in the preparation and grading of the semester test and ethics assignment for Pharmacy Law and Ethics and sections of the final examination papers on MSM for second years and Pharmacy Law and Ethics for final year students. SIAPS participated in the final oral examination for fourth year students on pharmacy practice. Among the second year students at NMMU 96 out of 99 completed the MSM examination. A total of 55 final year students completed the Pharmacy law and Ethics paper.

At NMMU technical assistance was also provided in the development of the training material relating to standard operating procedures and MSM for pharmacy technical assistants. NMMU will be the first institution to offer training for this new cadre of pharmacy support personnel in South Africa. The training will commence in 2013.

Meetings were held in October between representatives of SIAPS and NMMU to discuss TA to be provided by SIAPS to NMMU. This will include Pharmacy Law and Ethics, training in MSM and RxSolution for both pharmacy and pharmacy technical assistant students, as well as electives for final year pharmacy students on Pharmaceutical and Therapeutics Committees and Pharmacovigilance. The MOU between SIAPS and NMMU is being developed.

The final presentation evening for final year pharmacy students at NMMU was attended. A presentation was made by the group of students who had completed the SIAPS elective on Pharmaceutical and Therapeutics Committees.

The consultant contracted to develop the qualifications for Medical Representatives submitted the proposed qualifications to the South African Pharmacy Council (SAPC). The SAPC in turn communicated these qualifications to the industry for comments. This engagement with stakeholders from industry is still on-going.

Another consultant engaged by SIAPS to develop the curriculum for the General Pharmacy Assistants cadre also submitted his report and the draft curriculum to the SAPC for further action.

SIAPS held a meeting to discuss plans to conduct a review of the internship program in South Africa. This was building on work initiated under the SPS program. A plan to conduct an assessment of the current internship program using a consultant and an academic intern was updated and will be implemented in the upcoming quarters.

TA was provided to the SAPC in the facilitation of a workshop for the development of criteria for the approval of the new BPharm curricula submitted by the pharmacy schools. Criteria were drafted after the workshop and submitted to stakeholders for comment. Comment received was incorporated and the document submitted to the Council for final approval.

Challenges in progress toward sub-objective 2.1

With regard to MSM lectures attendance of students was sub-optimal (56%) and needs to be improved. The absence of site visits to health facilities in order to grasp theory learnt in class is a challenge in this program. The award for consultants to develop qualification for pharmacy specialties is still pending

Steps to address challenges:

- An overall report highlighting lessons learnt, challenges and recommendations for improving attendance will be submitted to the MSM course director at NMMU.

- SIAPS continues to engage with the Contracts Unit and USAID to finalize the awarding process for the contract

Quarterly progress toward sub-objective 2.2: Leadership and management practices of pharmacists improved leading to better quality pharmaceutical services

SIAPS facilitated the 3rd & 4th workshops for the Pharmaceutical Leadership Development Program (PLDP) in North West (NW). SIAPS engaged a facilitator from National Treasury to deliver the module on Financial Management for Pharmaceutical Services. A Human Resources (HR) specialist from NW Department of Health helped facilitate the HR Management in Pharmaceutical Services module

The 1st coaching visit was conducted for six teams in KwaZulu Natal (KZN) in Oct. Three of the teams had created broader multi-disciplinary team to help develop & implement identified improvement plans within their districts. The second workshop was held in November in Western Cape (WC), 12 teams from the Northern Tygerberg Suburbs Sub-structure (NTSS) each comprising of a facility manager & a pharmacy manager as well as representatives of the Sub-District Office participated in the first workshop of a customized PLDP. The teams identified a key challenge within their facility & set about developing their desired measurable result. The PLDP in the WC is a cost share arrangement as the counterparts are paying for all expenses with the exception of accommodation & travel for facilitators

In the Northern Cape (NC), a follow-up workshop was conducted for 2 teams that completed the PLDP in Apr 2012 One of the teams had identified insufficient reporting of adverse drug events (ADEs) at facilities within Frances Baard district as a challenge. Their measurable result was to have 20% of facilities in the district reporting ADEs by the end of Jan 2012. By the end of the PLDP program 25.8% of facilities in Frances Baard district were reporting ADEs. The level of reporting increased to 45.2% in the 8 months prior to the follow up visit. A further improvement was noted in the involvement of nurses in reporting ADEs whereas previously only doctors did so. The team is also working with the District Pharmacy Manager to ensure that pharmacovigilance is a standing discussion point at district meetings

The 2nd team aimed to develop a functional & sustainable inventory management system at a primary health care facility in Pixley Ka Seme district. The team was able to achieve their desired measurable result to attain “100% compliance with measures relating to medicine inventory management systems as per National Core Standards (NCS)”. During the follow up visit, the team shared several key achievements since completing the PLDP: a standard operating procedure for clinic supervision visits had been adopted by pharmacists in NC; all district pharmacists were reporting medicine availability using NCS checklists; medicine availability was incorporated as one of the indicators in the provincial Annual Performance Plan; nursing personnel assist in conducting assessments & understand why they need stock cards, regular ordering & monthly stock takes

A 2nd follow up workshop was held in the Eastern Cape (EC) for the teams that completed the PLDP in Jul 2012

One of the teams had identified the need for a referral system to enable clients to access chronic level 1–3 medication at 4 primary health care facilities (PHC) surrounding Midlands District Hospital in the Camdeboo sub-district. The team successfully established a system which facilitated the delivery of medicines supplied by Midlands Hospital, to the feeder clinics before the due date for collection by the clients. Of the 168 stable clients identified, 30 & 48% were able to collect their medication from a PHC of their choice by Jun & Oct 2012 respectively

A 2nd team had aimed to “reduce expired stock to below 3% of expenditure at Cecilia Makiwane Hospital & below 1% at Duncan Village Day Hospital”. Following the PLDP, the team implemented the system at another hospital with a notable decline in value of expired medicine

A TDS on the PLDP in SA was hosted in Dec to share lessons learnt during the development & implementation the PLDP. Work continued on the development of a CD incorporating all the PLDP material

Challenges in progress toward sub-objective 2.2

There was poor attendance of the PLDP follow up workshop by teams in the Eastern Cape. SIAPS will involve senior managers at follow up workshops in future.

Quarterly progress toward sub-objective 2.3: SIAPS will assist provincial pharmaceutical services with the development of their M&E frameworks.

The posts for ARV Monitors have been taken over by the National Department of Health (NDoH) with the funding for these posts being provided by the Global Fund. Discussions on the role of the monitors took place at the workshop held at the end of October for the provincial Heads of Pharmaceutical Services (HOPs).

All provinces continued to provide reports to the NDoH on the availability of ARVs, TB medicines, vaccines and a selection of tracer medicines for chronic diseases during this quarter.

Work commenced on the development of a compendium of indicators for monitoring of pharmaceutical services.

Discussions took place with the Northern Cape (NC) regarding the need for assistance in the development of a M&E framework for Pharmaceutical Services in the province. This work will commence in the next quarter.

Quarterly progress toward 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.

As an interim measure to facilitate reporting of medicine availability information SPS installed Infomaker, a report generating tool, at pharmaceutical depots in Limpopo (LP), Western Cape (WC), Eastern Cape (EC), Kwazulu-Natal (KZN), Gauteng Province (GP), and at the office of the Directorate: Affordable Medicine at NDoH. During this quarter, SIAPS conducted introductory training on the use of Infomaker at the depot in Limpopo. SIAPS continued to work with provincial counterparts to customize report templates to meet user requirements.

Challenges in progress toward sub-objective 3.1

Not all provinces are ready for installation due to hardware and staffing challenges. Steps taken to address challenges: Communication with senior management within the provinces and NDoH

Deliverables: Sub-Objective 3.1

- Infomaker report generating templates

Quarterly progress toward sub-objective 3.2: The SA based SIAPS development team will develop a new version of RxSolution© using newly available technologies and development tools

RxSolution won a National Award for Innovative use of Information Technology for Effective Service Delivery (http://www.cpsi.co.za/awards.php). This was delivered at the National Public Sector Innovation Awards ceremony hosted by the Centre for Public Service Innovation (CPSI). The accolade was awarded for the work at Dihlabeng Regional Hospital in Bethlehem, rural Free State, which recently moved from a paper-based system to using RxSolution for dispensing prescriptions for patients on ARVs. The RxSolution system was nominated

by pharmacists at the hospital and went on to win first prize in the Information and Communication Technology (ICT) category. RxSolution also won overall 3rd prize out of 150 entries for the awards.

RxSolution continued to be used at sites across South Africa. There are currently 219 active sites distributed as follows:

- 100 facilities using RxSolution in the Eastern Cape (EC).
- 43 facilities using RxSolution in the Free State (FS).
- 38 facilities using RxSolution in the North West (NW).
- 38 facilities using RxSolution in the remainder of South Africa.

During the quarter, the SIAPS electronic tools team finalized a new version of RxSolution. A report showcasing RxSolution's functions and capabilities was submitted to the Council for Scientific and Industrial Research (CSIR) as a step towards getting the system certified as a government approved software solution. SIAPS is also working with CSIR contributing to the task team evaluating a set of national software standards to enhance interoperability.

In the EC, 1.5 million patient records were imported into the RxSolution database at Port Elizabeth Hospital Complex. This is the first step towards initiating the use of the dispensing module at the facility. Work is on-going with the implementation of RxSolution in National Health Insurance (NHI) pilot districts in the province. Representatives from the EC Department of Health visited RxSolution sites in FS to assess the use of Automated Ordering from the Depot using the Remote Demander Module (RDM). Integration with the RDM enables automated ordering through the implementation of stock levels based on average product consumption rates. A technical team is being set up for RxSolution in the EC. The team will be driven by the EC Department of Health and will provide technical support to RxSolution users within the province.

SIAPS continued work on customizing the dispensing module for the pilot in Tshwane Metro. Implementation of the dispensing module is expected to commence once the standard treatment guidelines have been captured into RxSolution.

SIAPS continued to provide user support through the weekly "Tip of the week" mailing list.

A request was received for the implementation of RxSolution in Amajuba, an NHI pilot district in KwaZulu-Natal (KZN). Formal RxSolution training was conducted for the district pharmacist and eight pharmacy personnel. Support to the Free State (FS) and North West (NW) Province continues.

Challenges in progress toward sub-objective 3.2

- General IT infrastructure issues

  Low levels of computer literacy amongst staff trained

  Steps taken to address challenges:

  Support is provided to key departments with hardware purchases where their budgets have been exhausted.

Deliverables: Sub-Objective 3.2

- National Award for Innovative use of Information Technology for Effective Service Delivery. http://www.cpsi.co.za/awards.php

Quarterly progress toward sub-objective 4.1: SIAPS will assist the NDoH with the implementation of the Central Procurement Authority (CPA).

A new Ministerial Task Team, headed by the SIAPS Deputy Country Project Director (DCPD), has commenced research which is intended to inform the strengthening of the establishment of the Central Procurement Authority (CPA). This involves, inter alia, an assessment of the constitutional implications of establishing an entity which will have the power to control the national pharmaceutical budget, as is intended with the CPA; an assessment of the resources required to build the CPA into an effective organ for national procurement, and an investigation of the feasibility of increasing direct deliveries to facilities, thus reducing the role of the provincial medicine depots. As part of the work of the task team, a broad evaluation of depot services will be conducted.

Quarterly progress toward sub-objective 4.2: SIAPS will support the pharmacy component of the re-engineering of primary health care (PHC) Services.

In order to assist in establishing dialogue between policy makers and stakeholders from the public and private sectors to define their roles and develop models for the provision of pharmaceutical services, SIAPS attended two meetings of the "NHI Value Proposition for Pharmacy" forum. The forum is comprised of pharmacists outside the public sector (predominantly the community pharmacy sector). The group is examining, through research, dialogue and wide consultation, ways of placing community pharmacy resources and services at the disposal of the public sector. They have sought SIAPS' facilitation role as they explore opportunities to support the implementation of NHI. Models of service delivery being considered extend to roles at the PHC level, increased diagnostic and treatment activities in community pharmacies, distribution models and school health services.

Two SIAPS staff members are members of the Goods Procurement Sub-committee of the Ministerial Advisory Committee on NHI. No meetings of the sub-committee took place during this quarter.

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.

In the Western Cape (WC), TA continued to be 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. Input was provided on the call for service documentation which was subsequently published in the local press and placed on the provincial website. TA was also provided to both the WC Department of Health and the NDoH on the legislative requirements (Nursing Act, Pharmacy Act, Medicines Act) for the designation of private providers, the authority for the NDoH to charge fees for designation, prescribing rights of nurses and pharmacists, dispensing of nurses' prescriptions by pharmacists, supervision of nurses employed by private providers and requirements for nurses to hold a dispensing license. A meeting took place with the Directorate: Affordable Medicine and the NDoH Legal Unit adviser to address the challenges. Communication subsequently took place between the NDoH and the province to outline agreements reached and the process to be followed. A successful stakeholders meeting was held in the province in December.

Quarterly progress toward 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.).

Under the SPS program, quantification models were developed to estimate requirements for all relevant ART (1st Line, 2nd Line, PMTCT and PEP) and TB treatment. The focus of this activity was at the national and provincial levels. During this quarter, SIAPS continued to provide support to the National Department of Health (NDoH) in

the quantification of ARVs.

On World AIDS Day, the Minister of Health, announced a R6 billion tender for ARVs for public sector facilities for the period 1 January 2013 to 31 December 2014. This was the first tender to include fixed dose combination (FDC) therapy. SIAPS, in partnership with the Clinton Health Access Initiative (CHAI), provided technical assistance to all nine provinces as well as the NDoH in determining quantities required for this tender. Information collected from usage monitoring reports and supplier performance reports as well as program patient numbers were used to determine these estimates using the ARV quantification tool. The resulting product quantities were compared with current quantities issued by the depots, and agreement reached with all provinces on the correctness of assumptions made.

SIAPS will continue to provide support in monitoring off take vs. forecasted figures in partnership with provincial role players and suppliers.

Challenges in progress toward sub-objective 5.1

Changes within health program are not clearly circumscribed nor documented which contributes to uncertainties around assumptions for quantification. The rate of implementation of FDCs cannot be accurately predicted and may influence accuracy of forecasts.

Steps taken to address challenges: Constant monitoring of actual stock position & supplier performance, and engaging all role players in the process of monitoring ARVs usage trends through regular reporting and constant updating.

Quarterly progress toward 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.

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 by the NDoH. During the quarter, technical assistance (TA) was provided for the evaluation of bids for distribution of medicines and supplies to health facilities. Further support was provided for the preparation of monthly stock availability and expenditure reports.

Informaker was installed at the depot to facilitate reporting of information from PDSX (inventory management system). Reports for stock on hand and ordering were developed and implemented during this quarter.

The average stock availability at the LP depot increased from 65% in June to 70.55% during this quarter. This is a marked improvement from 56% in April when SIAPS began providing support to the depot.

SIAPS formed part of an NDoH team sent to support Mthatha Pharmaceutical Depot in the Eastern Cape (EC) where services were disrupted following industrial action that led to the suspension of staff. Technical assistance was provided to maintain functionality and provide stock to districts and facilities served by this depot. SIAPS provided support on preparing management reports to support decision making as well as liaising with suppliers.

Challenges in progress toward sub-objective 5.2

1. EC: Mthatha depot is faced with severe staff shortages, limited middle management capacity and lack of clear direction and support from provincial management

2. LP: Tender bids for distribution could not be processed and awarded after potential technical irregularities were identified

Steps taken to address challenges:

1. EC: A report was submitted to provincial management with recommendations for improvement. A draft Service Level Agreement (SLA) between both Eastern Cape depots and their clients is being drafted upon request from the province
2. LP: Concerns with the bid documents were referred to the Legal Services Department within the province.

Quarterly progress toward sub-objective 5.3: SIAPS will conduct provincial assessments of medicine supply management practices in at least two provinces.

A National Assessment of the Pharmaceutical Management of Tuberculosis in South Africa (PMTB) was completed by a consultant during this quarter. Strategic interviews were conducted with key respondents at selected facilities in NHI pilot districts in the Eastern Cape (EC), Free State (FS), Gauteng (GP), Limpopo (LP), Mpumalanga (MP), North West (NW) and Western Cape (WC) provinces. Interviews were also conducted with respondents from the National Health Laboratory Service, the HIV Directorate at NDoH, pharmacists at NDoH who are responsible for medicine tenders and suppliers. The assessment was finalized and presented to SIAPS during this quarter.

In LP, assessments of hospitals and clinics were conducted to check the availability of medicines and adherence to National Core Standards for Health Institutions in South Africa (NCS). A report of stock on hand and stock take values for all the 43 hospitals in the province was compiled for review by provincial management. The average stock availability was 71% for hospitals and 74% for clinics.

Medicine Supply Management (MSM) training was conducted for nurses (22) and pharmacist's assistants (19) working in the clinics attached to Hillbrow Regional Pharmacy in GP. MSM for TB training was conducted for 213 people in EC (64), LP (25), FS (27), KwaZulu-Natal (77) and MP (20) during the quarter.

Development of the online versions of the MSH TB/HIV courses was completed by the consultant contracted to do the work. The feasibility of implementing the online courses will be determined once all the materials have been reviewed.

Deliverables: Sub-Objective 5.3

- Proposed implementation plan for online TB/HIV courses
- Report on MSM training at Hillbrow Regional Pharmacy Nov 2012
- Assessment tool for clinics in the Vhembe district in LP
- Assessment of the Pharmaceutical Management of TB in South Africa 2012 5.Feedback presentation: Pharmaceutical Management of Tuberculosis in South Africa

Quarterly progress toward 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.

In Gauteng (GP) training was conducted for pharmacists on data collection tools & procedures for the study entitled "What are the reasons for switching patients, adults & adolescents, to second line ART regimen in public health care facilities in GP". Data collection was completed on 16 Nov. Data was captured into a database & validated before submission to a biostatistician for analysis. The report is being drafted based on preliminary

results

One of the recommendations in the SPS report "Promoting Rational Use of Medicines through PTCs in South Africa (SA)" was to develop generic terms of reference &tools to harmonize the role &functions of PTCs across SA. The report also recommends inclusion of sub-committees into the PTC structure; this mirrors the National Essential Medicine List Committee structure with its Expert Committees

The Gauteng Provincial PTC (GPPTC) terms of reference (ToRs) &processes were used as a basis to develop generic PTC governance tools. These tools include ToRs, a conflict of interest policy &declaration form, confidentiality declaration form, a step by step process for selection of members, as well as a template for the nomination of PTC members. SIAPS provided technical assistance (TA) to revitalize the Ekurhuleni District PTC. SIAPS did a presentation on PTC functions & revitalization at one of the committee meetings where PTC members identified the need for new ToRs & the appointment of new members as the first step for the revitalization process. Generic ToRs & governance tools for a district PTC were provided to the committee for review

The Gauteng Pharmaceutical Services Department also identified the need for the province to develop a policy on PTCs & guidelines for implementation of the policy. The policy aims at making local PTCs compulsory as well as harmonizing their functions using generic tools provided in the guidelines. A brainstorming meeting was held with the Acting Director of Pharmaceutical Services to identify the key topics that need to be included in the provincial guidelines for implementation of the PTC policy

SIAPS also provided TA in drafting procedures for local institutions to request access to medicines which do not appear on the National EDL or the Gauteng Medicine Formulary. The document was submitted to the chairperson of the GPPTC

TA was provided to the Rational Medicine Utilization sub-committee of the GPPTC for the following interventions:

- Polyvalent human immunoglobulin: MUE data collection tool to review usage of Polyvalent immunoglobulin has been approved by the GPPTC & submitted to the PTCs of seven hospitals for implementation
- Factor VIIII & Factor IX: MUE data collection tool to review usage of Factors VIII & IX has been developed; the submission to the GPPTC for approval was delayed by the postponement of the GPPTC meeting scheduled for November 2012
- Phenytoin IV & Insulin prefilled syringes: Interventions to promote the rational use of insulin prefilled syringes & Phenytoin have been developed and are also awaiting approval of the GPPTC
- Anti-microbial agents: During the pharmacy managers' meeting SIAPS presented on interventions to promote rational use of anti-microbial agents at facility level

The KwaZulu-Natal (KZN) Pharmaceutical Services Directorate requested assistance to strengthen PTCs in the province. A meeting took place to identify their needs and propose appropriate TA. The HOPS highlighted the pressure on his team to improve the governance of PTCs. Generic PTC governance tools and terms of reference were provided to the team

SIAPS also provided TA to provincial PTCs in Eastern Cape (EC), where terms of reference were adopted, as well as the Kimberly Hospital PTC in the Northern Cape.

In Limpopo, the stock availability tool developed by SIAPS to support monitoring within facilities was presented to the provincial PTC. In addition, the PTC approved the list of new pack sizes to be included in the provincial code list

Challenges in progress toward sub-objective 6.1

Among the facilities selected for the ARV switch study, some were from local government. The Ekurhuleni research committee requested an additional clearance from their research committee before data collection could be conducted in the district. The Johannesburg Metro also requested a specific clearance to conduct data collection in Diepsloot clinic.

In the Northern Cape, districts PTCs are chaired by the pharmacists who do not get much support from the medical doctors or the district managers. Steps taken to address challenges:

Thanks to strong support from senior provincial officials, the ethical clearance from the Ekurhuleni research committee was obtained quickly. Data collection from the Johannesburg Metro clinic was cancelled for the sake of expedience of the study. Extra files were instead collected from a local government clinic in Ekurhuleni to make up the sample size. The characteristics of the facilities being similar, any bias would be minimal.

In the Northern Cape discussions took place with the Head of Pharmaceutical Services to have PTC functionality as part of the key performance areas of all district managers

Deliverables: Sub-Objective 6.1

- Presentation on PTC functions and revitalization
- Generic TORs for District PTCs
- Step by step procedure for selection of district PTC members
- Procedure to request a non EML or non-Gauteng formulary medicine
- Generic TORs for Provincial PTC
- Step by step process for selection of PPTC members
- MUE data collection tool Factor VIII
- MUE data collection tool Factor IX
- Power Point presentation on RMU of antimicrobial agents

Quarterly progress toward 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 continued to contract two consultants to support the programmatic pharmacovigilance activities at the National Department of Health. These consultants are responsible for providing training at the provincial and supporting the implementation of routine pharmacovigilance data reporting.

SPS had provided support to the KwaZulu-Natal Directorate of Pharmaceutical Services to conduct two pharmacovigilance projects namely ACADEMIK and ARV solicited reporting system project. During this quarter, SIAPS held a meeting with the KZN Directorate of Pharmaceutical Services to agree on the way forward in terms of the support needed to finalize the ACADEMIK study and to support the pharmacovigilance programme in the province.

Challenges in progress toward sub-objective 6.2

The post of Senior Technical Advisor for Pharmacovigilance under SIAPS is still vacant since none of the previously identified candidate accepted the position.

Quarterly progress toward 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.

Through the Pharmaceutical Leadership Development Programme (PLDP), technical assistance was provided for the development of a patient information leaflet for Isoniazid Preventive Therapy. The leaflet, once completed, will be used to support patient education as part of the implementation strategy for IPT in Dr Ruth Segomotsi Mompati Health District.

South Sudan

Year 2 Work Plan

Quarterly Report Background

With the recent independence (July 2011) of South Sudan the need to set up/strengthen national institutions and systems has become urgent. In 2006, the USAID Sudan Field Office (SFO) mandated MSH/Rational Pharmaceutical Management Plus (RPM Plus) Program, to provide support to the Ministry of Health (MOH) to establish a functional (including the provision of office space, basic office infrastructure and operational facilitation) National Malaria Control Program (NMCP) and strengthen the national pharmaceutical management systems. In 2007, the Strengthening Pharmaceutical Systems (SPS) program, a follow on to RPM Plus Program, continued to support Ministry of Health (MOH) to build the organizational, technical and programmatic capacities of the NMCP and the Directorate of Pharmaceutical Services (DPS). In 2010, SPS was also requested by USAID to support the MOH in strengthening the national Expanded Program on Immunization (EPI).

These MOH programs have been supported to develop the required policy and strategic frameworks, draft operational guidelines and tools as well as establish coordination and monitoring mechanisms for pharmaceutical management of essential medicines and supplies, and specifically for the malaria and EPI programs. More than 1000 in-service health workers have been trained in various pharmaceutical concepts, a similar number in correct management of malaria and over 500 trained in correct immunization practices.

The Rational Pharmaceutical management (RPM) Plus and SPS Programs have supported MOH in product selection and quantification receipt and management of essential medicines and medical supplies including the management of USG procured ACTs and malaria Rapid Diagnostic Tests (RDTs). The program has been supported to scale up malaria control and prevention interventions including roll out of an ACT based treatment policy throughout the country and instituting systems for distribution of Insecticide Treated Mosquito Nets (ITNs) through rolling campaigns and as part of routine health facilities. A Malaria Indicator Survey (MIS) conducted in 2009 with support of SPS and other partners found that coverage of ITNs and ACTs has improved

In 2011, following the comprehensive essential medicine quantification exercise, the SIAPS program in collaboration with the MoH introduced the Continuous Results Management System (CRMS) in several health facilities and a medicine consumption database is now being established.

In FY12, Systems for Improved Access to Pharmaceuticals and Services (SIAPS), 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. Planned activities will aim to strengthen pharmaceutical sector governance; enhance capacity for pharmaceutical supply management and services; improve availability of information for decision-making; improve pharmaceutical services to achieve desired health outcomes; and, strengthen malaria planning, coordination, monitoring and evaluation systems

The proposed activities are consistent with the USAID Result Areas for SIAPS program and will contribute to the achievement of the USAID Sudan Field Office multi-sectoral strategy for infectious diseases and the related Intermediate Result for development of core institutional structures for an effective, transparent, and accountable Government of South Sudan.

Goal: To assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes

Overall Quarter Progress

To assure availability and quality of pharmaceutical products and services, SIAPS provided TA to MOH/DP&E and USAID on forecast and quantification of essential commodities to supplement the current stock and ensure the signing of necessary procurement documents to initiate the process of procurement of minimum essential commodities for the two states of WES and CES to avert any stock outs situation.

SIAPS contributed to ensuring uninterrupted supply of Miso in the piloted facilities through proper forecast and resupply. SIAPS continued to provide TA for the Minilab sites at the CMS in Juba by working with the MOH counterparts.

SIAPS has provided supportive supervision exercises and conducted on the job training for commodity managers in the facilities Mundri East and Mvolo in store management and inventory control and partnered with other NGOs to provide pharmaceutical management training.

To improve availability of information for decision making, SIAPS has facilitated the final distribution of all tools allocated to WES and currently distributing that of the CES.

SIAPS collaborates with the MOH to engage partners in sharing technical knowledge and resolve some of the challenges in the pharmaceutical sector, through Technical working group meetings.

To improve pharmaceutical sector governance, SIAPS played an instrumental role through participation in several meetings between IFC, MOH and the DFCA, to and ensured USAID got a slot on the program and drafted talking points for USAID for the DFCA launch. SIAPS also supported DFCA to plan and facilitate the induction workshop for Board members and Secretariat staff to orient them on the DFCA Act.

To build institutional capacity, SIAPS supported NMCP to draft Malaria Program Review (MPR) thematic reports for program management, case management thematic areas and thematic areas particularly malaria monitoring and evaluation/surveillance.

SIAPS supported NMCP draft a justification for use of First Response RDTs; fill a questionnaire on malaria M&E systems; review national malaria treatment guidelines to elaborate administration of injectable artesunate for treatment of severe malaria;

SIAPS supported NMCP to engage the GFATM PR to discuss and ensure that interventions such as LLIN distribution are carried out according to the national guidelines.

Key challenges faced during the quarter

Due to delay in approval of FY 2012 work plans and further delay in forward funding, most of the activities under this quarter delayed. Further, delays in disbursement of funds for malaria activities from the consolidated GFATM malaria grant negatively affected FY12 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. Staff attrition (2 senior technical staff and 2 technical staff) left the project under this quarter and that affected implementation of some of the activities.

The project has also drastically reduced staff (2 technical advisors and 2 senior technical advisors) have left the project. The recruitment of Malaria program specialist to replace the erstwhile Project Director and continue the M&E work is ongoing and it is important that Recruitment is finalized.

The CES warehouse renovation is also pending, due to non-performance of initial contractor hired; new RFQ has

been issued to select a new vendor.

Key activities planned for next quarter

Next quarter activities will continue to in line with the new SIAPS FY2012 work plan, which in principle has been approved by the Mission, some key areas like the budget template revision to be in line with USAID template, and our future collaboration with DELIVER partners has been emphasized by USAID to feature more in our current and future work plan and implementation of activities.

Quarterly Progress for Objective 1: Pharmaceutical services improved to achieve desired health outcomes

SIAPS provided TA to MOH/DP&E on forecast and quantification of essential commodities to supplement the current stock, SIAPS also supported USAID /DELIVER project to finalize and sign the CPIR with the MOH which led to the initiation of the procurement of minimum essential commodities for the two states of WES and CES to avert any stock outs situation.

SIAPS continued it support to the CMS to expedite the distribution plans for the distribution of essential commodities to the various counties and also supported the DP&E in the revision and finalization of bidding document which led to the procurement of supplementary commodities(3months supplies),for the country to avoid stock out.

SIAPS supported UNICEF and other implementing partners with obtaining necessary tax exemption request from the finance ministry to clear antimalarial commodities to support the malaria program.

SIAPS contributed to ensuring that pregnant women in Mvolo and Mundri East County received the MISO when they need it without any difficulty through uninterrupted supply of MISO, this was achieved through forecasting needs and to request for supplies before they run out. Secondly to ensure rational use and minimize abuse and avoid any leakage into the private sector SIAPS continued to provide TA for the Minilab sites at the CMS in Juba and detected some irregularities with the labeling of the medicines. SIAPS assisted with improvements in storage conditions and conduct on-job training on the PMIS tools in facilities in Mundri East and Mvolo.

Quarterly Progress for Objective 2: Capacity for pharmaceutical supply management and services increased and enhanced

SIAPS has provided supportive supervision exercises and conducted on the job training for commodity managers in the facilities Mundri East and Mvolo in store management and inventory control for 9 personals at various levels

The project also facilitated a training workshop on ARV pharmaceutical Management organized by Catholic Medical Mission Board (CMMB) and funded by UNHCR in Western Equatorial. 6 trained persons are to manage ARVs and other essential commodities in the near future.

Quarterly Progress for Objective 3: Information for decision-making challenge in the pharmaceutical sector addressed

To facilitate the generation and use of available information for decision making, SIAPS has facilitated the final distribution of all tools allocated to WES and currently distributing that of the CES. This has been followed with supportive supervision to ensure that the tools are accurately used and on-job training is provided to commodity managers in the facilities.

SIAPS has also ensured through the MOH to facilitate two(2) technical working groups within the quarter,

which included supporting MOH to send out invitations to partners; collect and analyze data on antimalarial drugs from the CMS; and drafting technical presentation for the TWG. Some of the data was shared with NMCP to aid the program's presentation at the Health Cluster meeting.

Quarterly Progress for Objective 4: Pharmaceutical sector governance strengthened

SIAPS played an instrumental role in rolling the setting up of the national drug regulatory body through participation in several meetings between IFC, MOH and the DFCA and SAIPS also supported DFCA to plan and facilitate the induction workshop for Board members and Secretariat staff to orient them on the DFCA Act.

Quarterly Progress for Objective 5: Scale up of malaria interventions better coordinated and documented

SIAPS supported NMCP to draft Malaria Program Review (MPR) thematic reports for program management and case management thematic areas. SIAPS also made considerable technical input to other thematic areas particularly malaria monitoring and evaluation/surveillance,

SIAPS supported NMCP to engage the GFATM PR to discuss and ensure that interventions such as LLIN distribution are carried out according to the national guidelines.

SIAPS also participated in a CCM South Sudan meeting organized to orient members on their roles and responsibilities.

Quarterly progress toward sub-objective 1.1: Improved availability of pharmaceuticals and medical supplies

SIAPS also provided TA to MOH/DP&E on forecast and quantification of essential commodities to supplement the current stock and to avert any stock out situations, which is preceded by information gathering and consensus building from the various heads of unit.

SIAPS Collaborated with USAID and Deliver Project to finalize and sign the CPIR with the MOH which led to the procurement of minimum essential commodities for the two states of WES and CES.

SIAPS provided support Deliver Project to address any challenges regarding the current procurement.

SIAPS facilitated the tax exemption request for UNICEF to enable the clearing of Anti-malarial commodities procured to arrive in the country to support malaria interventions.

As part of SIAPS continued support to the NMCP, we worked with the Program Manager to ensure the rapid distribution of the RDTS in the CMS due to the short shelf life to avoid expiry, and this was done through the directorate of Pharmaceutical and Equipment.

SIAPS supported facilities in Mundri East County, where MISO pilot is implemented, SIAPS provided supportive supervision and on-job training was done for staff on how to correctly fill the stock cards and dispensing registers to track consumption and to request for new supplies. This ensured un-interrupted supplies of the MISO commodity.

SIAPS in its support in the Supply chain management of MISO in the piloted facilities (WES) has finalized reviewing/ editing of the draft article on the support in the introduction of Misoprostol in South Sudan, this is to document how this happened and the future support the project will give full role out of the MISO scale up process.

Challenges in progress toward sub-objective 1.1

Urgent and ad hoc requests for TA from donors and partners, which often take significant staff LOE.MOH staff engaged in competing activities making it difficult to engage them in some key activities such as quantification, tax exemption and clearing of consignments request, supportive supervision, and warehouse management.

Delayed procurement of Vehicle for our program in WES has hampered the efforts of our technical staff to cover wide areas for support supervision.

Deliverables: Sub-Objective 1.1

CPIR for DELIVER to initiate procurement has been submitted to the Mission and procurement has commenced. Quantification for procurement of essential commodities for the MOH has been done and submitted to the DP&E, MISO request for re-supply has been received and stock replenished.

Draft article on the support in the introduction of Misoprostol in South Sudan has been done and submitted to editorial review.

Quarterly progress toward sub-objective 1.2: Patient safety and therapeutic effectiveness assure

To build capacity in quality assurance, SIAPS has worked with MOH staff (Mr. James Mayen) on Minilab® operations at the Juba Minilab® site at the CMS tested the samples we have collected from the CMS.SIAPS did inspection for 17 samples (antimalarials, quinine injections and some essential commodities).

Following reports from Kaya Minilab on illegal imports from Uganda, SIAPS supported the MOH to draft an official response to the offending companies and also communicate the matter officially to Uganda National Drug Authority NDA.

Challenges in progress toward sub-objective 1.2

The deployment of MOH technical person to start the mini lab in Nimule and the CMS in Juba has been delayed. This has hampered efforts to document and regulate the importation of medicines across the boarders into the country.

Appointment of Board members and key staff of the South Sudan Drug and Food Control Authority has just taken place and this delay hampered initiation or conduct of some quality assurance and regulatory activities.

Deliverables: Sub-Objective 1.2

- Officially communication to Uganda National Drug Authority NDA.
- Technical report on Mini lab testing and results available.

Quarterly progress toward sub-objective 2.1: Enhanced individual, institutional and organizational capacity for pharmaceutical management

SIAPS on its regular supportive supervision exercises conducts on –the job training for commodity managers in the facilities Mundri East and Mvolo in store management and inventory control, facilities visited and number of persons trained include: lanyi PHCC, (1 MCH and HHP supervisor), Doro PHCU (1 MCH worker and 1 TBA), Kedibah PHCC (1 MCH supervisor and 1 nurse in-charge of Pharmacy) and Wandi PHCU (1 facility in charge and 1 MCH worker).

The project also facilitated a training workshop (ARV pharmaceutical Management) organized by Catholic Medical Mission Board (CMMB) and funded by UNHCR. The training was conducted in Ezo county, Western Equatorial for six participants (all males) representing 4 facilities supported by CMMB. The participants are expected to handle ARVs and other essential commodities in the near future.

In Ezo County Health department, SIAPS met with the team and discussed major concerns of the county especially on pharmaceutical management, drug distribution and re-distribution strategies for the future to avoid stock out situations, SIAPS discussed issues of data gathering especially with the availability of tools in most facilities currently.

SIAPS technical staff, all nationals attended a supply chain summit in Kigali which is aimed at exposing them on new innovations on supply chain methods/technologies and how to apply them in public health globally.

SIAPS Senior Technical staff also attended a procurement and supply course organized by the UNDP in Kenya Nairobi to learn about Public procurement and how to undertake procurement in conflict environments where systems are not available to have best value for money.

Challenges in progress toward sub-objective 2.1

Complaints of poor remuneration to staff in the government institutions have demotivated personnel in implementation of some activities in the quarter.

Deliverables: Sub-Objective 2.1

- Training reports and certificates available.

Quarterly progress toward sub-objective 3.1: Information on pharmaceutical systems strengthening available and used

As part of SIAPS support to the MOH to engage partners in sharing technical knowledge and resolve some of the challenges in the pharmaceutical sector, SIAPS helped to prepare TWG meeting, which included supporting MOH to send out invitations to partners; collect and analyze data on antimalarial drugs from the CMS; and drafting technical presentation for the TWG. Some of the data was shared with NMCP to aid the program's presentation at the Health Cluster meeting.

SIAPS, after distribution of the PMIS tools ensured that the tools were used appropriately through facility visits to some selected facilities to verify the use of the tools and to provide on-job training when required, facilities visited include Lui Hospital, Lanyi PHCC, Doroh PHCU, Kediba PHCC, Wandi PHCU, and in Mvolo county facilities visited include Mvolo and Yeri PHCC, Domeri PHCU, Gira PHCU, Bogori PHCU and Lali PHCU all in WES.

SIAPS compiled PPMRm report for malaria commodity reporting as part of its regular update to USAID on stock levels on malaria, this include country stock levels, planned procurement, pipeline updates and future commitments to procure anti malarials.

Challenges in progress toward sub-objective 3.1

Collection of data from partners takes time and some partners are not forthcoming with information on procurement. This makes the PPMRm data collection effort difficult and sometimes delayed.

Lack of reliable transport in WES made our effort to carry out consistent follow up and supervision very difficult.

Delay in approval of work plan also reduced efforts in implementing some activities.

Deliverables: Sub-Objective 3.1

- Technical working group reports
- PPMRm report available

Quarterly progress toward sub-objective 4.1: Improved medicine policies, legislations, regulations, norms & standards

After the passing into law, the South Sudan Food & Drug Control Authority Bill that aims to establish an autonomous Medicine Regulatory Authority in the country, SIAPS played an instrumental role through participation in several meetings between IFC, MOH and the DFCA, to and ensured USAID got a slot on the program and drafted talking points for USAID for the DFCA launch.

SIAPS provided background information on USAID support towards development of the DFCA Act.

SIAPS also supported the MOH/DFCA to arrange a demonstration for the use of the minilab which was led by a South Sudanese whose capacity was built under the SIAPS capacity building efforts.

SIAPS also supported DFCA to plan and facilitate the induction workshop for Board members and Secretariat staff to orient them on the DFCA Act.

Deliverables: Sub-Objective 4.1

- DFCA induction workshop report available.

Quarterly progress toward sub-objective 5.1: Malaria planning and coordination mechanisms strengthened

SIAPS Participated in NMCP and GFTAM meetings and thereafter respond to agreed action points: supported NMCP draft a justification for use of First Response RDTs; fill a questionnaire on malaria M&E systems; review national malaria treatment guidelines to elaborate administration of injectable artesunate for treatment of severe malaria; and, draft a justification for postponement of MIS from 2012 to 2013.

SIAPS participated in NMCP recruitment processes for a Program Assistant – later worked with NMCP and Directorate of Public and Community Health to address misunderstandings related to the recruitment.

SIAPS participated in various malaria meetings aimed at improving coordination of malaria activities. In particular supported NMCP to engage the GFATM PR to discuss and ensure that interventions such as LLIN distribution are carried out according to the national guidelines. SIAPS also participated in a CCM South Sudan meeting organized to orient members on their roles and responsibilities.

SIAPS actively participated in the national vector control conference and supported NMCP to make a presentation on malaria programming in South Sudan – overview of strategies; status of implementation; challenges; and, proposed next steps.

SIAPS supported NMCP to orient state level participants on planned GFATM activities and their expected roles.

Challenges in progress toward sub-objective 5.1

Continued delays in disbursement of funds for malaria activities from the consolidated GFATM malaria grant negatively affected FY12 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.

Staff attrition has also reduced the human resources strength of the project (M&E technical advisor have left for further studies)

Deliverables: Sub-Objective 5.1

- Presentation at the Vector Control Conference available

Swaziland

Year 1 Work Plan

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.

Medicines 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: 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.

Overall Quarter Progress

During this quarter, SIAPS provided technical assistance in the tabling of the Pharmacy Bill no. 7 of 2012 and the Medicines and Related Substances Control Bill no.8 of 2012 before both Houses of Parliament. Both Bills are essential in regulating the country's pharmaceutical sector and ensuring that safe medicines and health products and effective pharmaceutical services are delivered in both private and public health sector of Swaziland. Technical assistance and support was also provided for the Certificate in Pharmacy training program at the Southern Africa Nazarene University (SANU) in order to improve pharmaceutical services in the country. Twenty five students are registered with SANU for the pharmacy certificate program. To further strengthen this program, SIAPS is recruiting a lecturer for the program.

SIAPS also continued to provide technical assistance in preparing for the establishment of the Medicines Regulatory Authority. This will facilitate the assurance of the quality and safety of pharmaceuticals used in the country. SIAPS also supported the training of pharmaceutical personnel in quality control testing of key essential medicines using the GPHF-Minilab testing kit, as part of the activities of ensuring that medicines in the public sector are safe and of high quality.

These activities are all in line with the Swaziland Pharmaceutical Strategic Plan 2012 – 2016, which was also costed and finalized this quarter.

To ensure the appropriate and rational use of medicines, SIAPS continues to disseminate and orient health care workers on the Standard Treatment Guidelines and Essential Medicines List. Use of these documents will ultimately standardize care; improve management of communicable and non-communicable diseases, and selection and use of essential medicines. Sensitization of health care workers on medicine and patient safety issues as well as adherence monitoring for TB patients is an ongoing effort. Capacity building, mentorship and supervision of health care workers were also major areas SIAPS worked during this reporting period.

The annual forecasting for health commodities (HIV, TB, SRHC, Malaria, Laboratory and Essential Medicines) was conducted this quarter. This is one of the key processes to ensure that appropriate demand of health products is quantified, budgeted and submitted to the Ministry of Finance to provide accurate allocation of funds towards assuring the availability of quality pharmaceutical products to achieve desired health outcomes. In addition, a regular quarterly supply planning was also done for ART commodities to make sure that products are delivered on time and ensure uninterrupted availability. Regular mentorship and capacity building have been conducted to facilities to ensure inventory records have been updated and reports and orders are properly placed on time. Support is ongoing to strengthen the capacity of the procurement unit in procuring health commodities in the country.

Key challenges faced during the quarter

The challenge of shortage of pharmacy trained personnel reported last quarter still poses a challenge in various interventions aimed at ensuring availability of medicines and rational use thereof. This has further been worsened by the withdrawal of regional pharmacists who were mentoring clinics and health centers on supply chain management.

SIAPS has since used the quarterly supportive supervisory visits to breach the gap left by the regional pharmacist.

The slow lead time on Government side in progressing towards some activities such as reviewing and approving Procurement guideline and SOPs poses a great challenge in the full implementation of the guidelines.

There are difficulties in attracting suitable candidates for the position of lecturer for the pharmacy certificate.

Due to the fact that parliament was wrapping up its activities for the calendar year, the discussion of the Medicines Bill and Pharmacy Bill were rescheduled to the new year.

Key activities planned for next quarter

- Strengthen the 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
- Conduct an advocacy workshop for Senate and Parliament Health Portfolio Committees on the Pharmacy and Medicines Bills, their contents and their importance in regulating the pharmaceutical sector.
- Finalize Laboratory Equipment Standardization Guideline, Trainings (Laboratory SOPs, CTS, PipeLine, LMIS refresher), Finalization of procurement guideline and SOPs.

Quarterly progress for objective 1: Strengthen governance in the pharmaceutical sector

SIAPS has continued to play an advocacy role to the MOH to ensure that the Pharmacy Bill, and The Medicines and Related Substances Bill are pushed through the parliamentary processes for enactment. Working with the Senior Pharmacist in the MOH and SIAPS supported Medicines Policy Advisor; the Minister of Health tabled these Bills before both houses of Parliament. Both these Bills are essential in regulating the country's pharmaceutical sector, and ensuring that safe and effective medicines and health products are available in both the public and private sector. The next step for these Bills is to be debated by both houses towards enactment. This is planned to take place between quarter 2 & 3. Whilst we wait for the process, SIAPS will continue to work on the support to establish the Medicines Regulatory Authority.

The National Pharmaceutical Strategic Plan 2012 - 2016 has been costed and finalized, ready for approval by the Minister of Health. The plan has been presented to the MOH senior management and approved. It is going to be very important in the country in terms of coordinating and prioritizing resources dedicated to pharmaceutical sector strengthening. SIAPS is a key player in this field as the lead technical partner to the MOH in pharmaceutical systems strengthening. The year two of the strategic plan begins in April 2013 and implementation of certain activities has begun through SIAPS year 1 work plan.

The launch of the first ever Standard Treatment Guidelines (STG) and Essential Medicines List (EML) in the previous quarter was the beginning of various activities to improve access and rational use of medicines. The reception and response to this STG/EML has been positive with many facilities requesting copies and an orientation on the guidelines. Of importance in this quarter has been the great enthusiasm of the training institutions. The introduction of these guidelines at pre-service level is an important step to ensure that student nurses are familiar with these guidelines and are trained on them early on in their practice before they can develop any habit that are contrary to the national standard guidelines.

In this quarter, SIAPS supported the national pharmacy week activities. A lecture on medicines safety was given to an audience of 60 pharmacy personnel from both public and private health sector. This forum was also used to introduce the Standard Treatment Guidelines and Essential Medicines List to the private sector pharmacists. Copies of the documents were given to these pharmacists.

The Supply Chain technical Working Group (SCTWG) continues to play a vital role in coordinating supply chain activities in Swaziland. The SCTWG has made tremendous progress in ensuring that supply chain management in the country is well coordinated and potential areas for integration are being considered. In this quarter, the SCTWG developed a proposal and concept paper for the pharmaceutical services quality improvement project. This project

will provide mentorship and supervision of facilities on pharmaceutical management including supply chain.

Quarterly progress for objective 2: Increase capacity for pharmaceutical supply management and services

Capacity Building in supply management and pharmaceutical services is an ongoing activity. SIAPS is working closely with other partners to ensure that the supply chain management skills are expanded to other health professionals. The absence of regional pharmacist has the potential of negating all the gains achieved in supply chain management at clinics in the past two years. SIAPS is working closely with MOH to consider alternative ways of continuing the work of the regional pharmacist in strengthening supply chain systems at facilities. In this quarter, SIAPS has started working with partners such as EGAPF, ICAP and CHAI to make use of the clinic mentors in supply chain capacity building. These mentors visit facilities frequently and will benefit in gaining experience on routine supply monitoring. In this quarter, 14 health facilities were visited jointly with ICAP, EGAPF and CHAI. This was the first visit for this fiscal year and more facilities are planned for joint visits in the next quarter.

Leadership in the supply chain system is an area that requires urgent attention. With a lot of investment and technical assistance provided to the Central Medical Stores in supply management of health product, a gap is being noticed in the leadership of the supply chain. SIAPS is working closely with the MOH and local counterparts to put in place an appropriate leadership structure for supply chain management. The work of recruiting a CEO for the central medical stores is ongoing albeit some bottlenecks in the government human resources department. Discussions are continuing with the Ministry of Health and Ministry of Public Services on the role / function of this CEO in line with government organizational structure. The proposed organizational structure has been submitted to the Ministry of Public services for approval.

SIAPS participated in the 5th Global Supply Chain meeting in Rwanda where global experts in supply chain systems strengthening were gathered to share experience and latest knowledge. This was an important opportunity for SIAPS to share lessons learnt in Swaziland and get input from other experts in ways of improving supply management in Swaziland

SIAPS provided input and support in the 1st semester examinations of the pharmacy certificate program at the Southern Africa Nazarene University's Faculty of Health Science. The process of recruiting a course coordinator was delayed as a suitable candidate for this position couldn't be identified in the first round of recruitment. The recruitment continues with a target of having the incumbent on board in the next quarter.

Quarterly progress for objective 3: Address information for decision making challenges in the pharmaceutical sector

- Information management is an important component in the supply chain and pharmaceutical management work of SIAPS in Swaziland. Tools such as RxSolution, APMR, Quantimed and Pipeline are being used effectively to provide necessary data for decision making in the country. The Data management unit at the Central Medical Stores is being supported to collect and collate logistics data from facilities before it can be presented to decisionmakers. This unit has been very successful in ensuring the availability of quality data to be used in quantification and forecasting. In this quarter, SIAPS participated in discussions to potentially expand the scope of this unit to include TB, Reproductive Health and Malaria. The process of developing the manual forms for TB has begun with plans to implement in the next quarter. SIAPS has trained the team in the data management unit on the web-based commodity tracking tool. Logistics data for ARVs and laboratory commodities is being captured into this database and full implementation will begin in the second quarter.

The first data dissemination meeting was held in October where 37 facilities were represented. In this meeting, facilities were given feedback on their data for the period January to June 2012. Special attention was given to

data quality concerns which SIAPS was tasked to assist in addressing.

Quarterly progress for objective 4: Improve pharmaceutical services to achieve desired health outcomes

Improving product availability is a key activity of SIAPS in Swaziland. The availability of ARVs, TB medicines, reproductive health commodities is priority focus in ensuring success and achievement of the government's ambitious treatment targets. A total of 400 million emalangeni is proposed in the medicines budget of the MOH for the next two fiscal years 2013/14 and 2014/15. This is a significant amount of money considering the national health budget. SIAPS is supporting the use of information in forecasting and supply planning as well as reducing wastage of health products. Quantimed and Pipeline are important databases in ensuring that the country conduct accurate quantification of needs. The Standard Treatment Guidelines and Essential Medicines list that were introduced in the previous quarter will also contribute in reducing wastage by changing medicines use and prescribing habits. SIAPS is also supporting product quality control activities in the country. 16 pharmacy personnel were trained on conducting quality control test using the GPHF-Minilab kits. This is a basic kit that can be used even in remote settings for basic quality control testing. A database to record product quality concerns has been designed to be used by the Quality Control Pharmacist at the Central Medical stores.

The Medicines Safety Watch newsletter is gaining a lot of acceptance by health professionals with the 4th edition published in October. Featured in this edition was a discussion on the safety issues of tenofovir in the national treatment program. The newsletter is distributed via e-mail and 500 print copies are sent out to health facilities.

SIAPS presented at the 2nd Africa TB Conference in Zanzibar, the work done to monitor adherence to treatment amongst patients on TB medicines. The presentation was received positively by the participants at the conference with even recommendations for countries to rethink the methods used in monitoring adherence to TB medicines as poor adherence often lead to development of resistant strains. SIAPS has also worked intensively to support the TB pharmaceutical management at the TB hospitals which cares mainly for drug resistant TB clients. This pharmacy is managed by one pharmacy technician who is responsible for ARV, TB and inpatient dispensing. Storage space for medicines is inadequate and dispensing records are not accurate. With SIAPS support, the facility has an up to date inventory record of all medicines stored and record of patients on treatment. The storeroom has been cleared up with expired medicines removed from the storeroom to make room for more products to be stored. Working with the Central Medical Stores, the minimum and maximum stock levels of TB medicines in the hospital has been revised taking into consideration the available space.

Quarterly progress toward sub-objective 1.1: Improve medicines policies, legislation

The Pharmacy Bill, no.7 of 2012 and the Medicines and Related Substances Control Bill, no.8 of 2012 were tabled before both Houses of Parliament for discussion by the legislators. In preparation for the enactment of the two pharmaceutical Bills, the process of development of draft regulations was commenced. The contents and implications of the two Bills were presented before approximately 400 health care worker, health profession students and members of the public at the 2nd National Health and Research Conference. This is part of the public awareness and advocacy activities towards the Parliamentary discussion and subsequent enactment of the Bills.

SIAPS conducted an orientation on the STG/EML to the Royal Swaziland Sugar Company group health care workers as well as to Hhohho region clinic supervisors and mentors. a total of 3,544 copies of the STG/EML have been distributed to health workers throughout the country. Copies were also sent to the nursing colleges in the country for their students - University of Swaziland, Good Shepard Hospital, and Southern Africa Nazarene University.

Challenges in progress toward sub-objective 1.1

Difficulties were encountered in attempting to schedule a workshop for the Parliamentarians to inform them on the contents of the two Bills, this was due to the tight schedule of the legislators. However SIAPS has rescheduled this workshop for the next quarter when Parliament re-opens.

Deliverables: Sub-Objective 1.1

- Parliament Order Paper and STG/EML dissemination Report

Quarterly progress toward sub-objective 1.2: Support the development of a strategic and evidence based pharmaceutical sector development plans

The Swaziland Pharmaceutical Strategic Plan (SPSP) 2012-2016 costing exercise and report were finalized. The SPSP was presented to the MOH senior staff meeting for endorsement and adoption. This is part of the process leading up to the Minister for Health adopting the SPSP and the Cabinet approving the Strategic Plan. The Pharmaceutical Services Baseline Survey report was finalized and endorsed by the MOH after the Survey report was presented to the MOH Senior Staff.

Challenges in progress toward sub-objective 1.2

Challenges were encountered regarding obtaining financing information and fund commitment for SPSP activities from Partners, limiting the financing gap analysis.

Deliverables: Sub-Objective 1.2

- SIAPS Costing Report and Pharmaceutical Services Baseline Survey Report

Quarterly progress toward sub-objective 1.3: Improve coordination of stakeholders in pharmaceutical systems

SIAPS continued to coordinate and participate in the SCTWG activities. One meeting was held on November 2012 where a number of supply chain issues were discussed and these included the following:

- Quantification and Budget for 2013/14
- Procurement update: HIV Commodities, TB, Laboratory, Essential Medicines -Updates on Laboratory supply chain: Standardization, Lab Supportive Supervision

SIAPS collaborated with the Swaziland Pharmaceutical Association on activities of the annual, National Pharmacy Week 2012. A lecture on medicines safety and pharmacovigilance was held, with 60 pharmacists from public and private sector in attendance.

Challenges in progress toward sub-objective 1.3

- No major challenge experienced in progress towards this sub-objective.

Deliverables: Sub-Objective 1.3

- Supply Chain Technical Working Group Meeting Minutes

Quarterly progress toward sub-objective 1.4: Support the health commodity procurement system (Pharmaceuticals, supplies and laboratory commodities) within the MOH Procurement Unit

In this quarter SIAPS has supported the MOH Procurement Unit in the development of draft Procurement SOPs based on the guideline developed. SIAPS contributed in the development of tender / bidding documents for ARVs, essential medicines and medical supplies for the 2013/14 budget year. These tenders have been published with closing date in January 2013. The adjudication will take place, and be concluded before March 31, 2013. SIAPS is working with local partners (URC, MSF, and CHAI) in the standardization of laboratory equipment. Dr Charles Kagoma from MSH Tanzania is providing technical assistance in this exercise. In this quarter, two consultation meetings have been held with laboratory personnel and stakeholders to determine and inform the standardization exercise. Laboratory equipment inventory has been collected including the state of operation of the different platforms. It is anticipated that the finalization and implementation of this standards will simplify the procurement of laboratory supplies and also the training requirement of laboratory personnel using the various machines.

Challenges in progress toward sub-objective 1.4

- Slow processes in getting documents for standardization of equipment, as well as finalizing and adopting procurement manual.

Deliverables: Sub-Objective 1.4

- Quantification and Budget Estimate; and Supply Plan Report

Quarterly progress toward sub-objective 2.1: Increased pharmaceutical management capacity for individuals, institutions and organizations

An intensive supportive supervision was conducted in 14 sites in Lubombo region focusing on Pharmaceutical Services, Supply Chain and Information Management. The facilities visited include Sithobela Health Centre, Good Shepard Hospital and 12 clinics in the region. All these facilities were ART treatment sites (either initiating or feeder). SIAPS worked with EGAPF and ICAP in conducting these visits. In December, 12 health workers were trained on dispensing using RxSolution and these included data clerks, nurse and pharmacist. This number included health workers from the Cabrini Compassionate Ministries, St Phillips Clinic in Lubombo region. This training was one of the interventions recommended from the supportive supervision visits mentioned earlier.

In a bid to improve pharmaceutical management capacity in the country, SIAPS has conducted mentorship for 9 laboratory testing sites on inventory management and Lab LMIS implementation. The mentorship activity is aimed, among other things, to enhance the skill of laboratory personnel on inventory record keeping, and LMIS reporting. Reporting rate for Lab LMIS has increased to 95% (n=14 laboratories).

SIAPS participated in the 2nd National Health Research Conference wherein seven papers (oral and poster) were presented. During this conference, SIAPS also led a panel presentation on Supply Chain Systems Management, and Governance in the Pharmaceutical Sector.

SIAPS participated in the Semi-Annual ART program review meeting organized by the MOH. This was an opportunity to review progress of the country in the HIV&AIDS program management and also address some potential bottlenecks.

The recruitment process of the Certificate in Pharmacy Course Coordinator position identified suitable candidate who turned down the offer. The recruitment is ongoing with plans to have the incumbent in place in the next quarter. SIAPS also provided guidance and input in the 1st semester examination for the certificate program at SANU.

Challenges in progress toward sub-objective 2.1

- Difficulties in attracting suitable candidates for the Pharmacy Course Coordinator
- Absence of regional pharmacist

Deliverables: Sub-Objective 2.1

- Training report on Rx Solution
- Supportive Supervision Report

Quarterly progress toward sub-objective 3.1: Support pharmaceutical management information systems for both products and patients

In supporting the pharmaceutical management information systems for patient, SIAPS participated in three (3) unique patient identifier meetings to develop an inception report for the project. This project is meant to establish a standard process of uniquely identifying patients on health systems. This will help reduce duplication in service provision for the same patients. The unique identifier project is led by Institute of Health Measurement (IHM)

A firm to redesign the RxPMIS / APMR has been identified and plans are underway for the firm to commence activities in Jan 2013. The redesign is expected to lead to a finalization of the web-based tool which will then be the basis for future health management systems platform in the country.

In October 2012, SIAPS supported data dissemination workshop by the data management unit at CMS. A total of 37 facilities attended and participated in the data dissemination. A general feedback was presented to the facilities and a facility specific report was prepared for each facility highlighting the performance and challenges of that facility concerning data and reporting. SIAPS provided technical assistance in the discussions, where a number of challenges were raised, including Electronic System (RxSolution); Human Resource issues; and Reporting Timeline challenges with respect to Baby Clinics. From these challenges, SIAPS developed an action plan to address the challenges; the plan was shared with the relevant counterparts within MOH. The action plan informed some of the interventions and mentorship visits SIAPS continuously carried out during the quarter to support the facilities.

Challenges in progress toward sub-objective 3.1

- There was no major challenge experienced in the past quarter regarding this sub-objective

Deliverables: Sub-Objective 3.1

- Unique Patient Identifier Project Report
- Data dissemination feedback meeting report

Quarterly progress toward sub-objective 3.2: Support proven, innovative tools for the pharmaceutical management information system

SIAPS provided continuous technical assistance to facilities on hardware issues and Rx-Solution use for store & dispensing. SIAPS supported the ongoing IT Network Infrastructure project. This included assisting the MOH with selecting, receiving and verification of hardware and software for the IT Network Infrastructure required. SIAPS further participated in the assembling of the server rack, mounting of servers and other server components in the server room located within Government Computer Services premises. The IT infrastructure work is part of the greater health IT strategy to support HMIS. This infrastructure will be a platform for the Commodity Tracking System and RxSolution software used in logistics information management

In this quarter data on HIV and Laboratory commodity has started being entered into the commodity tracking system (www.lmis.org.sz). SIAPS has supported the revision and implementing of the manual Logistics Management Information System (LMIS) tools for HIV, Laboratory and reproductive health products. The new LMIS tool for TB has also been drafted and implementation will start in the next quarter. When the tool is finalized and implemented, it will link facilities with CMS on TB supply management and support facilities to estimate appropriate quantity demand on time to avoid stock outs.

SIAPS has provided mentorship to about 60% (n = 14 laboratories) of ART and Laboratory testing sites on how to complete stock cards and LMIS report and order forms.

SIAPS supported and strengthen pharmaceutical data collection processes and analyses at the CMS and NLS – two new reports on Variances and "Accounts Stores Requisition Form" were generated from the Rx-Solution system. The NLS products list data in Rx-Solution was revised and aligned to the Supply Planning list – all historical transactional data was preserved. Routine monthly reports such as stock status report were generated.

SIAPS continued expansion of Rx-Solution use for Stock and Inventory management to all other essential Medicines and supplies in two health facilities (Matsanjeni Health Centre and Hlathikhulu Hospital) situated in the Shiselweni region. This involved mentoring and supporting facility staff to record physical inventory stock-take, generate purchase Orders, and requisitions into the Rx-Solution system of all ARVs, TB Drugs, essential medicines and medical supplies.

In addition, nine (9) facilities (Dvokolwako Health Centre, Matsanjeni Health Centre, Mankayane Hospital, Good Shepherd Hospital, Hlathikhulu Hospital, Nhlangano Health Centre, National TB Hospital, Cabrini Ministries, and Raleigh Fitkin Memorial Hospital) were provided with continuous support on their computer hardware/systems, Rx-Solution use and database backups.

As part of strengthening the use of the Pipeline and Quantimed tools, two users (SCTWG members) were supported in the installations and data manipulation of Pipeline and Quantimed tools.

Challenges in progress toward sub-objective 3.2

The MOH electronic tool tends to slow down due to server capacity issues and network traffic, this affects the transmission of data from the regions to the central server. There are, however plans to improve the IT network infrastructure within the MOH.

Deliverables: Sub-Objective 3.2

- MOH IT Network Infrastructure project report (draft)

Quarterly progress toward sub-objective 4.1: Improved availability of pharmaceuticals

SIAPS has supported and facilitated 3 National Quantification exercise for health commodities (HIV, TB, Reproductive Health, Malaria, Laboratory and Essential Medicines). Support was also provided in quantification of co-trimoxazole, Isoniazid, PMTCT, Sexual and Reproductive Health commodities including Condom. Quantimed®, a quantification tool, has been utilized to estimate HIV commodity requirement for the years 2012/13 and 2013/14.

Budget have been estimated at a sum total of about SZL413 million; submitted to MOH planning unit and MOF and Tenders have been published. Three supply planning meetings have been conducted using PipeLine®

monitoring tool to estimate quarterly requirement of HIV commodities and generated Purchase Requests. This enables the MOH to procure appropriate quantities.

SIAPS is working with the Central Medical Stores to redesign the product flow of TB medicines from CMS to facility. TB medicines used to be distributed from CMS to the TB Program then to facilities. This has led to longer lead times and such that facilities will at times run out of stock. Working with MOH, a pharmacist has been placed at CMS to oversee the direct distribution of TB medicines to TB facilities, cutting out the TB Program "sub-store".

SIAPS has also supported the revision and introduction of PMTCT LMIS to facilities. This facilitated accurate reporting and order of PMTCT products from facilities to maintain availability. The LMIS reports are submitted monthly to the Data Management Unit at CMS.

SIAPS has also initiated discussions on the integration of TB and SRH commodities with CMS warehousing and distribution system. In this quarter SIAPS has engaged orderlies and MOH counterparts and facilitated 'de-junking', warehouse rearrangement and implemented cyclic stock take at the National Laboratory warehouse, TB Hospital and other 9 laboratory testing sites.

SIAPS has supported enhancing the security of central warehouses by putting burglars bar and alarm system. This activity was necessary as part of reducing potential pilferage in the CMS

Challenges in progress toward sub-objective 4.1

- Lack of adequate warehouse/storage space at the national laboratory warehouse and laboratory testing sites.

Deliverables: Sub-Objective 4.1

- Quantification and Budget report for TB/HIV products, Site visit activity reports

Quarterly progress toward sub-objective 4.2: Assure patient safety and therapy effectiveness

SIAPS remains committed to ensuring patient safety and therapy effectiveness. This is evident in the number of interventions undertaken including, engaging developers of Rx Solution to enhance the system for Pharmacovigilance activities. Pharmacovigilance activities were presented to create awareness in Swaziland during the Pharmacy Week in October. The drafting of the active surveillance protocol has been one of the priority activities in the past quarter, 3 meetings were held with Pharmacovigilance consultant.

Two-day training on the GPHF-Minilab quality control testing kits was conducted for 16 pharmacy personnel. A draft sampling plan for priority medicines to be tested using the GPHF-Minilab was also developed.

SIAPS developed, printed and distributed 500 copies of the October issue of the Medicines Safety Watch Newsletter. The October newsletter featured a Q&A section on tenofovir in treatment of HIV. Global medicines / patient safety alerts were shared in this quarterly newsletter.

In November, the portfolio was able to develop and present an abstract on patient safety at the Swaziland National Health & Research Conference.

SIAPS continued to provide technical support to Hlathikulu, Nhlangano and Matsanjeni PTCs on the implementation of the STG/EML and prescription books in these facilities.

Following two supportive supervisory visits to the TB Hospital Pharmacy, a number of challenges and gaps were

identified with regard to effective pharmaceutical management. Noted challenges were poor inventory management, poor utilization of space and inadequate information management on TB patients at Pharmacy level. A work plan to address the identified challenges was developed with MOH and National TB Program Pharmacist. Major activities in the plan included, training the TB pharmacy staff on inventory management, supporting the staff to conduct physical stock count of all items and recording them on the stock cards. In addition to this, all expired medicines were to be quantified and isolated for disposal according to laid down procedures. To optimize storage space, stock was rearranged into designated areas and clearly marked. Protocols for TB medicines were to be developed and entered into the Rx Solution software for TB patient management. There has been significant improvement in the storage space utilization and the data on patients on DR TB is more complete than before.

Challenges in progress toward sub-objective 4.2

- Absence of a dedicated pharmacist at the National TB hospital.

Deliverables: Sub-Objective 4.2

- Protocol for active surveillance
- Medicine safety newsletter
- Quality control training report

Quarterly progress toward sub-objective 4.3: Provide technical assistance in the decentralization of HIV, TB services to improve access to quality pharmaceutical services

SIAPS continued to provide technical assistance in the decentralization of HIV and TB services. In the past quarter SIAPS received and collated adherence reports (102 for the month of September, 102 for the month of October). Adherence scores for the month of October were 92%. SIAPS-Swaziland sent two representatives to the 2nd Africa TB conference to share experiences on adherence monitoring in Swaziland.

SIAPS continued to provide technical support to Hlathikulu, Nhlangano and, Matsanjeni PTCs on the implementation of the STG/EML and prescription books in these facilities.

In November an abstract on TB adherence monitoring was presented at the Swaziland National Health & Research Conference. And this was a milestone for the project as it generated a lot of interest in the TB adherence activities, the project is undertaking.

Challenges in progress toward sub-objective 4.3

- Delays in finalizing the HIV/FP guidelines

Deliverables: Sub-Objective 4.3

- Trip report for the 2nd Africa TB report with work plan and TB hospital pharmacy quality improvement report

Quarterly progress toward sub-objective 2.2

- There was no activity under this sub-objective. Feedback from the Ministry of Public Service is still pending after the submitting the proposed organizational structure for the Central Medical Stores with terms of reference for the Chief Executive Officer to the ministry through MOH.

Challenges in progress toward sub-objective 2.2

- Delays in finalizing the process of reviewing the proposed organizational structure

Deliverables: Sub-Objective 2.2

- CMS Organizational structure review report

Turkmenistan/Uzbekistan

Year 2 Work Plan

Quarterly Report Background

Tuberculosis (TB) continues to be a critical public health threat in Central Asia. All five Central Asian countries are included in the WHO European Region's 18 high priority countries for TB. In Uzbekistan and Turkmenistan the current epidemiological situation for TB remains a serious challenge, despite strategic efforts by both the governments and donors in scaling up the WHO-recommended TB diagnostic, treatment and programmatic management strategies. In addition to high TB incidence, Uzbekistan and Turkmenistan also experience alarmingly high rates of multi-drug resistant tuberculosis (MDR-TB). Decision making and managerial interventions aimed at overcoming these challenges are often limited by a lack of reliable data resulting from weak information systems.

As part of the USAID-funded Strengthening Pharmaceutical Systems (SPS) program, MSH developed an electronic web-based information system - e-TB Manager© that aims to strengthen TB programs by supporting databases and information flows into one comprehensive management tool. Under SPS, MSH implemented e-TB Manager in Uzbekistan. As part of this implementation and expansion e-TB Manager was adapted to the requirements of the National Tuberculosis Program (NTP) of Uzbekistan and an Uzbekistan version of e-TB Manager was installed on the local server.

Implementation of e-TB Manager was included in the National TB Control Program of Uzbekistan (2011-2015). All TB facilities in the city of Tashkent, and the majority of TB facilities in Tashkent Oblast and Kara-Kalpakstan, started entering TB case data in e-TB Manager. The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) project supports implementation of e-TB manager through development of information technology infrastructure such as procurement of computers and ensuring internet access. Historically, the NTP (Republican DOTS Center) of Uzbekistan and the GFATM project have worked in a very collaborative manner. Recently the MOH suspended use e-TB Manager until they are fully convinced about the data security of e-TB Manager. But in recent communications with the different stakeholders including Deputy Minister of Health of Uzbekistan by WHO and SIAPS has shown that there is very big interest in implementation of e-TB Manager. WHO and SIAPS were ensured that all problems will be solved soon and there will be possibility for resuming of implementation of e-TB Manager.

In partnership with the WHO headquarters and the European Regional Office, SPS developed a test version of the Laboratory module of e-TB Manager. The module allows TB laboratories to manage efficiently their data. The laboratory data is connected to the TB cases entered in case management module. The module was tested in Uzbekistan and modified according to the findings. It is now ready for an additional round of testing.

In addition to the NTP, SPS also collaborated with the GFATM project, the WHO country office, and Project Hope on the implementation of e-TB Manager in Uzbekistan.

SPS did not work in Turkmenistan, and the introduction of e-TB Manager will comprise the first SIAPS activities in the country.

The USAID-funded Strengthening Access to Pharmaceuticals and Services (SIAPS) program, the follow-on to SPS, will build off the successes of the SPS program through adaptation and customization of e-TB Manager in Uzbekistan, and strategically plan the introduction of e-TB Manager in Turkmenistan.

Goal: The primary goal of the project is to strengthen the tuberculosis control system of Uzbekistan and Turkmenistan by improving information systems to address the threat of MDR-TB.

Overall Quarter Progress

The primary goal of this project is to strengthen the tuberculosis control system of Uzbekistan and Turkmenistan by improving information systems to address the threat of TB and MDR-TB. The SIAPS Team spent the first part of this quarter formulating a work plan and budget for work in Uzbekistan and Turkmenistan. The October 1, 2012 to September 30, 2013 workplan was submitted to the USAID regional mission in Central Asia and is awaiting approval.

Under Objective 1, the SIAPS Team had a trip planned to Uzbekistan but this has been delayed due to the challenges being presented by the Information Technology Center of the MOH. Without this restriction being lifted progress and expansion of activities cannot move forward. There has been progress in finalizing the laboratory module of eTB Manager and it is currently being tested by the National Reference Laboratory of Uzbekistan.

Under Objective 2, due to the challenges in Uzbekistan, the initial assessment trip to Turkmenistan is also delayed. WHO is procuring computers to support implementation of eTB Manager in Turkmenistan and SIAPS has provided specifications for this effort.

The SIAPS Team at HQ continues to communicate regularly with USAID, WHO, the MOH in Uzbekistan and Turkmenistan and other partners regarding the issues and the plan for moving forward and particularly in lifting the restrictions in Uzbekistan. The Team is planning for a February trip to both countries.

Key challenges faced during the quarter

The primary challenge in making progress toward the objectives has been that the Information Technology Center of the MOH has banned use of eTB Manager due to data security concerns. This has been put into place without a clear explanation, clarification, or information regarding which documents they require to be convinced that data security is ensured in eTB Manager.

This decision is part of the current wave of general suspicion to web based information systems. Archil Salakaia, SIAPS Senior Technical Advisor, met the Deputy Minister of Health of Uzbekistan and he assured us that the problem will be solved soon. Further, SIAPS counterparts from WHO EURO met the Deputy Minister of Health and they also were ensured that the problem will be solved soon. However, use of web based eTB Manager still is not allowed and it makes impossible to work with the system, develop it and train people. SIAPS is in communication with the USAID mission in Central Asia, WHO Euro and NTP to coordinate actions to solve the problem.

This key challenge further compliments activities under Objective 2 for Turkmenistan. The assessment trip will be more efficient and cost effective if it is conducted in combination with the trip to Uzbekistan. Delay of solving the problems in Uzbekistan delays a trip to Turkmenistan.

Quarterly Progress for Objective 1: Strengthen the National TB Program of Uzbekistan through improving the TB management information system countrywide

Activities were just getting started this quarter for SIAPS in Uzbekistan. Work under Objective 1, focused on planning with WHO and the regional USAID Mission. The Case Management module of e-TB Manager web version has been finalized and is currently in use by the NTP with technical support from SIAPS.

The Drug Management module is also being used; however, it is still in test mode. One of the current limitations of e-TB Manager is that it was not yet customized to meet the needs of programs that use GDF-type patient medicine kits. The e-TB Manager in Uzbekistan will be modified to overcome this limitation and feedback from the NTP

will be incorporated based on Drug Management module testing. The Laboratory module of e-TB manager is also now being tested and based on the results the module will be finalized.

The laboratory module is close to its final shape. It's being tested by the National Reference Laboratory of Uzbekistan. There is no progress in further implementation of eTB Manager (including drug management module) due to the challenges described in the Key Challenges section. This challenge further extends itself to no progress made under Activity 1.2: Build Capacity for country-wide utilization of eTB Manager.

Quarterly Progress for Objective 2: Strengthen the National TB Program of Turkmenistan through provision of technical assistance for improving the TB management information system

Once the work plan has been approved by USAID, the first step will be an assessment of the current TB management information system in Turkmenistan. It was agreed with WHO Euro representatives that there will be joint mission to Turkmenistan (SIAPS and WHO Euro) for this purposes and WHO country mission will provide support in organization of all meetings and site visits. This trip is pending the lifting of the eTB Manager ban in Uzbekistan so that the Technical Teams can provide these initial technical assistance and assessment trips close together. Further, WHO plans to procure computers to support implementation of eTB Manager in Turkmenistan and SIAPS HQ has provided specifications for that.

Ukraine

Year 2 Work Plan

Quarterly Report Background

Ukraine has the most severe HIV epidemic in Eastern Europe and Central Asia and the second highest burden of TB in the European region after Russia. Since 1992, the Ukrainian government has sought to transition from the Soviet model of health care to one that can effectively meet the needs of its citizens. Antiretroviral therapy (ART) services, substitution maintenance therapy (SMT) services for opioid addiction, and TB services in Ukraine are currently organized as vertical systems, each with its own supply chain and management information system with little coordination between them. Improving coverage of ART for persons who need it is a priority for the MoH of Ukraine and its partners. Other strategies to facilitate scale up of HIV treatment and care include decentralization of ART services, expansion of SMT provision, and improved prevention, diagnosis, and treatment of TB in persons living with HIV.

Critical to the success of these interventions and TB control strategies in Ukraine is the provision of quality pharmaceutical services and the timely availability of medicines and other critical pharmaceuticals and supplies. SIAPS will use a health system strengthening approach, build local capacity and develop strategic partnerships to achieve the program goal of improving access to, use and accountability of life-saving medicines and health commodities of assured quality to support priority health services in Ukraine to achieve desired outcomes.

The Ukraine Results Framework is aligned to the USAID Ukraine Mission's expectations of SIAPS as an implementing partner and contributes overall to US Government (USG)/Ukraine Global Health Initiative (GHI) goal and principles as well as the GoU efforts to combat HIV/AIDS and TB.

In Ukraine, SIAPS focuses on achieving the following objectives: 1. Improve Pharmaceutical Management Information Systems to Support HIV/AIDS and TB Programs. 2. Improve Supply Chain Management Systems for HIV/AIDS and TB Commodities. 3. Enhance Organizational and Human Resource Capacity for Pharmaceutical Management. 4. Improve Pharmaceutical Services for TB and HIV/AIDS Programs. 5. Improve Pharmaceutical Management Governance.

SIAPS will also build on achievements made under SPS and the SPS Ukraine Associate Award to adapt and implement the MSH tool e-TB Manager, a web-based comprehensive information system that brings together all elements of directly observed treatment short-course (DOTS) strategy and provides patient-specific and summary information on TB diagnosis, case management, and pharmaceutical management.

SIAPS will focus on improvement of the quality of the data entered into e-TB Manager, piloting the e-TB Manager medicines management module to enable the TB program to better quantify, manage, and monitor the appropriate use of TB medicines at national, oblast, and facility levels. Beginning in Year 1, SIAPS Ukraine will complete the Assessment of TB & HIV/AIDS pharmaceutical management practices and assist in the development of appropriate recommendations for the different service centers. Support will be also focused on establishment of two working groups on measures for continuous improvement of medicines prescription practices and the working group on pharmacovigilance; enhancement of DCAT to meet local requirements; and development or refinement of proposed PV audit guidelines that are convergent with EU guidelines (audit of manufacturers).

Goal: Through a health systems strengthening approach, build local capacity and develop strategic partnerships to achieve the program goal of improving access to, use of and accountability for life-saving medicines and health commodities of assured quality to support priority health services in Ukraine to achieve desired health outcomes.

Overall Quarter Progress

During the quarter SIAPS made some progress toward the program overall goal. TB Cases Management module in e-TB Manager was improved. MoH approved the Order on TB Register operations (an Order N818 dated October 19, 2012). SIAPS Ukraine supported UCDC jointly with the Fund of Development of Ukraine (PR for the Global Fund Round 9, the Phase 1) on preparation of the drafts of CCM Request for Renewal and the Procurement and Supply Management Plan for 2013-2015. A Draft of the Long-Term Strategic Plan for PV development in Ukraine was presented at the stakeholders meeting. Activities under Objectives 1, 2, and Objective 4 contributed to improvement of access to, use and accountability of life-saving medicines of assured quality and therefore, contributed to improving patients' health.

Key challenges faced during the quarter

- Liquidation of the National TB Center. In October 2012 the Ministry of Health of Ukraine established the Ukrainian Center for Diseases Control (UCDC) to take over the implementation of nationwide disease control policies and strategies including TB and HIV/AIDS (an Order #201-0 dated October 17, 2012). UCDC was created based on the existing capacity of the National AIDS Center by its merging with the National TB Center and with support from the State Service of Ukraine on HIV/AIDS and Other Socially Dangerous Diseases. The capacity of UCDC to perform these functions will need to be assessed, and strengthened as necessary.
- Absence of common vision and low coordination as for the PMIS between the main counterparts on the National HIV/AIDS Program.
- Additional time is necessary to develop Memo of understanding and cooperation between SEC and SIAPS.
- The lack of registration is a barrier to Project implementation.

Key activities planned for next quarter

- Local staff in close collaboration with HQ team and appointed Project Recipient will prepare set of documents (MOU, Letters of support, Procurement Plan) necessary for submission to the Ministry of Economic Development and Trade of Ukraine to obtain official state registration of SIAPS Project as International TA Project in Ukraine;
- Adaptation, implementation and initiating use of Drug Management module of e-TB Manager. However, due to the changing environment it is not very clear at this stage with which state agency SIAPS Ukraine should work in order to start using of the Drug management module (for testing purposes). This should be followed up mainly in communication with UCDC and the State Service;
- Establishment of national level official working group on e-TBM development directions;
- Closer cooperation with WHO country office in a scope of MIS systems implementation/usage for Ukraine National TB and HIV/AIDS Programs;
- Routine monitoring and support visits of SIAPS staff to the regions to make sure that the PCs procured under the SPS program are used appropriately for entering data in e-TB Manager and provide technical support for starting up of use of computers where needed;
- Data quality monitoring visits to the regions;
- Post supervision workshop to discuss findings of data quality monitoring visits and ways for its improvement;
- Development and testing of e-TB Manager data quality manuals and guidelines;
- Piloting the full cycle of automatic TB07 / TB08 / TB10 / TB11 reports generating in eTBM (most likely in Zakarpatska oblast);
- Organize and conduct e-TBM user training events for 3 oblasts;
- Continue communication with UCDC and other stakeholders in relation to SIAPS Ukraine support to UCDC in PSCM capacity development. It is expected that SIAPS will support calculation of TB medicines state annual 2013 request. If specialists responsible for state annual request from regions will need

additional Quantification training sessions (to receive guidelines and calculate TB medicines with new TB Quantification tool) SIAPS Ukraine will support them;

- Proceed further with Assessment of TB & HIV/AIDS pharmaceutical management practices: (i) preparation of tables with collected data (both – TB and HIV/AIDS) for analysis in SPSS and SPSS analysis; (ii) finalization of the indicators list; (iii) preparation of the drafts of the Reports (both – TB and HIV/AIDS); (iv) selection of the regions for expert visits and conducting these visits. SIAPS is planning to involve local consultant (-s) for supporting with expert visits and/or preparation of the reports;
- Continue support of the Foundation of Development Ukraine (FDU)(the PR for the Global Fund Round 9, the Phase 1) on supply chain management issues and UCDC support to develop of PSCM capacity;
- Organize two working groups (i) on measures for continuous improvement of medicines prescription practices; (ii) working group on PV;
- Enhance DCAT to meet local requirements;
- Develop or refine proposed PV audit guidelines that are convergent with EU guidelines (audit of manufacturers).

Quarterly progress for objective 1: Strengthen pharmaceutical management information systems (PMIS) to support the HIV/AIDS and TB Programs

Over the reported period SIAPS Ukraine has improved the software modules of e-TB Manager. In cooperation with National TB Center and FDU SIAPS has developed and ensured approval of MoH Order on TB Register operations. SIAPS has started cooperation with UCDC and Network of PLWH on the PMIS for the National HIV/AIDS Program development. SIAPS has started cooperation with USAID funded STBCU Project in the direction of e-TBM data quality control and ensuring. Activities under the Sub-Objective 1.1 contributed to improvement of PMIS to support TB Program.

Quarterly progress for objective 2: Improve supply chain management systems for HIV/AIDS and TB commodities

During the reported period SIAPS Ukraine provided support to regional specialists in filling in of check-lists for Assessment of TB & HIV/AIDS pharmaceutical management practices. 28 completed check-lists (14 TB and 14 HIV/AIDS) from 14 pilot regions were collected. The draft indicators list for pharmaceutical management monitoring and supervision was reviewed and updated. SIAPS Ukraine team supported UCDC with preparation of the drafts of CCM Request for Renewal and the Procurement and Supply Management Plan for 2013-2015. Activities under the Sub-Objective 2.1 and 2.2 contributed to improvement supply chain management systems for TB and HIV/AIDS commodities.

Quarterly progress for objective 4: Improve pharmaceutical services for the TB and HIV/AIDS Programs

During the reporting period, the stakeholders' meeting on "Strengthening PV System in Ukraine: Strategic Planning" (December 12, 2012) was carried out. The Long-Term Strategic Plan for PV development in Ukraine was presented to partners at stakeholders meeting. The draft Memorandum of Understanding and cooperation between SEC and SIAPS Ukraine was prepared.

Quarterly progress toward sub-objective 1.1: Support the development and improved use of innovative and proven information systems for TB case management and pharmaceutical management

During the reporting period 21 oblasts were routinely entering data in e-TB Manager database and the total number of TB Cases entered in e-TB Manager at facility level has reached 51,300 cases.

In order to leverage resources to facilitate implementation of e-TB Manager SIAPS Ukraine has worked with two partners: the National Tuberculosis Center and USAID funded STBCU Project implemented by Chemonics. The main approach for e-TB Manager data quality ensuring and monitoring is technical lead and supervision of the process by SIAPS Ukraine (eTBM user's guides on data quality, manuals, datasheets, software automatic data quality control & etc.) and implementation of this approach in regions in close cooperation with partners working for NTP.

USAID funded Tuberculosis Control in Ukraine Project STBCU project implemented by Chemonics provides regular supportive supervision to TB programs in 10 oblasts of the Ukraine. SIAPS has trained on e-TB Manager the supervisors (12 persons) from STBCU project during 3-day workshop (November 28-30, 2012, Kiyv) to make them able to support the oblasts in data entry process in timely and quality manner. The workshop was collaboratively funded by SIAPS and STBCU Programs. The last day of the workshop was devoted to discussion of possible problems with the data quality.

Under the scope of infrastructure development to support further e-TB Manager Implementation in regions and the State Penitentiary System SPS has procured 178 PCs and 1 server. SIAPS has followed up on this with updating the equipment distribution lists and executing official equipment legal transfer procedures with the TB Center.

In order to enhance the functionality of e-TB Manager the following updates to the e-TB Manager software were implemented over the reporting period: (i) Added interoperability with UA data security system; (ii) Crypto channel established and tested; (iii) Search data capability was enhanced; (iv) New search capabilities from International version tested and implemented; (v) Added new UA - specific search fields; (vi) All case input screens revised and aligned with the last edition of MOH form #081-2o; (vii) Added auto fill service for some fields (Citizenship etc.); (viii) Adjusted TB08 and TB10 reports in accordance with new requirements; (ix) Added new check rules and improved existed check rules to the report generation tool.

During the reported quarter SIAPS has started to monitor not only number of TB cases entered to the e-TB Manager but also has started to work towards the direction of improving and ensuring quality of data entered to the e-TB Manager. One of the main challenges for successful implementation of e-TB Manager at this stage is ensuring high quality of data entered in e-TB manager. Until the quality of data is ensured it is not possible to be sure about the accuracy of reports produced by e-TB manager and they could not be officially used for decision making purposes, thus main purpose of implementation of e-TB Manager will be unmet.

Further e-TB Manager Implementation was slowed down due to delay with approval of the MoH Order on TB Register operations (an Order N818 dated October 19, 2012). This order developed by the National TB Center in collaboration with the Charitable Foundation for Development of Ukraine (FDU) and USAID SPS/SIAPS Programs was signed by the MOH in October and has received the Ministry of Justice approval only in November 2012 (the registration number at the Ministry of Justice of Ukraine N1864/22176 dated as of November 6, 2012).

Challenges in progress toward sub-objective 1.1

In October 2012, the Ministry of Health of Ukraine has started the procedure of liquidation of the National TB Center. Also in October 2012 the Ministry of Health of Ukraine established the Ukrainian Center for Diseases Control (UCDC) to take over the implementation of nationwide disease control policies and strategies including TB and HIV/AIDS (an Order #201-0 dated October 17, 2012). UCDC was created based on the existing capacity of the National AIDS Center by its merging with the National TB Center and with support from the State Service of Ukraine on HIV/AIDS and Other Socially Dangerous Diseases.

The capacity of UCDC to perform these functions will need to be properly assessed and strengthened as

necessary.

Deliverables: Sub-Objective 1.1

- The Ministry of Health Order on TB Patient Electronic Register operations.
- Improved TB Cases Management module in e-TB Manager.

Quarterly progress toward sub-objective 1.2: Develop and implement a PMIS to support effective pharmaceutical management and patient care for the HIV/AIDS Program

Over the reported period SIAPS was also focused on development of cooperation with partners on PMIS for the HIV/AIDS program. SIAPS has taken part in the presentation and technical committee meeting on ACCESS Project (financed by CDC and implemented by the Network of PLWH). SIAPS has conducted working meeting with UCDC to discuss their approach as for the PMIS system development. As the follow up to the meeting SIAPS has received the first draft SOW on PMIS system to review and comment.

Challenges in progress toward sub-objective 1.2

- Absence of common vision and low coordination as for the PMIS between the main counterparts on the National HIV/AIDS Program.

Due to the involvement of UCDC in GF Round 9, Phase 2 application process, less attention was given to the HIV/AIDS direction by UCDC.

Deliverables: Sub-Objective 1.2

- Meeting reports.

Quarterly progress toward sub-objective 1.3: Strengthen capacity for data analysis and use of information for evidence-based decision making

The main activities under this sub-objective were planned to be implemented in close cooperation with the National TB Center. However, due to the liquidation of National TB Center over the reported period the activities were postponed till the next quarter.

Challenges in progress toward sub-objective 1.3

- Liquidation of the National TB Center over the reported period.

Quarterly progress toward sub-objective 2.1: Strengthen forecasting, supply planning, and monitoring of TB and HIV/AIDS commodities

In October 2012, the Ministry of Health of Ukraine has started the procedure of liquidation of the National TB Center. Also in October 2012 the Ministry of Health of Ukraine established the Ukrainian Center for Diseases Control (UCDC) to take over the implementation of nationwide disease control policies and strategies including TB and HIV/AIDS (an Order #201-0 dated October 17, 2012). UCDC was created based on the existing capacity of the National AIDS Center by conjoining the capacities of the National TB Center and support from the State Service of Ukraine on HIV/AIDS and Other Socially Dangerous Diseases.

UCDC was nominated as the Principle Recipient of the Global Fund Round 9 TB grant, the Phase 2. Many

stakeholders expressed concerns that newly established UCDC do not have enough capacity to manage successfully GF grant including Procurement and Supply Chain Management (PSCM). It was discussed to nominate co-PR or sub-Recipient with PSCM and grant management experience. However, this proposal was declined by the National Coordinating Council.

During this quarter SIAPS Ukraine team supported UCDC and the Fund of Development of Ukraine (FDU), the PR for the Global Fund Round 9, the Phase 1 with preparation of the drafts of CCM Request for Renewal and the Procurement and Supply Management Plan for 2013-2015.

Challenges in progress toward sub-objective 2.1

The capacity of the UCDC to perform these functions will need to be assessed and strengthened as necessary.

Deliverables: Sub-Objective 2.1

- Input into the CCM Request for Renewal and into the Procurement and Supply Management Plan for 2013-2015.

Quarterly progress toward sub-objective 2.3: Improve storage, inventory management and distribution for TB and HIV/AIDS commodities

Over the reported period SIAPS Ukraine continued with Assessment of TB & HIV/AIDS pharmaceutical management practices, which was started under SPS. Assessment was initiated by the State Services of Ukraine on HIV/AIDS and Other Socially Dangerous Diseases (the State Service) in April 2012 with involvement of SPS (MSH) and USAID|HIV/AIDS Service Capacity Project (HSCP) (Futures group) to provide technical assistance.

The State Service requested that Assessment aimed at (i) assessing all structure of SCM on TB and HIV system separately; (ii) indicating gaps; (iii) analyzing regional experience and identifying the best practice models of SCM mechanism in TB and HIV systems; (iv) preparing recommendations for improvement of SCM mechanism in TB and HIV systems. The State Service expected that the following areas will be included into Assessment: (i) structure of supply chain (including supply mechanism, terms and controls of supplies, redistribution); (ii) awareness of regional specialists about cold chain and adherence to it (including storage and temperature conditions); (iii) electronic programs; (iv) human resource capacity; (v) TB medicines accounting and reporting TB medicines dispensing; (vi) quality control. It was planned (i) to develop TB and HIV/AIDS check-lists; (ii) complete these check-lists by regional specialists; (iii) provide check-lists data collection and analysis; (iv) conduct few site visits by experts; and (v) Prepare the final report.

SPS and USAID|HIV/AIDS Service Capacity Project in Ukraine in close cooperation with the State Service provided technical assistance for development of TB and HIV/AIDS check-lists, instructions to them, and the State Service letter to regions for this assessment. Pilot regions were chosen: Luhanska, Dnipropetrovska, Khersonska, Lvivska, Odeska, Kharkivska, Kyivska, Sumska, Khmelnytska, Cherkaska, Ivano-Frankivska, Kirovohradska oblasts, Autonomous Republic Crimea and Kyiv (city). The check-lists for self-filling, instructions to these check-lists, and the State Service official letters to oblasts were approved and sent to regions. It was expected that assessment (in the format of self-filling of forms by local specialists) will be carried out in 14 regions.

During the reported period SIAPS Ukraine translated the final version of check-lists and instructions to them into English.

SIAPS Ukraine provided support to regional specialists in filling in of check-lists and collected 28 completed

check-lists (14 TB and 14 HIV/AIDS) from all above- mentioned pilot regions.

During the reporting period the draft indicators list for pharmaceutical management monitoring and supervision was updated. SIAPS Ukraine team has started with preparation of data table (HIV/AIDS) for analysis of collected data. The USAID|HIV/AIDS Service Capacity Project in Ukraine was finished in November, 2012 as well as its collaboration with SIAPS was finished too.

At the request of the Foundation of Development Ukraine (FDU) SIAPs provided consultation on adherence to temperature regime during the distribution of 2nd line TB medicines under the Round 9, phase 1 (maintenance of cold chain process from the stage when medicines arrive at national customs till they are reaching the patients including the stage of outpatient treatment).

Challenges in progress toward sub-objective 2.3

Taking into account, that the USAID|HIV/AIDS Service Capacity Project in Ukraine was finished in November, 2012 SIAPS will continue Assessment of TB & HIV/AIDS pharmaceutical management practices using its own capacities.

It was expected that specialists from regions will submit completed check-lists according to the official letter till October 22, 2012. However, SIAPS team received all check-lists only at the end of December, 2012.

Quarterly progress toward sub-objective 3.1: Build pharmaceutical management capacity of the UAC and the National TB Center and other institutions, organizations and networks in Ukraine

In order to strengthen government organizations' human resource and organizational capacities in terms of pharmaceutical management SIAPS supported participation of one SEC representatives in 35th Annual Meeting of representatives of the National Centres participating in the WHO Drug Safety Program with SIAPS financial and organizational support. SIAPS Ukrainian and American teams have organized and supported the business trip of the Head of SEC post-registration surveillance board Mrs. O. Matveyeva to Brazil on November 11-14, 2012.

Challenges in progress toward sub-objective 3.1

Because of family circumstances Mrs. Matveyeva had to give up the trip at the last moment, but she was represented by other SEC official –Deputy Head of Post-registration Board- Mrs. Iryna Logvina who took an active part in the event.

Quarterly progress toward sub-objective 4.1: Improve the rational use of HIV/AIDS and TB pharmaceuticals

Under SIAPS's predecessor project, SPS, a Retrospective Pilot Study on the Use of National Standard Treatment Guidelines for Treating Tuberculosis in Kiyv Oblast was performed and completed. As the study was a pilot one and held within one oblast only, it was not planned to make its results public because of ethical considerations. Therefore, the Study report was prepared only in English for SPS use. However, as the objectives for rational use of ARVs and TB medicines were continued under SIAPS Ukraine project (which is the logic successor of SPS project) the need in the Study results translation into Ukrainian arose for spreading among all study participants and stakeholders who can be potentially involved into activities on improving rational medicines use. Thus, under the framework of developing measures for continuous improvements of medicines prescription procedures we have made the translation of A Retrospective Pilot Study on the Use of National Standard Treatment Guidelines for Treating Tuberculosis in Kiyv Oblast. We ordered the translation to the representative of IU in Ukraine that was our partner and implementer of the Study.

Challenges in progress toward sub-objective 4.1

Translation of the report was delayed, thereby preventing the team from sharing the Survey results with the meeting participants. Therefore, this task was postponed till beginning 2013.

Deliverables: Sub-Objective 4.1

- The report A Retrospective Pilot Study on the Use of National Standard Treatment Guidelines for Treating Tuberculosis in Kiyv Oblast, Ukraine is translated into Ukrainian and ready for dissemination among stakeholders.

Quarterly progress toward sub-objective 4.2: Strengthen pharmacovigilance systems and procedures to assure medicines safety and therapeutic effectiveness

After SIAPS startup Ukraine team proceeded with activities aimed at strengthening PV and medicines safety system begun under SPS. The stakeholders' meeting "Strengthening PV System in Ukraine: Strategic Planning" took place on December 12, 2012 and 29 participants attended from government and NGOs that are interested in PV system development in Ukraine. The purpose of the meeting was to discuss findings and recommendations and develop a long-term strategic plan for PV development in Ukraine, particularly for implementing active surveillance and risk management, identify stakeholders that would lead activities, the resources needed, and define timelines.

After some initial discussion, the participants decided that it was necessary to establish a working group of key stakeholders that would take responsibility for this task and for follow up on implementation. The participants of this meeting committed to working together under SEC leadership to strengthen pharmacovigilance in Ukraine and to develop a priority action plan for implementation. One of the issues raised by WHO was the need for a secretariat to support the working group; WHO indicated that existing commitments did not allow WHO to take on this role and it was agreed that support from another partner such as SIAPS would be needed to support the secretariat to enable the working group to function effectively.

SIAPS also shared international experience in PV audit implementation. Special attention at the meeting was paid to the issues of active PV and PV audit system development. These issues were considered in detail as these areas of activities have been identified as potential areas of support for the first year of SIAPS and are the priority for SEC as well as for TB and HIV/AIDS PHPs.

In general, stakeholders confirmed the urgent need in active PV system implementation in Ukraine and PV audit system for health facilities and manufacturers. They expressed appreciation to USAID for potential technical assistance from SIAPS for active PV development in Ukraine and agreed for cooperation.

During the preliminary meetings with SIAPS team SEC director noted that SEC specialists lack both experience and knowledge in PV audit development and SEC relies on SIAPS regarding PV audit development in Ukraine.

In the line of preparation for stakeholders' meeting, SIAPS Ukraine held a series of meetings with SEC management examining and analyzing the existing basis for active PV implementation in Ukraine.

In compliance with MOH Orders SEC initiated activities on active monitoring system implementation in 2010. This project implementer and SEC strategic partner was EDD (RGD) company, which jointly with SEC has designed "State Formulary" and "State Medicines Register of Ukraine" information systems which currently are actively used in Ukraine. In 2010 SEC concluded the contact with EDD on implementation of the first stage of

works on information technology design for medicines safety and efficacy monitoring in health facilities. SEC has independently financed this stage of works. In compliance with the contract, EDD defined information system needs and developed the concept of active monitoring medicines safety IS approved by SEC and MOH for continued information technology elaboration. However, because of lack of financing further work on this has been suspended.

As the state has certain experience and progress in developing automated information systems used in medical sector such as "State Formulary" and "State Medicines Register of Ukraine" as well as developing the concept for setting up "Medical-Information Network for Monitoring Medicines Safety and Efficiency," SIAPS planned cooperation with SEC on active PV implementation should take into account these achievements and build on them SEC is ready to start cooperation with SIAPS in the nearest future under conditions that the Memorandum of understating and cooperation between SIAPS and SEC is approved.

Challenges in progress toward sub-objective 4.2

- Additional time is needed to develop Memo of understanding and cooperation between SEC and SIAPS.

Deliverables: Sub-Objective 4.2

- Report on stakeholders' meeting "Strengthening PV System in Ukraine: Strategic Planning" (December 12, 2012)
- Draft of the Memo of understanding and cooperation between SEC and SIAPS.

Quarterly progress toward sub-objective 5.1: Improve pharmaceutical management policies, legislation, regulations, norms and standards

Despite the fact that such group was established in July 2012 by State Service and SIAPS Ukraine received an official invitation to participate in its work, actually not any meeting of the group was held.

Challenges in progress toward sub-objective 5.1

To participate in the working group dealing with legislative basis improvements it is necessary firstly to analyze the operational legislation in terms of gaps and deficiencies and develop recommendations to be discussed and approved during such working group meetings.

Vietnam
Year 1 Work Plan

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: Bring positive patient and health outcomes through improved availability and use of pharmaceuticals

Overall Quarter Progress

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)]. Written feedback obtained from stakeholders attending the curriculum development workshop held at the end of the previous quarter was incorporated into the PSM curriculum PowerPoint presentational slide sets for the Undergraduate and Postgraduate courses. The slide sets were delivered as planned prior to the end of the quarter.

Key activities planned for next quarter

Final client deliverables including the curricula and presentational slide sets for the Undergraduate and Postgraduate PSM courses have been fulfilled. During the final quarter of our Mission approved no cost extension in the amount of $12,000 we expect to receive and respond to a small number of requests for clarifications related to the slide sets.

Quarterly progress for objective 1: In-country human resource capacity for pharmaceutical services strengthened

Presentational materials (PowerPoint slides) for all 9 modules for Postgraduate and Undergraduate courses were drafted and delivered to HUP.

Quarterly progress toward sub-objective 1.1: Provide technical assistance to Hanoi University of Pharmacy to develop pre-service curriculum on pharmaceutical supply management

The PowerPoint slides (3,000 slides total) for the Undergraduate and Postgraduate PSM course were submitted to the client (HUP) for review, editing and translation to Vietnamese.