

## **SIAPS Quarterly Report**

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Project Year 2, Quarter 3

April 2013–June 2013



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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

ACT	artemisinin-based combination therapy
ADE	adverse drug event
ADR	adverse drug reaction
AIDS	acquired immunodeficiency syndrome
AMI	Amazon Malaria Initiative
AMR	antimicrobial resistance
APTS	Auditable Pharmaceutical Transactions and Services (Ethiopia)
ART	antiretroviral therapy
ARV	antiretroviral
CAMEBU	Central Essential Medication Purchasing Agency (Burundi)
CCM	community case management
CDC	US Centers for Disease Control and Prevention
CECOMA	Central Medical Stores (Angola)
CENAME	National Essential Drugs Procurement Center (Cameroon)
CHAI	Clinton Health Access Initiative
CHWs	community health workers
CMS	Central Medical Stores
CNLS	AIDS Control Program (Cameroon)
DGFP	Directorate General of Family Planning (Bangladesh)
DIGEMID	General Directorate of Drugs and Medical Supplies (Peru)
DNME	National Directorate of Medicines and Equipment (Angola)
DPML	Directorate of Pharmacy, Medicines, and Laboratory (Burundi)
DRC	Democratic Republic of the Congo
DTC	Drug and Therapeutics Committee
EDT	Electronic Dispensing Tool
EHRIG	Ethiopian Hospital Reform Implementation Guideline
EML	essential medicines list
EUV	end-user verification (survey)
FDA	US Food and Drug Administration
FDA	US Food and Drug Administration
FMHACA	Food, Medicines and Health Care Administration and Control Authority (Ethiopia)
FY	fiscal year
GDF	Global Drug Facility
Global Fund	Global Fund to fight AIDS, Tuberculosis and Malaria
GHeL	Global Health eLearning Center
HIV	human immunodeficiency virus

IEC	Information, education, and communication
IMCI	Integrated Management of Childhood Illness
IT	information technology
JSI	John Snow, Inc.
KM	knowledge management
LMIS	logistics management information system
M&E	monitoring and evaluation
MDG	Millennium Development Goal
MDR	multidrug resistant
MoH	Ministry of Health
MoHFW	Ministry of Health and Family Welfare
MoHSS	Ministry of Health and Social Services
MSH	Management Sciences for Health
NDoH	National Department of Health
NDSO	National Drug Service Organization (Lesotho)
NHTC	National Health Training Centre (Namibia)
NMCP	national malaria control program
NMRC	Namibia Medicines Regulatory Council
NTP	national TB program
PAHO	Pan American Health Organization
PCG	Central Pharmacy of Guinea
PD	Pharmacy Department
PEPFAR	US President's Emergency Plan for AIDS Relief
PFSA	Pharmaceutical Fund and Supply Agency (Ethiopia)
PMI	President's Malaria Initiative
PMIS	pharmaceutical management information system
PMTCT	prevention of mother-to-child transmission
PNILP	national malaria control program (Burundi)
PNLP	national malaria control program (Guinea)
PNLS	national AIDS control program (DRC)
PNME	Program for Essential Medicines (Angola)
PPMRm	Procurement Planning and Monitoring Report for Malaria
PSI	Population Services International
PTCs	Pharmaceutical and Therapeutics Committees
RHB	Regional Health Bureau
RDT	rapid diagnostic test
SAIDI	South American Infectious Disease Initiative
SCMS	Supply Chain Management System (project)

SIAPS	Systems for Improved Access to Pharmaceutical Services (program)
SOP	standard operating procedure
SPS	Strengthening Pharmaceutical Systems Program
SSM	Supportive Supervision and Mentoring
STGs	standard treatment guidelines
SUGEMI	national pharmaceutical management system (Dominican Republic)
TB	tuberculosis
TIPC	Therapeutics Information and Pharmacovigilance Center (Namibia)
TOT	training-of-trainer
UCDC	Ukrainian Center for Disease Control
UNAM	University of Namibia
UNICEF	United Nations Children’s Fund
UoW	University of Washington [Seattle, WA, USA]
USAID	US Agency for International Development
USG	US Government
WHO	World Health Organization
XDR-TB	extensively drug-resistant tuberculosis

## INTRODUCTION

The last decade's global health initiatives have helped reduce pharmaceutical prices and supply them to countries in need, but this does not automatically lead to *access* to medicines. To ensure good health worldwide, governments must create sound, efficient health systems that can provide effective disease prevention and treatment to all. SIAPS takes a holistic approach that looks beyond product availability and price to include other essential access components such as the availability of quality pharmaceutical services and the ability of the patient to access both products and services.

Providing effective technical assistance requires addressing a country's critical short-term access needs while building on existing systems and local capacity to increase the country ownership, and therefore sustainability of USAID efforts in the long term. SIAPS deploys strategies that incorporate both: while understanding and responding quickly to emergency situations, our focus is on local capacity building, which helps to create country-led, sustainable solutions.

The program's five result areas are as follows—

### **Intermediate Result 1: Pharmaceutical sector governance strengthened**

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

National medicine regulatory authorities in developing countries are often confronted with systematic challenges; for example, backlogs of drug registration applications wait for review, and regulatory activities are not conducted transparently or with accountability. SIAPS provides support to national medicine regulatory authorities to improve pharmaceutical sector governance and strengthen regulatory systems to ensure timely access to medicines and other health supplies.

Determining the appropriate technical assistance involves a review of the existing regulatory system, legislation, and policies, and an assessment of a country's regulatory capacity and operations. Those results then form the basis of a strategic framework and plan to strengthen the regulatory system. To bolster the policy and regulatory environment, SIAPS helps countries apply appropriate technological and capacity-building initiatives to create efficient and sustainable drug registration systems, monitor medicine quality, and fulfill other regulatory mandates. The result is better access to quality, safe, and effective health products.



**Intermediate Result 2: Capacity for pharmaceutical supply management and services increased and enhanced**

Sustainable access to medicines and other health technologies critically relies on the availability of skilled workers to provide and manage pharmaceutical services. SIAPS helps countries engage in comprehensive workforce planning to address challenges such as increasing demands, resource constraints, and health workforce policy reforms. This involves collecting and reporting data to help determine workforce needs, matching workforce and educational outcomes, and building a compelling case for funding posts in the public sector.

To increase pharmaceutical sector efficiency, SIAPS works with stakeholders to assess a country's or program's capacity to manage pharmaceuticals—from facility to national level. Then, using a stakeholder consensus approach, we identify areas for improvement and develop long term interventions to strengthen the system, such as building capacity among facility-level staff to track medicine consumption. Meanwhile, SIAPS provides short-term assistance when countries have immediate problems that threaten commodity security.

**Intermediate Result 3: Information for decision-making challenge in the pharmaceutical sector addressed**

SIAPS activities focus on aggregation, analysis, presentation, and dissemination of the information to support evidence-based decision making. Through our tools, software solutions, and pharmaceutical management information system activities, SIAPS helps ensure that quality pharmaceutical information is available to formulate pharmaceutical policy and plans and monitor supply chain systems and pharmaceutical services.

To address these areas, SIAPS strategies include assessing and evaluating local information needs; leveraging mobile phone and other technology in designing tools; harmonizing tools to help integrate pharmaceutical management information systems; and strengthening local organizations to customize, maintain, and take ownership of the tools and also to analyze, manage, and use the resulting data. As a result, SIAPS country partners use innovative and proven tools to generate accurate and timely information on pharmaceutical systems to improve access to products and services.

**Intermediate Result 4: Financing strategies and mechanisms strengthened to improve access to medicines**

Traditionally, pharmaceutical system financing has been perceived as relating to funding pharmaceutical purchasing, and initiatives such as the Global Fund to Fight AIDS, Tuberculosis and Malaria and US President's Emergency Plan for AIDS Relief (PEPFAR) focus heavily on such funding. However, even countries that have adequate funds to procure medicines cannot always manage the flow of funds and assure availability of health supplies. Financing, therefore, broadly covers resource mobilization and maximizing efficiencies, resource pooling, and payment and purchasing.

SIAPS helps countries conduct analyses to improve decisions regarding cost containment, greater efficiency, and options for mobilizing financing. Examples of this work may include evaluation of alternate supply chain systems; analysis of financial flow and sustainability;

identification of options to remove roadblocks; development and implementation of systems for tracking, monitoring, and controlling pharmaceutical spending; and analysis and evaluation of pricing policy options. Our health management expertise combined with SIAPS partners' knowledge and experience in innovative financing strategies allows countries to maximize their pharmaceutical resources.

**Intermediate Result 5: Pharmaceutical services improved to achieve desired health outcomes**

Pharmaceutical services comprise the activities that pharmaceutical staff carry out to support patient care and treatment. Beyond the supply of pharmaceutical products, pharmaceutical services include educating and training staff, providing medicine information and counseling, monitoring medicine use to assure patient safety and achieve desired health outcomes, formulating policies and regulations to improve pharmaceutical care, and disseminating information and educational materials to promote public health.

SIAPS improves pharmaceutical services by using strategies, approaches, tools, and activities to support rational medicine use and antimicrobial resistance (AMR) advocacy and containment. Our technical focus areas include medication adherence; standard treatment guidelines, essential medicines lists, formularies, and clinical algorithms; facility and community-based case management; medicine and therapeutics information; and infection control.

To achieve these results, SIAPS uses a flexible approach to designing a tailored intervention, implementing and managing that intervention, monitoring performance, and measuring outcomes. We fully engage local partners to ensure that they are contributing to and building skills at each stage of the intervention and that solutions are locally relevant. The key to many of our project achievements has been the broad-based support from all stakeholders built through a participatory approach to project design and implementation.

This report presents highlights of SIAPS' activities organized both by intermediate result area, representing multiple countries where we work, as well as by our global, regional, and country portfolios for the April through June 2013 period.

## **PROGRESS TOWARD RESULTS**

### **Intermediate Result 1. Pharmaceutical sector governance strengthened**

#### ***Pharmaceutical registration and licensing***

In the Democratic Republic of Congo (DRC), the Department of Pharmacy has now taken full ownership of the registration process from SIAPS. This quarter, SIAPS provided only limited financial assistance to the Drug Regulatory Authority (DRA) registration session, during which 273 dossiers were examined and 173 new medicines were registered. The cumulative number of registered medicines is 1,479, against the target of 1,200 for the entire fiscal year ending in September 2013 (123% of target). To increase transparency, the DRA publishes the list of medicines submitted before the registration and the list of medicines registered within 15 days after the registration. There is no longer any backlog of applications; therefore, the number of dossiers processed at future sessions will now depend solely on the number of new applications. In addition, the DRA accepted SIAPS' proposal of inviting new registration committee members from outside the Department of Pharmacy (e.g., universities, professional societies) to increase the transparency and credibility of the registration process.

The DRC has made remarkable progress from the initial stage where SIAPS wrote the standard operating procedures (SOPs) for the registration process and was a leading member of the DRA registration committee, to today, where SIAPS' staff presence is no longer needed during these meetings. SIAPS' technical assistance is now provided to the DRA on demand, and our financial assistance has been reduced to a token for the members during the registration sessions.

#### ***Strategic planning***

A major accomplishment in Swaziland during the quarter was the finalization and printing of the Swaziland Pharmaceutical Strategic Plan, which followed endorsement by Ministry of Health (MoH) senior management, signature by the Principal Secretary and Minister, and approval by the Cabinet. The strategic plan, which SIAPS helped develop, provides the overall roadmap for pharmaceutical services development in the health sector. The next step will be to disseminate the 600 copies of the document to every health facility. SIAPS is monitoring the strategy's implementation on a quarterly basis.

SIAPS Swaziland has also been promoting effective quantification and procurement systems for medicines and laboratory commodities. For example, we helped budget and produce a tender for HIV commodities as well as draft a quarterly supply plan for first- and second-line TB medicines and reproductive health commodities. We also facilitated meetings on the revision of TB and reproductive health commodity forecasts. In addition, SIAPS drafted the first quarterly supply plan for laboratory commodities using Pipeline, and providing MoH staff technical assistance on the use of the tool. As a result of SIAPS's planning support, the first quarter procurement budget for ART products and reproductive health commodities was reduced by 2,027,194.36 Swaziland Lilangeni (SZL) (6.44%) and SZL 18,420,978.68 (69.2%), respectively.

### ***Policies and procedures***

In Bangladesh, SIAPS helped the Directorate General of Family Planning to launch their new *Procurement Procedure Manual* and convinced the Ministry of Health and Family Welfare that developing a procurement manual for the ministry as a whole would benefit the health system. As a result, a workshop was held in April 2013 to begin developing the manual.

As part of the strategy to establish a central procurement authority, the SIAPS program in South Africa supports good governance in procurement by helping the National Department of Health manage its pharmaceutical tenders. In this quarter, SIAPS provided assistance for three tenders for antibiotics, TB medicines, and family planning commodities. The first two will be published within the 16-week target period. In addition, SIAPS implemented a draft supplier performance reporting tool and progress report for each tender.

Building on work that began last quarter in Mozambique, SIAPS submitted a concept note, committee terms of reference, as well as procedures and guidelines for updating and reviewing the national essential medicines list. The updated procedure guidelines were approved by the Pharmacy Department Director and the Minister of Health. The next step is to appoint the committee that will initiate the essential medicines list review and update procedures.

Additional activities under Intermediate Result 1 include the following—

- **Philippines.** SIAPS, as the technical lead in the laboratory working group, supported the National TB Reference Laboratory's development of the National TB laboratory strategic plan that aims to improve the laboratory services' effectiveness, quality, accessibility, and sustainability. The plan also forms part of the foundation for the new Global Fund support for the Philippines. The strategic plan was presented and approved by the Department of Health's TB technical working group and presented to stakeholders including laboratory and program managers at regional and local levels, patient groups, and other partners for comments.
- **Ethiopia.** New health facility standards that include pharmaceutical service standards for different levels, to which SIAPS contributed, were launched by H.E the Minister, Dr. Kesetebirhan Tadesse, Federal Ministry of Health, in a ceremony with stakeholders. SIAPS was awarded a certificate of merit and one staff member received a gold medal for contributing to this effort.
- **Amazon Malaria Initiative.** The pharmaceutical management guidelines for malaria in primary health facilities were finalized and validated in Colombia and Bolivia.
- **Ukraine.** SIAPS provided inputs to the State Service to revise the National TB Program (NTB) strategy (2012–16) including sections related to rational use of medicines, quantification, and pharmacovigilance.

- **Bangladesh.** SIAPS facilitated two workshops on procurement planning and how to effectively use the Supply Chain Management Portal in procurement. Consequently, with assistance from SIAPS Bangladesh, the Ministry of Health and Family Welfare developed 32 integrated procurement plans using the portal.
- **DRC.** SIAPS assisted one province to harmonize and standardize the cost of health services to patients in all health facilities.

## **Intermediate Result 2. Capacity for pharmaceutical supply management and services increased and enhanced**

### ***Leadership and management***

SIAPS continued to support health service quality in South Africa through its Pharmaceutical Leadership Development Program to improve compliance with National Core Standards. To date, 96 pharmacists and 11 facility managers have completed the program. As a result they implemented changes that improved services at their facilities. Examples include—

- One of the teams in KwaZulu-Natal achieved an average 13 percentage point increase in compliance with core standard measures in 8 clinics; the facility scores improved from a range of 65–79% in March 2013 to 80–93% in April 2013.
- The percentage of medicine packs pre-dispensed from Northdale Hospital for collection from Bangalore Road Clinic increased by 10.5% over 6 months.
- The percentage of uncollected pre-dispensed medicine packs decreased from 34% to 15% over 4 months at Umzinto primary health care clinic.
- A 53% decrease was observed in chronic repeat prescriptions containing inappropriately prescribed medication at Imbalenhle Community Health Centre.
- The value of expired stock was reduced from 3.4% to less than 0.5% of stock holding in 6 of 11 clinics in Sisonke District.
- At Kraaifontein Community Health Centre, the average patient waiting time fell from an average of 41 to 19 minutes over a 6-month period.

### ***Pre-service training***

In May and June, SIAPS assisted the University of Namibia's School of Pharmacy in linking the school with Ministry of Health and Social Service's Pharmaceutical Services Division to improve recruitment of pharmacy students for four-week placements at health facilities in rural communities as part of their practical training. The placement provides students with hands-on experience, while helping to increase coverage in rural areas that lack trained providers. The School of Pharmacy recently added data collection on pharmaceutical-related indicators to build

students' capacity to assess pharmaceutical service delivery at health facilities and gather insight into pharmaceutical management practices. SIAPS also provided technical assistance for defining the indicators, developing methodology spreadsheets, and facilitating the training.

In addition, SIAPS support to Namibia's National Health Training Center (NHTC) enabled 28 pharmacy assistants to graduate in May. SIAPS helped develop teaching materials, provided technical assistance to improve classroom learning, and supported the installation of information technology equipment. This equipment is enabling NHTC tutors to use a cost-effective computerized local area network to deliver virtual lectures and electronically manage student assignments, assessments, and course work. SIAPS continues to help NHTC strengthen its output and the quality of its pharmacy assistant training, which helps fill a severe gap in the country's pharmaceutical workforce. NHTC has enrolled 34 students for the 2014 pharmacy assistant course.

### ***In-service training and supervision***

During this quarter, SIAPS worked with its partner, the Accreditation Council for Pharmacy Education, to finalize an accreditation credentials framework for pre-service education, in-service training, and continuing education programs to support pharmaceutical systems strengthening. In South Sudan, SIAPS trained 26 personnel from various disciplines in Western Equatoria State in its effort to strengthen pharmaceutical system and to establish a model county pharmaceutical management information system in Tambura County.

Additional SIAPS-supported activities related to Intermediate Result 2 include the following—

- **South Africa.** The South African Pharmacy Council approved the curriculum outline for the authorized pharmacist prescriber.
- **Ethiopia.** In the reporting quarter, 302 professionals attended in-service training events, supportive supervision and mentoring were provided at 57 health facilities, 49 dispensers and 5 data clerks received on-the-job training on real-time dispensing including how to manage patient and pharmaceutical information using the Electronic Dispensing Tool.
- **Dominican Republic.** Thirty professionals completed the certified course on pharmaceutical management facilitated by SIAPS. SIAPS shared the results of the final evaluation with university professors and authorities. The course was organized by the Santo Domingo Autonomous University. USAID and public and private institutions paid for the tuition fees.

### **Intermediate Result 3. Information for decision-making challenges in the pharmaceutical sector addressed**

### **Data utilization**

SIAPS made considerable progress to increase the use of data for pharmaceutical and laboratory decision-making. In Lesotho, antiretroviral therapy (ART) and laboratory information system data are routinely analyzed and presented in a two-page stock status report and in technical reports that have inventory and information management performance indicators for the Supportive Supervision and Mentoring (SSM) program. The RxSolution system has been extended to other hospitals, now totaling 13 in all. Information from RxSolution will be part of a feedback mechanism to the facilities as indicated in the cross-sectional information flow chart for the national ART program. In Angola, the semi-annual end-user verification (EUV) survey findings were used to facilitate increase in quantities of rapid diagnostic tests to be procured; the distribution of condoms bought by the national AIDS control program will be integrated into the general distribution of other products and more condoms will be included health kits; and the national program for essential medicines will be encouraged to assure that stock cards and other key management tools are available and implemented in all health facilities, depots, and warehouses.

### **Data quality and reporting**

In Guinea, over the past quarter, SIAPS has made major progress in making pharmaceutical management information available for decision making at the national level. SIAPS Guinea and its in-country partners, particularly the National Malaria Control Program (PNLP) and the national health information system unit worked together to finalize preparations for launching a new monthly report template for malaria at the health district and facility level. This new reporting template, along with a new comprehensive product order and delivery form for antimalarials, have been the subject of two SIAPS workshops and multiple working sessions with a wide range of partners over the past six months.

The major benefit of the new malaria reporting template is that it now includes a detailed section on pharmaceutical management, including stock status and monthly consumption at the facility level. To encourage reporting on time, especially for pharmaceutical management, SIAPS proposed a series of concrete activities that were validated by all regional and district health directors in March. For example, district level reporting by e-mail to a generic PNLN address using a standardized Excel template started to show results even before the official launch. To maximize this success, SIAPS is distributing Internet connections to the 19 President's Malaria Initiative (PMI) districts. SIAPS and partners also established a quarterly reporting competition among districts, where the winner will receive institutional prizes that are related to reporting activities, such as laptops, printers, and additional Internet credit.

In late June, SIAPS, PNLN, and the health information unit organized a first training for all health centers, hospitals, and district-level data managers and pharmacists in Conakry to officially introduce the new reporting tools. Coordination with Global Fund implementing partners has ensured that the new reporting template will also be scaled-up to the other 19 districts of the country.

Within days after the Auditable Pharmaceutical Transactions and Services program was introduced at Woldia Hospital in Ethiopia on May 17, dispensers were able to detect a number of medication errors. The majority of the errors were problems of indication or duration of therapy. In addition, the accountant found no errors in the daily summaries, and there were no voided receipts or deleted data in any of the registers. Much effort has been made to encourage dispensers to use the program to make evidence-based decisions.

As of June 30, 2013, 24 of 27 oblasts were routinely entered data in the e-TB Manager database, and the total number of TB cases entered in e-TB Manager reached 67,000 cases. To improve monitoring and transparency of e-TB Manager implementation, the Ukrainian Center for Disease Control (UCDC) started publishing the number of TB and MDR-TB cases entered into the e-TB Manager by oblast on the UCDC's official website.

As the number of cases entered increased, UCDC, with SIAPS support, focused on improving the quality of data entered to e-TB Manager. The SIAPS team drafted a protocol for standardizing data quality monitoring procedures for e-TB Manager. SIAPS began piloting the quality assurance procedures and creating automatic reports in Odess'ka, Kyivs'ka, and Khersons'ka oblasts. The first goal is to show consistency between routine manual reports prepared by each oblast and respective reports generated by e-TB Manager for Q1 of 2013.

Other SIAPS information-related activities this quarter follow—

- **Bangladesh.** With support from SIAPS, the Directorate General of Family Planning master trainers successfully helped their peers optimize use of the upazila information management system. As a result, the tool is currently functional in all 488 sites, and approximately 80% of the sites are uploading logistics data directly to the central supply chain information portal/logistics management information system.
- SIAPS helped the **Philippines** National TB Program draft and finalize its country surveillance report (TB profile of the Philippines), that was published in the April–June 2013 issue of the WHO *Western Pacific Surveillance and Response Journal*.
- **Amazon Malaria Initiative,** DIGEMID (Peru's Directorate General for Drugs and Medical Supplies), and SIAPS transferred the coordination of the malaria regional stock monitoring system to the Pan American Health Organization Strategic Fund. Through its national consultants, SIAPS supported national counterparts to collect data in 10 countries (including some in Central America). The bulletin corresponding to the 1st quarter of 2013 was distributed by the Pan American Health Organization.

#### **Intermediate Result 4. Financing strategies and mechanisms strengthened to improve access to medicines**

##### ***Tracking pharmaceutical spending***

In DRC, SIAPS assisted the Katanga provincial medicines committee to conduct a gap analysis of medicines needs in the entire province. The result showed that the financial



contribution of all health partners in 2012 covered only 20% of the total pharmaceutical needs, and USAID's contribution was equivalent to 8% of the total. Subsequently, a series of National Medicine Committee meetings were held with SIAPS technical and financial support and the Minister of Health created a task force that included SIAPS as a member to quantify essential medicines for 65 health zones. As a result, the MoH allotted, for the first time in decades, more than 1.5 million US dollars (USD) of government funds to purchase essential medicines for six months in the 65 health zones that do not receive donor support.

### ***Maximizing resources***

SIAPS South Africa helped the Eastern Cape provincial pharmaceutical and therapeutics committee to conduct a medicine cost analysis. The results prompted the committee to adopt a resolution to use enalapril as the ACE inhibitor of choice in the province. Similarly, SIAPS technical assistance to the Gauteng provincial pharmaceutical and therapeutics committee related to cost analysis prompted the committee to adopt the following cost-saving resolutions—

- Enalapril will be the ACE inhibitor of choice in the province
- Amlodipine will be the calcium channel blocker of choice
- Surfactant 4ml and 8ml will be used in preference to 1.5ml and 3ml, respectively
- The cost-effective use of insulin prefilled syringes will be strengthened
- Safe and cost-effective use of intravenous phenytoin will be promoted.

SIAPS Ethiopia in collaboration with the regional health bureaus implemented Auditable Pharmaceutical Transactions and Services in seven of the eight hospitals planned. As a result of this intervention, which comprised a bin location system, VEN selection, minimized wastage, and pharmaceutical sales financial management, efficiency has improved and gross profit has increased. SIAPS provided mentoring and on-site training on ABC value analysis and ABC/VEN reconciliation activities in six hospitals and provided pharmaceutical management mentoring at an additional four hospitals.

As a result of the mentoring—

- One of the hospitals finalized ABC analysis and ABC/VEN reconciliation and is now conducting a stock status analysis.
- Dil-Chora Hospital completed a five-year aggregated ABC analysis and reported the results to hospital management. Ongoing analysis includes drug utilization, ABC/VEN matrix, and stock status analysis,
- Felegehiwot Hospital did an ABC and ABC/VEN reconciliation analysis for the last three years.

In the Dominican Republic, SIAPS supported the estimation of needs for a pooled procurement of medicines and supplies for all public institutions and an estimation of needs for the TB, HIV/AIDS, Maternal and Child Health, and Protected Diseases departments. SIAPS estimates that the government will save USD 32 million by implementing pooled procurement.

SIAPS provided technical and financial assistance to a pilot medicines costing exercise

conducted in five health zones in DRC's Kasai Occidental province, which led to the decision to scale-up the pilot to all 44 health zones. As part of the analysis, SIAPS gave advice on making adjustments for a number of health zones, based on elements such as the existence of partner-subsidized medicines. This standardization of the health care costs in Kasai Occidental is expected to increase the access to health services in health zones where the tariff was originally higher.

## **Intermediate Result 5. Pharmaceutical services improved to achieve desired health outcomes**

### ***Pharmacovigilance***

SIAPS staff in Swaziland have collaborated with the World Health Organization (WHO)/Afro office to strengthen systems and improve adverse drug reaction reporting for the TB, HIV and immunization programs. The MoH has relied on spontaneous adverse drug reaction (ADR) reporting; however, the development of a sustainable active surveillance system for TB/HIV will greatly complement spontaneous reporting. This system will generate safety signals for medicines used by HIV and TB patients. In Q3, SIAPS finalized the active surveillance protocol, SOPs, and related training materials to launch the system. Thirty-four health care workers were trained—4 medical doctors, 13 pharmacists, 6 data clerks, and 13 nurses. SIAPS is supporting the MoH to install software at all six pilot sites and is conducting onsite mentoring on how to document and report ADRs. SIAPS will feature ADR reports in a consolidated Q3 and Q4 medicine safety watch newsletter.

SIAPS Ethiopia organized face-to-face discussions in collaboration with facility drug and therapeutics committees on how to identify, prevent, and report ADRs at four health facilities. A total of 72 health providers from the facilities participated in the discussions. Since then, 54 reports were entered into the national pharmacovigilance database and into WHO's Vigiflow system.

### ***Treatment adherence***

In Namibia, SIAPS staff developed a concept note on implementing adherence interventions that the government's Adherence Technical Working Group discussed in May. The working group and its partners prepared a work plan for the adherence activities, and SIAPS staff worked with members of the working group to draft a plan for creating a reminder system using of SMS technology to improve ART adherence. Discussions are ongoing to strengthen linkages between facility staff and community-based organizations that can trace patients who are late for appointments or lost to-follow-up to enhance ART retention rates.

### ***Community case management***

SIAPS continued to support a pilot malaria community case management project, called PEDACOM, in two districts in Burundi; for example, participants of consensus meeting that also included provincial, district, and health facility representatives developed and validated a

supervision checklist for district teams to supervise PECADOM health centers, and participants also analyzed errors found in monthly reports. At the end of the meeting, each health center had completed community health worker supervision plan and offered recommendations to improve the data reporting system.

As a result of the SIAPS support to the project—

- 8,304 children under five years with fever were received by community health workers during April and May, and 7,211 of them were received within 24 hours
- 8,157 were tested for malaria using an RDT and 5,325 diagnosed as positive
- 5,147 malaria cases were treated with ACTs with 4,725 treated within 24 hours

### **Supply management**

To ease the pressure on the central medical stores in South Sudan and to ensure that malaria and family planning commodities are stored appropriately, SIAPS worked with UNICEF and the state MoH to initiate the procurement process to renovate the MoH medical store in Juba. In addition, SIAPS continued to work with the medical stores to respond to stock-outs of some commodities before the quarterly distribution. Typical examples of this assistance include SIAPS checking the current stock at the national level, identifying which partner was best suited to supply it, and facilitating the orders (e.g., Lanyia artemisinin-based combination therapy [ACT] stock-outs supplied through PSI). SIAPS also shares supportive supervision reports indicating gaps and challenges in the pharmaceutical management systems at the counties and facilities with the state MoH so that actions can be taken; for instance, Lanyia and Tereka had stockpiles of infusions and the MoH took steps to return them to the central medical stores for redistribution, and in Lanyia, stock-outs of ACTS were mitigated in a timely way.

SIAPS helped Mali's Department of Pharmacy to organize a national workshop in March with the key supply chain actors from all level of the health system (central, regional, district and community) and USAID implementing partners, such as PSI, ATN Plus, and PKCII. At the workshop, participants defined roles and responsibilities regarding Malian logistic information system for pharmaceuticals, and they agreed on tools, frequency, and mechanisms to report logistics data from the community level to the central level. The output of this workshop was the development of an SOP manual for Mali's pharmaceutical logistics information system, which SIAPS helped validate. The next step will a training workshop planned for September.

SIAPS worked with National Department of Health and other PEPFAR partners to create a Provincial Medicines Procurement Unit in South Africa's Limpopo province as a means of strengthening the pharmaceutical supply chain. SIAPS customized RxSolution this quarter to facilitate the management of direct deliveries—the first batches of direct deliveries for ARVs and oncology agents were made to 40 hospitals with support from the new unit. The software enables procurement unit to routinely monitor supplier performance related to quantities and values of orders processed. Since May, 939 orders have been captured for the 40 hospitals supported by the unit. SIAPS also helped in finalize the list of products that a facility may order based on the level of patient care it provides. Assistance was also provided in allocating order codes for products on tender that the procurement unit is managing.

In Swaziland, thanks to a coordinated effort among SIAPS and other partners such as PSI, AIDS Healthcare Foundation, and local community-based organizations, there has not been a stock-out of TB medicines, antiretrovirals (ARVs), or condoms in this reporting period, and the average stock holding period for the essential items has been between two to four months. The stock status of condoms has improved from 4 months of stock to 17 months at the end of the quarter. The next step is to ensure wide distribution; therefore, SIAPS and PSI are working with local Peace Corps volunteers to help distribute condoms to rural communities. SIAPS conducted inventory management and logistics management training for 246 health workers from laboratories and TB treatment facilities. SIAPS staff also visited 21 facilities in the Manzini region to assess pharmaceutical systems and services; gaps in the management of pharmaceuticals were identified; and possible interventions were implemented.

With the goal of improving pharmaceutical quantification to ensure the consistent availability of antimalarials in care centers, SIAPS helped the national malaria control program (PNLP) in Mali to organize a training workshop in May 2013 to strengthen the capacity of stakeholders involved in needs forecasting. This workshop was attended by managers (pharmacists and other staff) from the central and regional levels, as well as from nongovernmental organizations involved in antimalarial management. Including regional participants allowed them to better grasp the need to collect and transmit information, which has been a major challenge to previous quantification efforts. During the workshop, the participants developed a national quantification improvement plan. They also recognized the need to establish a national coordination committee to monitor data inputs into the national level quantification. Participants were also introduced to tools such as Quantimed to be used for quantification.

SIAPS worked hard this quarter to help mitigate stock-outs of first-line ARVs in Cameroon. The government was unable to meet funding commitments to procure the medicines to avoid stock-outs. SIAPS worked with the National AIDS Control Committee to reconsider patient projections, stock levels and pipelines, reassess the funding gap, and facilitate communication with donors and other stakeholders.

SIAPS partnered with the Clinton Health Access Initiative to help the National AIDS Control Committee to—

- Update the quantification (ART patient projection, ART regimen, and stock of HIV/AIDS commodities) to place a second order through the Global Fund. In agreement between the Global Fund, PEPFAR and the National AIDS Control Committee, first-line ARV orders were made under the HIV/AIDS emergency commodity fund mechanism immediately address the stock-out.
- Estimate HIV/AIDS commodity quantities and budget breakdown for a USD USD 10 million order to be placed through the Global Fund New Funding Model.

In DRC, SIAPS coordinated medicines management data collection and analysis from all partners by preparing stock status reports for malaria and family planning commodities. As a result, provincial medicines committees were able to redistribute medicines and other commodities within health zones that were at risk of expiry. At MoH's request, and in

agreement with the USAID Mission, SIAPS successfully dispatched PMI malaria commodities (overstock and near expiry) from two provinces to another newly adopted PMI province on behalf of another USAID project, PMI-EXPANSION.

In Ukraine, SIAPS collaborated with the Global Drug Facility (GDF) and WHO to organize and conduct Management of Tuberculosis Medicines Supplies—Planning, Quantification, and Monitoring in Kiev, Ukraine in June. There were 26 participants from 6 countries representing NTPs, ministries of health and Global Fund Principal Recipients. The training was focused on TB pharmaceutical management including forecasting and quantification of anti-TB drugs, planning of supply chain management, early warning indicators, and monitoring. The testing version of QuanTB, SIAPS's new TB drugs quantification tool, was introduced in the course.

### ***Antimicrobial resistance***

SIAPS provided technical and financial assistance to organize a training and orientation meeting with journalists on prevention and containment of antimicrobial resistance and rational medicines use. Twenty-six journalists working on the health programs of different federal and regional governmental and private radio programs, television programs, and print media participated. Almost all the journalists reported on rational medicines use AMR after the training, including live interviews with end users. Some of the journalists felt challenged by the topic because they are generalists (i.e., working on a wide variety of topics rather than just health).

Additional activities this quarter related to strengthening pharmaceutical services include the following—

- **Angola.** SIAPS finalized the national public supply chain analysis report (English and Portuguese) and shared it with Directorate for Medicines and Equipment and central medical stores for dissemination. . SIAPS also helped reorganize a Huambo provincial warehouse by re-arranging antimalarials and other essential medicines including health kits according to good storage and distribution practices. Top officials of the provincial health directorate were highly satisfied with the effort when they visited the warehouse.
- **Bangladesh.** As part of our regulatory and pharmacovigilance system assessment recommendations, SIAPS is helping the Directorate General of Drug Administration to develop national pharmacovigilance guidelines; a draft version has been finalized and is under review.
- **Mali.** This quarter, the maternal and child health (MCH) portfolio continued to support the Mali country team in finalizing the SOPs for the logistics management information system. The SOPs were approved by the Directorate of Pharmacy and Medicines and will be disseminated after sign off from the Ministry of Health Secretary General.
- **Namibia.** SIAPS helped the Namibia Medicines Regulatory Council to develop a data collection and reporting system for post marketing surveillance and to draft a memo to encourage problem reporting. The memo was sent to hospitals and private sector facilities along with a form for reporting medicine quality issues.

- **Swaziland.** SIAPS continues to support the Ministry on monitoring treatment adherence for TB patients. In Q3, reports for the months of April and May were analyzed, and the average adherence rates were 90% and 93%, respectively.
- **Guinea.** The April EUV survey found good availability of PMI products at the facility level: 100% of facilities visited had ACTs for small children and adults in stock; 95% had ACTs for adolescents; 85% had ACTs for infants; 83% had sulfadoxine-pyrimethamine; 91% had injectable quinine; and 87% had rapid diagnostic tests (RDTs), although the quantity of RDTs available in country was minimal at the time. The good availability of products was due to another one-off distribution that SIAPS conducted in March 2013.
- **Burundi.** During the quarter, SIAPS worked with the NMCP and AIDS Control Program to conduct a pipeline analysis of malaria commodities for the period of April through June 2013. This analysis showed necessary quantities of each commodity to procure to cover needs through the end of 2013. USAID/PMI and the Global Fund have started procuring the estimated quantities of ACTs and RDTs.
- SIAPS initiated work this quarter to develop a manual to guide locally appropriate operational strategies to promote medication adherence in resource-limited settings. SIAPS constructed a matrix of adherence-related support that SIAPS and its predecessors have provided over the years in **14 countries** and conducted a literature search on adherence support approaches, methods, experiences, lessons learned, and recommendations.
- To facilitate PMI procurement decisions, SIAPS aggregated the data from EUVs and reported on malaria commodity stock status from **Angola, Burundi, DRC, Ethiopia, Kenya, Mali, and Uganda**. SIAPS also provided PMI with a list of EUV commodities for **Angola, Burundi, DRC, Ethiopia, Guinea, Kenya, Liberia, and Mali**, as well as the data collection tools used.
- In May, SIAPS/MCH staff coordinated with Supply Chain for Community Case Management (CCM)/JSI, to co-present a webinar on supply chain in CCM. The webinar was organized by the Supply Chain Management working group of the CCM Taskforce. Under the working group, SIAPS also developed a description of key supply chain issues to consider when planning for CCM (*Tips on Supply Chain Management Issues for CCM*). This resource, available in French and English, was uploaded to the CCM central website.
- We developed a model for training and engaging private pharmacy networks to ensure the proper use of TB medicines and to promote their collaboration with national TB programs (NTPs). The model was field-tested in Pakistan. We also finalized and field-tested two innovative approaches—one for mitigating risk through active surveillance for multidrug-resistant (MDR)-TB and TB/HIV and one for improving medicines use and patient safety through drug use reviews for MDR-TB.

## COMMON AGENDA

### **Objective 1: Strengthen pharmaceutical sector governance**

**Develop e-Learning module in pharmaceutical governance:** At the request of USAID, SIAPS reconfigured this activity to focus on developing an eLearning module on good governance in pharmaceutical systems for USAID and other users with Internet access. The content will be based on the 2011 SPS white paper, *Pharmaceuticals and the Public Interest: the Importance of Good Governance*.

In June 2013, the SIAPS technical lead for this activity traveled to South Africa to work with SIAPS South Africa program staff to develop an outline for the eLearning module that reflects in-country concerns and opportunities. The SIAPS team met with staff from the Knowledge for Health project, and based on these discussions and a review of eLearning guidance documents, the SIAPS team drafted a course design, high-level objectives, and concepts to be addressed in each session. We received USAID feedback and their broad agreement on the content. The activity lead also worked with SIAPS South Africa staff to learn about local governance-strengthening activities to inform case studies.

SIAPS will work with USAID's Global Health eLearning Center and the Bureau of Democracy, Rights, and Governance to finalize the course materials and upload to the eLearning platform.

### **Objective 2: Capacity for pharmaceutical management and services increased and enhanced**

**Develop an accreditation credentials framework for pre-service education, in-service training, and continuing education programs to support pharmaceutical systems strengthening:** In Q3, SIAPS worked with Accreditation Council for Pharmacy Education to finalize the concept paper on the framework for in-service training and continuing education programs to support pharmaceutical systems strengthening. The Council will complete the Framework in Q4.

**Support regional networks and institutions:** SIAPS continued to support the Ecumenical Pharmaceutical Network by reviewing a concept note and scope drafted by the network on initiating pooled procurement among faith-based organizations in Cameroon and on strengthening the Mission for Essential Medical Supplies as a drug supply organization in Tanzania. This initiative is designed to strengthen the linkage between four faith-based drug supply organizations in Uganda, Kenya, Rwanda and Tanzania.

### ***Deliverables***

Ecumenical Pharmaceutical Network training report, *Expert training of Trainers on Antimicrobial Resistance and Antibiotic Use*

### **Partner contributions**

- Ecumenical Pharmaceutical Network conducted a workshop and training on AMR in Zimbabwe
- The Accreditation Council for Pharmacy Education completed the concept paper and scope of work related to accrediting pharmacy education

### **Objective 3: Information for decision-making challenges addressed in the pharmaceutical sector**

**Develop a framework and metrics for measuring pharmaceutical systems and evaluating systems strengthening interventions:** During this reporting period, SIAPS received USAID approval on the revised concept paper and approach for developing the framework and metrics. The technical team started the literature search to identify frameworks and approaches related to pharmaceutical systems and metrics that have been used to assess a pharmaceutical system or to track pharmaceutical strengthening initiatives. In the next quarter, SIAPS will synthesize the findings of the literature search and prepare a draft framework and an initial set of metrics for internal review.

Standard treatment guidelines (STGs) are often not followed systematically, particularly in resource-limited settings. To help address this challenge, SIAPS started an activity this quarter to support the development of a how-to manual on STGs. The basis of the guidance will include a matrix showing support provided by SIAPS and its predecessors for the development and implementation of STGs in 22 countries throughout Africa, Asia, Europe, and Central and South America. We also conducted a detailed literature review on evidence and recommendations relating to STG development, implementation, and monitoring.

**Identify facility-level practices or practice-related behaviors impacting central supply chain performance and develop indicators to measure them:** In Q3 the draft concept paper was developed and shared with Harvard University, which will result in a task order with USAID concurrence.

We conducted a systematic review of existing information management tools to identify those most promising to support pharmaceutical services and logistics/supply chain management "to/the last mile." Toward the end of the reporting period, we held a meeting with VillageReach to discuss the activity vision and to pin down some of the details for a scope of work. VillageReach agreed to share the first draft by early next quarter.

### **Deliverables**

- A matrix of support provided by SIAPS and its predecessors for the development and implementation of STGs in 22 countries throughout Africa, Asia, Europe, Central and South America
- Compilation of international evidence and recommendations on appropriate practices relating to STG development and implementation



#### **Objective 4: Strengthened financing strategies and approaches**

SIAPS initiated discussion with the University of Washington, the Health Commodities and Services Management Program (the SPS Associate Award in Kenya) and the University of Nairobi towards the development of a generic pharmacoeconomics training manual and country-specific training materials for Kenya. This activity therefore provides an opportunity for building the capacity of a local institution and supporting curriculum that includes pharmacoeconomics principles to guide essential medicines selection and analysis. The course will be offered as a training of trainers and facilitated by the University of Washington and SIAPS using the generic pharmacoeconomics manual and materials.

#### **Objective 5: Quality of pharmaceutical products and services improved**

SIAPS initiated work this quarter to develop a manual to guide locally appropriate operational strategies to promote medication adherence in resource-limited settings. SIAPS constructed a matrix of adherence-related support provided by SIAPS and predecessors in 14 countries and conducted a literature search on adherence support approaches, methods, experiences, lessons learned, and recommendations.

Additionally during this quarter, SIAPS updated flyers on AMR and infection control. These flyers will be used to advocate for combating the emergence and spread of AMR. During the quarter, SIAPS also collaborated with the Global Antibiotic Resistance Partnership Project of Center for Disease Dynamics, Economics & Policy in South Africa to assist the National Department of Health and other stakeholders in their plans to strengthen antimicrobial stewardship and infection control activities.

#### ***Deliverables***

- A detailed matrix of support provided SIAPS and its predecessors to 14 countries for activities related to treatment adherence.
- Flyers to advocate for continuing investments to combat the emergence and spread of AMR: Containing Antimicrobial Resistance: From Global Strategy to Community Implementation and Supporting Infection Control in Resource-limited Settings.

#### **Objective 6: Contribute to the generation of new knowledge and dissemination of evidenced-based approaches and best practices**

In Q3, SIAPS used common agenda funding to review the supply management section of the draft *WHO Consolidated Guidelines on the Use of Antiretroviral Drugs for the Treatment and Prevention of HIV Infection*. As a result of SIAPS's feedback, WHO asked SIAPS to rewrite the supply management section. On June 30, 2013, WHO launched the new guidelines including the revised text section.

As members of the Child Survival Working Group of the Interagency Task Team on the Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and Children, SIAPS attended the biannual meeting at UNICEF in New York City. SIAPS also participated in a meeting with the Clinton Health Access Initiative to discuss optimization of pediatric ARV formularies, including next steps for updating the optimal list and developing a toolkit for country programs and their partners.

In addition, funding from the common agenda was used this quarter to assist the working group members to develop a paper on treatment as part of a special edition of *AIDS* on the state of the art knowledge on HIV-exposed infants and HIV-positive children follow-up and treatment.

Presentations and meetings related to SIAPS' role and achievements in pharmaceutical systems strengthening included the following—

- The Technical Deputy Director presented at the French Technical Briefing Seminar on Pharmaceutical Policy held by WHO in Geneva in April.
- The SIAPS Director attended the WHO meeting held in Senegal on April 29–30 to formally launch the WHO Renewed Partnership program for strengthening pharmaceutical systems and improving access to quality medicines in 15 African countries.
- The Director and the HIV/AIDS Principal Technical Advisory attended the annual AIDS Medicines and Diagnostic Service partners meeting. SIAPS presented on its experience in the implementation and monitoring of WHO's early warning indicators of HIV drug resistance in Namibia.

SIAPS continued to support development of the WHO knowledge management portal by contracting for a systems upgrade allowing the addition of documents and display of search results. The upgrade met the SIAPS Global Meeting deadline. The system will be finalized after USAID review. However, we determined that WHO is unable to receive funds directly from MSH through the SIAPS sub-grant mechanism. This issue has taken several months to resolve given the need to coordinate USAID General Counsel and WHO legal departments. In response, SIAPS is now looking at opportunities to fund related activities such as participation in events as in-kind support.

### ***Deliverables***

WHO knowledge management portal document was uploaded and document search and retrieval functions incorporated.

## GLOBAL PROGRAMS

### Malaria Core

***Goal: Improve the supply, quality, and use of malaria commodities to reduce the burden of malaria***

#### ***Overall Progress***

SIAPS activities contributed to meeting all the three objectives during this reporting period. Under the first objective, we held monthly meetings with PMI/Washington to discuss implementation of activities in PMI-supported countries. Under the second objective, SIAPS facilitated PMI procurement decisions by reporting on stock status of malaria commodities from Angola, Burundi, DRC, Ethiopia, Kenya, Mali, and Uganda. Significant progress was made toward the third objective when the subcontract for assessing the cost of distributing malaria commodities was approved.

#### ***Objective 1: Improve coverage of malaria interventions***

To improve coverage of malaria interventions, SIAPS held monthly coordination meetings with PMI/Washington to discuss project implementation. In a separate meeting, we shared accomplishments and challenges in implementing malaria activities in DRC with the USAID/PMI country back stops.

At the SIAPS global meeting in June, the malaria team presented SIAPS' roles and responsibilities within PMI and facilitated a discussion to share challenges and missed opportunities in providing technical assistance among field staff from Angola, Burundi, DRC, Ethiopia, Kenya, Liberia, Latin America and the Caribbean, Mali, and South Sudan. The team also presented a poster, "Implementation of the End Use Verification (EUV): Experience from PMI-supported Countries."

Dissemination of the malaria quantification manual to countries continues. During May, the first quantification training workshop using the new manual was held in Bamako Mali. Eighteen external participants represented the National Malaria Control Program, the Direction de la Pharmacie et du Médicament, USAID/PMI, US Centers for Disease Control and Prevention/PMI, the central Pharmacie Populaire du Mali, the Direction Nationale de la Santé, and PSI. In addition, regional pharmacists from Kayes, Koulikoro, Sikasso, Segou, and Mopti regions participated.

#### ***Objective 2: Improve metrics and monitoring and evaluation of malaria interventions***

During this quarter, DRC, Guinea, and Liberia conducted EUV surveys. SIAPS reviewed the findings and provided feedback on appropriate and viable follow-up activities and interventions. To facilitate PMI procurement decisions, SIAPS aggregated the data and

reported on malaria commodity stock status from Angola, Burundi, DRC, Ethiopia, Kenya, Mali, and Uganda. SIAPS also provided PMI with a list of EUV commodities for Angola, Burundi, DRC, Ethiopia, Guinea, Kenya, Liberia, and Mali, as well as the data collection tools used.

***Objective 3: Strengthen financing strategies and mechanisms to improve access to medicines***

USAID approved the subcontract with William Davidson Institute to study the costs of distributing malaria commodities. Their team is now collecting data.

## **Maternal and Child Health Core**

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

### ***Overall progress***

This quarter the SIAPS Maternal and Child Health portfolio continued to contribute to global initiatives, such as the UN Commission on Life-Saving Commodities for Women and Children to raise awareness on the importance of pharmaceutical management for MCH commodities. Also, SIAPS attended the Women Deliver Conference in Kuala Lumpur and presented during a webinar organized by the Supply Chain Management Working Group of the CCM Taskforce on supply chain management. The MCH portfolio also field-tested the methodology for estimating potential unmet medical need for maternal health commodities in Bangladesh and is planning on field-testing the intervention guide for the management of child illness.

***Objective 1: Global awareness of the importance of pharmaceutical management for MCH medicines and supplies increased.***

The SIAPS MCH Core portfolio focuses on increasing awareness of the importance of pharmaceutical management for MCH medicines and supplies by providing global technical leadership on pharmaceutical systems issues related to maternal and child health. SIAPS/MCH portfolio actively participates in the following working groups: Maternal Health Supplies Working Group, the Systems Strengthening Working Group and the Maternal Health Caucus of the Reproductive Health Supplies Coalition, and the CCM Taskforce, specifically the supply chain management sub-group.

This quarter, SIAPS was active highlighting supply chain issues related to increasing access to MCH commodities. The portfolio has not only participated in many seminars and meetings, but also co-facilitated sessions and presented at global conferences.

### ***Maternal health***

In May 2013, we attended the Women Deliver Conference in Kuala Lumpur, Malaysia. During the meetings, MCH staff members facilitated a discussion on pharmaceutical management through participation in the scavenger hunt organized by the Maternal Health Supplies Working Group. We presented on women's health in Pakistan at the Regional Briefing on Health in South and Southeast Asia organized by MSH for Congressional staffers. Another staff member made a presentation on how to make a successful career in public health by moving from a clinical background.

SIAPS participated in a meeting of the Systems Strengthening Working Group of the Reproductive Health Supplies Coalition in June, 2013. During the meeting, opportunities for coordination between the Systems Strengthening Working Group and the Recommendation 6 working group of the UN Commission on Life-Saving Commodities (UNCoLSC) were

identified.

### Child health

In May, MCH staff coordinated with Supply Chain for Community Case Management/JSI, to co-present a webinar on supply chain in community case management. The webinar was organized by the Supply Chain Management working group of the CCM Taskforce. Under the working group, SIAPS developed a description of key supply chain issues to consider when planning for CCM (*Tips on Supply Chain Management Issues for CCM*). This resource for program managers was uploaded to the CCM central website. French and English versions of both the webinar presentation and the tips document are available.

MCH staff attended the launch of the Global Action Plan for Pneumonia and Diarrhea on April 12, 2013.

During the 2013 SIAPS Global Meeting the MCH team facilitated a session on maternal, newborn, and child health for SIAPS field staff, including an update on MCH issues and the UNCoLSC work. Countries where UNCoLSC activities are ongoing committed to a closer communication with the MCH portfolio to assure updates and transfer of information.

### **Deliverables**

- Supply Chain in Community Case Management presentation
- *Tips on Supply Chain Management Issues for CCM* (English and French)

### **Objective 2: Guidance and tools for improving pharmaceutical management for maternal and child health developed and disseminated**

This quarter SIAPS/MCH tested the methodology for estimating potential unmet medical need for maternal health commodities in Bangladesh. We facilitated a workshop in April to validate the approach and presented information on the UNCoLSC, highlighting the recommendation related to increasing supply of essential commodities. Following the presentation, SIAPS outlined the methodology for estimating unmet need for maternal health commodities. Participants then engaged in group work to review the assumptions used in the estimation based on the Bangladeshi context. Participants then developed action plans to address access barriers for three commodities. Dr. Syed Abu Jafar Md. Musa, Line Director for Maternal, Newborn, Child and Adolescent Health of the Directorate General of Health Services provided feedback.

Staff met with DGHS and Directorate General of Family Planning (DGFP) to discuss the upcoming assessment of local procurement of essential maternal health commodities and procedures for sub-national procurement of essential maternal health commodities. Both meetings suggested that information on the status of sub-national procurement by civil surgeons is limited. A meeting is planned for early next quarter to assess the timelines for this activity although testing of the tool is now expected in September 2013 in Dhaka district.

MCH completed the intervention guide for the use of medicines for the management of child illness and sent it to the editorial department last quarter. We planned to conduct a validation exercise of the guide in Uganda; however, the Mission did not grant approval citing the potential lack of follow-up because SIAPS does not have a country presence. We will explore alternative countries for the validation exercise.

During the SIAPS Global Meeting we discussed the roadmap activity for scaling up access to maternal health commodities. The purpose of this activity has shifted to align with UN Commission priorities, and the focus of the document will now be to guide countries in the introduction of new MCH technologies—particularly UN Commission commodities. A draft should be available next quarter. In relation to this activity, an MCH staff member traveled to South Sudan to assess the introduction of misoprostol for prevention of post-partum hemorrhage. She met with stakeholders to discuss scale-up plans and worked with the SIAPS/South Sudan team to outline pharmaceutical management considerations for scale-up.

### ***Constraints to progress***

- Political unrest in Bangladesh led to delays in developing the sub-national procurement assessment tool.
- Limited staff level of effort and competing priorities further delayed the roadmap activity, although this is now expected to move forward next quarter.

### ***Partner contributions***

Harvard University developed the final draft of the intervention guide with guidance and contributions from the SIAPS technical team. Harvard also participated in preparations for the validation process.

### ***Objective 3: Evidence base for effective strategies to increase access to pharmaceuticals and services increased***

The SIAPS/MCH portfolio works to increase the evidence base for increasing access to maternal and child health medicines and services by providing technical support to improve availability of medicines for CCM in Mali, Guinea, and Burundi and supporting the implementation of recommendation and commodity work plans developed under the UNCoLSC for Women and Children.

This quarter, the MCH portfolio continued to support the Mali country team in finalizing the SOPs for the logistics management information system. The SOPs were approved by the Direction de la Pharmacie et du Medicament (Directorate of Pharmacy and Medicines) and will be disseminated after sign off from the Ministry of Health Secretary General. Next quarter SIAPS/ MCH will help prepare for and conduct the training-of-trainers session on the SOPs.

In Guinea, SIAPS drafted the report of the quantification exercise conducted in late March shared it with the MoH for comment. Once comments were received, the report was finalized

and disseminated. In addition, MCH printed and distributed job aids and order form books and began to work with the MoH to set up monitoring systems to track consumption and availability of CCM commodities at community health worker and health center levels.

SIAPS worked with the MSH staff that developed the integrated CCM (iCCM) costing tool to make some final revisions because this will be used as part of the evaluation. The guidance document for the evaluation protocol was finalized by the technical committee; SIAPS provided important technical guidance and suggestions in implementing the research. The evaluation coordinator will finalize the protocol and training and data collection will follow in the next quarter.

Under the UNCoLSC, SIAPS is a member of the Maternal Health Technical Reference Team (MHTRT) for the three maternal health commodities, the Diarrhea and Pneumonia working group, the Chlorhexidine working group, the Neonatal Resuscitation working group, and the Recommendation 6 group. During biweekly calls of the MHTRT and Recommendation 6 working group, the MCH team provided updates on SIAPS work in preparation for the Dakar meeting of the pathfinder countries. SIAPS/MCH also attended a joint meeting of the MHTRT and Recommendation 6 working group in New York in May. Country plans were reviewed and feedback provided to the working groups. SIAPS/MCH also participated on the working group formulated to develop dissemination materials for maternal health commodities under the UN Commission.

UN Commission work under the tools subgroup of the MHTRT was delayed because the key point of contact at the Reproductive Health Supplies Coalition left the organization. A meeting was held with RHSC on the process of uploading the tools information sheets onto the Reproductive Health Supplies Coalition Supplies Information Database and coding the tools to be searchable. The tool fact sheets will be finalized and uploaded to the RHSC website in the beginning of next quarter.

SIAPS continued to participate in regular meetings of the Pneumonia and Diarrhea working group, and specifically in the Amoxicillin and Monitoring and Evaluation working groups. SIAPS helped finalize the amoxicillin survey by collecting further information in selected countries and compiling the results from countries where UNICEF obtained responses. SIAPS also reviewed several documents prepared by the working group, specifically, SIAPS helped finalize a document advocating for the use of amoxicillin dispersible tablets for diarrhea management in the community and translated this document into French. The SIAPS team started developing the content of the amoxicillin dispensing job aids, which SIAPS committed to working on.

For the Chlorhexidine working group, SIAPS translated several group documents into French, which are now posted on the working group website. In DRC, SIAPS/ MCH has supported SIAPS/ DRC and the MoH to review the country work plan for the UN Commission and to ensure that chlorhexidine 7.1% and misoprostol are included in the revision of the national essential medicine list for umbilical cord care and prevention and treatment of post-partum hemorrhages, respectively. The list revision has been very slow due to delays in provincial lists preparation and submission to the central level for provinces not supported by USAID.



Next quarter, SIAPS/ MCH will help the country team conduct a stakeholder workshop on the introduction of chlorhexidine 7.1% for umbilical cord care.

SIAPS/MCH also attended the regular conference calls of the Recommendation 6 working group. For the Outcome 1 work (best practices for supply chain management), SIAPS' partner Village Reach is taking the lead. During this quarter, Village Reach drafted a summary of challenges and barriers along supply chains which was circulated and discussed among the organizations working on Outcome 1. For Outcome 2, SIAPS is working with JSI to develop a quantification guide for the 13 commodities including the priority commodities in the Quantimed tool. Because funding issues had not been resolved for JSI, limited progress was made. SIAPS staff began reviewing available information on the commodities that SIAPS is responsible for (three maternal health commodities, chlorhexidine, antenatal corticosteroids, and injectable antibiotics). Work on the quantification guidance will begin soon because the funding situation is close to resolution for JSI.

### ***Deliverables***

- *Manual of Standard Operating Procedures for the Management of the Logistics Information System for Essential Medicines in Mali*
- MoH job aids and order form book for CHWs in Guinea

### ***Partner contributions***

VillageReach contributed to the Recommendation 6 working group meetings and discussions. They have also taken a leading role in the implementation of Outcome 1 of the Recommendation 6 work plan.

### ***Constraints to progress***

In DRC, there are delays in preparation of provincial lists and submission to the central level for provinces not supported by USAID and delays in country work planning process for the UN Commission.

## **TB Core**

***Goal: Assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve Global TB goals***

### ***Overall progress***

At the global level, SIAPS continued to help strengthen the global TB medicines supply by improving the governance and operations of GDF.

At the regional level, we developed a new training course on quantification and an early warning system for countries to prevent stock-outs and conducted regional courses in Africa and Europe. SIAPS also established a model for regional technical assistance and a capacity building mechanism for the public sector, starting with eight countries in Africa.

We developed a model for training and engaging private pharmacy networks to ensure the proper use of TB medicines and to promote their collaboration with NTPs. The model was field-tested in Pakistan. We also finalized and field-tested two innovative approaches—one for improving medicines use and patient safety through drug use reviews for MDR-TB, and one for mitigating risk through active surveillance for MDR-TB and TB/HIV.

SIAPS also made strides in promoting increased utilization of TB management information systems; for example, we enhanced e-TB Manager functions and developed and tested the final test version of QuanTB, a unique tool for forecasting and quantifying TB medicines.

### ***Objective 1: Pharmaceutical governance for TB strengthened at global level and country level***

The SIAPS goal is to continue to strengthen the global TB medicines supply and avoid stock-outs through improved governance and operations of the Global Drug Facility. We are achieving this goal through our placement of an interim manager at the GDF.

Important results and products include the following—

- The GDF interim manager developed a concept paper on a global strategic stock pile and flexible procurement fund and discussed the benefits of this model with the Global Fund and other donors; a dedicated expert consultant will be selected in July 2013 to help the GDF implement this model.
- The GDF developed a new organogram and terms of reference for all positions as part of a reorganization of its operations based on SIAPS's 2012 assessment of limitations of the current model.
- SIAPS and the GDF are working at the country and global level on promoting a zero tolerance policy for TB drugs stock-outs and overstock. The model is based on collaboration between the GDF Regional Support Officers and the SIAPS regional technical assistance portfolio (described below in Objective 5). The focus of this effort is

on improving quantification, inventory management, and establishing country and global level early warning systems for preventing stock-outs and waste of TB medicines.

- GDF client satisfaction surveys conducted on each order show an increase in highly satisfactory grades for GDF services. The GDF demonstrated high responsiveness and commitment in several urgent situations (e.g., in Bangladesh and Pakistan access to second-line drugs) and in Jordan for Syrian refugee camps (supply of first-line drugs).
- GDF has commissioned independent studies to gather evidence from countries focusing on the root causes of stock-outs and providing evidence on how financing models and planning practices result in shortages, especially during the transition period from GDF grant support to direct procurement.
- GDF initiated discussions with Janssen, Otsuka, the WHO Global TB Program, the Gates Foundation, and partners to offer its services for the introduction of new TB medicines, bedaquiline and delamanide.

SIAPS participated in the following meetings—

- WHO Expert Group Meeting on the Use of the Xpert MTB/RIF assay for the diagnosis of pulmonary and extra-pulmonary TB in adults and children on May 20–21 in France.
- 28th meeting of the GDF Technical Review Committee of Global Drug Facility on May 6–7, 2013 as a member. GDF proposals from 21 countries were reviewed and recommendations were provided to countries, the GDF, and partners.

### **Deliverables**

- The GDF concept paper on a global strategic stockpile and flexible procurement fund: *Core interventions to improve anti-TB medicines supply landscape. Concept Paper for discussion between Global Fund and GDF for introducing new joint interventions for improved TB commodities supply to countries*
- *Global Drug Facility: Eight months of implementing a new strategic framework for 2013–2016. Progress update November 2012–July 2013*
- Two GDF interim manager presentation to USAID: Update from Global Drug Facility: Improving Access for IQA TB Drugs + Diagnostics; New GDF Strategic Direction and Main Challenges and Perspectives

### **Objective 2: Capacity for TB pharmaceutical supply management and services increased and enhanced**

SIAPS developed a new training course built around the QuanTB tool and early warning system concept in conjunction with the GDF. This training is a part of regional capacity building and technical assistance package that SIAPS is now offering with core funding, starting in Africa region. This quarter, SIAPS conducted the training course in Africa and Europe regions, focusing on the NTP pharmacists/drug coordinators and the Global Fund Principal Recipient representatives in charge of quantification and supply planning.

SIAPS facilitated the following trainings—

- Management of Tuberculosis Medicines Supplies— Planning, Quantification, and Monitoring: conducted in Kiev, Ukraine from June 25–27, 2013 in collaboration with GDF and WHO. There were 26 participants from 6 countries representing NTPs, ministries of health and Global Fund Principal Recipients. The training was focused on TB pharmaceutical management including forecasting and quantification of anti-TB drugs, planning of supply chain management, early warning indicators, and monitoring. The testing version of QuanTB, SIAPS’s new TB drugs quantification tool, was introduced in the course and the next training for the WHO Europe region will be conducted in Almaty, Kazakhstan in September 2013.
- SIAPS led a course at the WHO Collaborating Center in Cepina, Italy from April 30–May 4, 2013. The course was attended by 27 participants (15 male; 12 female) from 16 countries and included country TB managers, international consultants, and donor representatives. SIAPS conducted sessions on pharmaceutical management for TB and MDR/extensively drug resistant (XDR)-TB with the vision to expand participant skill sets around planning, implementing, and evaluating TB control programs based on the WHO-recommended Stop TB strategy.
- The TB Health Element team is reviewing the Inventory Management eLearning module for the Global TB Online Platform to refine the topics and the narrative.
- MSH has also procured and finalized the upload of the new open-source software platform, Moodle, which will allow for the easy and effective delivery and tracking of this course and the entire TB platform participation across the globe.

### ***Deliverables***

Training materials, including presentation slides, handouts, practical exercises, training evaluation forms for Management of Tuberculosis Medicines Supplies— Planning, Quantification, and Monitoring

### ***Partner contributions***

SIAPS collaborated closely with GDF and WHO Euro to prepare Management of Tuberculosis Medicines Supplies—Planning, Quantification, and Monitoring; the organizational aspects of the training, agenda, and training materials were mutually agreed upon and financial expenses were shared among SIAPS, GDF, and WHO Euro. The GDF Technical Officer presented the GDF operations session.

### ***Objective 3: Improved utilization of information for TB control decision making***

Progress continues on the generic version of e-TB Manager to increase its usability and alignment with new international TB management standards and definitions. Specifically, SIAPS released a new version of the tool that has enhanced functions for case and suspect management/outcomes and corrections to previously detected bugs. SIAPS hired a Java information technology specialist consultant based in Brazil to support the tool.

Enhancements to e-TB Manager include the following—

- First version of Data Analysis Tool (e-TB Manager reports module) for testing and adaptation by countries currently using the system
- Test version of stand-alone (desktop) application for case management with the first version planned to be released by next quarter
- First version of QuanTB (downloadable version of e-TB Manager web forecasting tool) was tested in TB medicines quantification workshops in Italy, Swaziland, and Ukraine. The final version of the tool is planned to be released by next quarter with official presentation at the UNION TB Conference in Paris in October 2013.
- Support from SIAPS, TB CARE, and local funds continue to drive adaptation and implementation of the e-TB Manager in Armenia, Azerbaijan, Brazil, Cambodia, Indonesia, Turkmenistan, Ukraine, Uzbekistan, and Vietnam.

SIAPS' country-specific updates include the following—

- Namibia: Disseminated and agreed on the new rollout plan with the MSH local office and NTP; additional customizations defined with NTP and final users; final version of the system planned to be released next quarter. (SIAPS TB Core funded).
- Kenya: Implementation process suspended indefinitely because of the implementation of an alternative electronic system (SIAPS TB Core funded).
- Bangladesh: Received short-term technical assistance; final customizations defined with country team and NTP; drug management information system was customized and the test version should be released next quarter (SIAPS local office funded).
- Ukraine: drafted key information/indicators for data quality assurance and shared with local team; defined key information and draft methodology for TB pharmacovigilance and overall TB medicines management adapted to country needs (SIAPS local office funded).
- Nigeria: Received short-term technical assistance; additional customizations defined with NTP including interoperability issues between e-TB Manager and GxAlert (TB CARE funded).
- Uzbekistan: The technical documentation requested by the Ministry of Health was shared with the country via WHO regional office. Upon approval, SIAPS will finalize technical adjustments surrounding the laboratory module and begin piloting.

Regarding the development of an e-TB Manager implementation strategy, multiple meetings were held between activity leads to begin defining the scope of work aimed at assessing TB program needs to strengthen information systems for decision making.

### ***Deliverables***

- New version of the generic e-TB Manager
- New rollout plan for Namibia
- e-TB Manager content updated on MSH website

### **Constraints to progress**

- Reshuffling information technology staff at headquarters to face high demands for developing and adapting the system and its tools/applications.
- Lack of MSH country presence (i.e., high turnover or deficiency of information system and TB specialists) in charge of conducting and monitoring implementation activities. This has led to communication gaps with NTP and partners and delayed planned activities (e.g., Kenya, Nigeria, and Cambodia).
- Language has been a barrier in some non-English speaking countries.
- Delayed progress on the development of an e-TB Manager implementation strategy has hindered progress around monitoring local activities and results.

### **Objective 5: Improved pharmaceutical services and access to TB products to achieve TB goals<sup>1</sup>**

Key achievements in addressing Objective 5 included: establishing a model regional technical assistance and capacity building mechanism for the public sector (starting with eight countries in Africa) and a model for training and engaging private pharmacy networks to ensure the proper use of TB medicines and collaboration with NTPs (field test in Pakistan); finalizing and field testing/implementing two innovative approaches—one for improving medicines use and patient safety through drug use reviews for MDR-TB, and one for mitigating risk through active surveillance for MDR-TB and TB/HIV.

SIAPS participated in the following—

- Mid-term evaluation of national strategic plan for TB control in Nigeria in April 2013 focusing on TB pharmaceutical and supply chain management. SIAPS staff took the lead in data compilation and summary report writing for procurement and supply management.
- Five-day Regional Support Officers training organized by GDF in Geneva from 29 April –3 May 2013. After agreeing to implement an early warning system to prevent stock-outs of TB medicines, SIAPS and GDF decided to use the new QuanTB tool. Plans are underway to implement this tool in the six TB focus countries. The GDF asked that SIAPS staff serve as focal persons in regions where the GDF does not have Regional Support Officers, including WHO/AFRO (ANGLO and LUSO), WHO/WPRO, and WHO/AMRO.
- 4th Conference of the Union Asia-Pacific Region in April 2013. During the conference, SIAPS staff also met with partners from WHO Global Drug Facility, Stop TB TEAM, TB CARE 1, and the Green Light Committee to discuss upcoming monitoring missions and provide updates on SIAPS tools.
- Three GDF monitoring missions to Kenya, Fiji, and Kiribati to assess the use of GDF drugs and quantify needs for future orders.
- SIAPS conducted a five-day training on applied TB health supply chain management targeting NTP drug coordinators and TB program managers from select African countries

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<sup>1</sup> Objective 4 was removed from the SIAPS TB Core work plan at the direction of the USAID TB team.

in Swaziland in May. The workshop goal was to improve participants' skills to manage first- and second-line TB medicines; 17 participants from 8 countries documented work plan progress from the Zanzibar conference and made plans for technical support visits to those countries that requested it.

- Assessment of the feasibility of collecting early warning system data to prevent stock-outs of TB medicines continued in Nigeria and Kenya.

### ***Deliverables***

- Finalized Swaziland protocol for active surveillance
- Customized data capture and data analysis tool for Swaziland
- Final guideline and tools for TB risk management activity
- Revised country-specific action plans to strengthen pharmaceutical management system for TB
- Safety and monitoring of use of MDR-TB medicines: Drug Utilization Review
- Training materials for drug utilization review implementation
- Facility readiness assessment tool for treatment of MDR-TB through public-private partnership-workplace policy for TB and DR-TB care and control, Kenya
- Policy guidelines for public-private mix for TB care and control in Kenya
- A policy to engage all care providers in all aspects of TB care and control in Kenya Tanzania

### ***Constraints to progress***

- Active surveillance activity: challenge with receiving reports from some of the sites that were trained.
- Implementation of a drug utilization review program in Namibia has been put on hold until at least late 2014 because the NTP is focusing on the implementation of new guidelines and tools. SIAPS will follow-up with them again in mid-2014.
- The Kenya training-of-trainers workshop was originally planned for NTP provincial coordinators who would then train NTP district coordinators to conduct drug utilization reviews during their regular supervisory and support visits to health facilities. Since that plan was put into place, the country's new constitution has restructured the health care administrative units, resulting in the phasing out of provincial and district administrative levels. The new structure will consist of a national level and a county level. To move forward, it was decided that SIAPS would train clinicians, pharmacists, and nurses from each region to conduct drug utilization reviews at the county level until a new system for supervisory and support visits is in place.
- In the public-private partnership activity in Tanzania, changes in drug outlet names without notifying the Pharmacy Council caused a delays in locating the outlets; therefore, not all referrals reached the health facilities and very few counter-referrals are returned to drug outlets. In addition, trained dispensers who moved to other places did not transfer their acquired knowledge on TB case detection.

## US FDA Core

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

### ***Overall progress***

In the quarter under review, SIAPS received comments from reviewers of the Pharmacovigilance Assessment Report for Asia. SIAPS staff analyzed the comments and is revising and finalizing the report—expected in early September. The close-out report on the activity is currently being drafted.

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

We drafted two tools for pharmacovigilance that are under review: (1) the Template Protocol for Implementing Active Safety Surveillance, which guides the development of protocols for active surveillance activities, and (2) the pharmacovigilance module of e-TB Manager, which provides a standard adverse events reporting feature.



## COUNTRY PROGRAMS

### Angola

***Goal: Improved availability of quality products and effective pharmaceutical service delivery for better health outcomes***

***Objective 1: Pharmaceutical sector governance strengthened***

A meeting was organized with the DNME Director to discuss reactivating meetings of the Interagency Coordinating Committee (ICC)/R sub-commission, which have been suspended since January 2013. As a result of SIAPS' preparatory efforts, it appears that sub-commission meetings will resume in July 2013.

The process of selecting a consultant to provide technical assistance to CECOMA on its processes and procedures was concluded. The contract is being prepared for signatory approval.

***Deliverables***

- Scope of work for a consultant to be sub-contracted under SIAPS partners to provide technical support to CECOMA

***Constraints to progress***

Other competing high-level meetings, such as the International Congress for Pharmaceutical Associations from Portuguese-speaking countries organized by the DNME and the Second Scientific Workshop on HIV/AIDS organized by the National Institute for the Fight against AIDS, plus missions by high-level officials outside the country negatively impacted the organization of the monthly ICC/R logistics sub-commission meetings. SIAPS is working with the DNME to organize an ICC/R logistics sub-commission meeting in July to reactivate these important coordination meetings.

Due to internal administrative sub-contracting procedures, delays were encountered in finalizing the sub-contract for a consultant to provide direct technical support to CECOMA for its processes and procedures.

***Objective 2: Local capacity for pharmaceutical supply management enhanced***

Preparations for a training-of-trainers in pharmaceutical management for all Huambo municipal warehouse managers, malaria supervisors, and reproductive health coordinators were completed. SIAPS worked with national facilitators from the Program for Essential Medicines (PNME), the national malaria control program, and the national reproductive health program to review the training materials, and with the Huambo Provincial Directorate for Health to arrange for local facilitation and logistics. Other key US Government implementing

partners, such as Strengthening Angolan Systems for Health (Forca de Saude), Pathfinder International, and the Mentor initiative, were involved in the process and will be represented at the training, which is scheduled for July. Following the TOT, the trained municipal facilitation team will be supported to organize training for their respective health facilities. Ministry of Health's supportive supervision will be regularly conducted to improve and measure selected supply chain performance indicators.

### ***Partner contributions***

PNME and the national malaria and reproductive health programs made facilitators available to organize the training-of-trainers.

### ***Constraints to progress***

The PNME national training coordinator was not available due to illness. Finalization of the integrated supervision tool has been delayed.

### ***Objective 3: Information for decision-making challenge in the pharmaceutical sector addressed***

SIAPS provided assistance to the national malaria control program and, in collaboration with the national directorate of medicines and equipment and the national program for essential medicines, conducted an end-user verification survey in thirty health facilities, ten municipalities, and five provincial warehouses in Luanda, Huambo, Bie, Kuando Kubango, and Moxico provinces. Although the assessment was mainly done for the purposes of malaria case management and checking the availability of malaria products, the availability of other selected essential medicines, including HIV and reproductive health/family planning commodities, were examined. Findings will be used to formulate recommendations. One of the key findings was the general unavailability of rapid tests kits for malaria diagnosis in four of the five provinces visited. The consequence is the over-prescription of ACT, even to suspected cases of malaria, frequent stock outs, and the use of monotherapies.

The assessment also found limited availability of condoms in facilities and lack of key management tools, like stock cards and requisition forms across all facilities. Even when available, such management tools were not correctly filled in. The respective malaria, HIV, and reproductive health programs were informed about the survey results. There is a plan to increase the quantity of RDTs since PMI is the only donor procuring them. There is also a need to integrate the distribution of condoms bought by the National Institute for the Fight against AIDS into the general distribution of other products and to increase the quantity of condoms in health kits. It has been recommended to the essential medicines program that stock cards and other key management tools be available and used by all health facilities and municipal and provincial warehouses.

A quarterly Procurement Planning and Monitoring Report for Malaria (PPMRm) products report was prepared covering the months of January, February, and March. One of the recommendations was to review distribution plans and align them to the current needs of

provinces. Some provinces continue to receive more stock than needed while others constantly have insufficient supplies. The issue of stock outs of RDTs was also documented.

### ***Deliverables***

- PPMRm report
- EUV report

### ***Partner contributions***

- The National Malaria Control Program (Programa Nacional de Controle da Malaria= [PNCM]), Provincial Directorate for Health (Direcção Provincial de Saude) = DPS participated in the EUV.
- PNCM: Contributed to the completion of the PPMRm.

### ***Constraints to progress***

The unavailability of key pharmaceutical management tools at the facility level. When working with the PNME and in the provinces, SIAPS will advocate for making the availability and use of these important tools mandatory as they contribute to better management of health commodities. A challenge to completing the PPMRm is incomplete data on consumption and stock levels.

### ***Objective 4: Pharmaceutical services improved to achieve desired health outcomes***

SIAPS worked with the Huambo provincial warehouse to reorganize one provincial warehouse and rearrange malaria and other essential medicine products, including health kits, according to good storage and distribution practices for improved management. This support was well received by high-level officials from the Provincial Health Directorate who visited the warehouse. Through CECOMA, SIAPS requested that significant quantities of key LMIS tools (produced by SIAPS' predecessor program, SPS), such as stock cards, prescription pads, weekly consumption registers, and patients registers, be distributed to all municipalities and health facilities. Similar support was provided to a warehouse in Luanda. Apart from the reorganization of the warehouses, standard operational procedures and tools will be reviewed and disseminated.

As regards the quantification of all malaria health commodities initiated last quarter; additional information was collected to finalize the report. Once the report has been translated into Portuguese, SIAPS will support the NMCP to organize a validation meeting before the report is officially approved.

Meanwhile, data collected for the quantification of HIV medicines was not sufficient to complete the exercise. Rather, the collected data will be used to improve the logistics management information system for the next quantification. The national program is currently procuring commodities already budgeted, before this quantification exercise was started. A budget revision is planned so that the results of the new quantification may be used.

As regards reproductive health/family planning commodities, SIAPS is exploring the introduction of SMS reporting for selected commodities in pilot health facilities. A draft concept note from the Mission was shared with SIAPS for technical and programmatic input. SIAPS is using lessons learned elsewhere to design a more cost-effective and reliable intervention. It is anticipated that different stakeholders will be involved, such as the national reproductive health program, the national directorate for medicines and equipment, private telecommunication network companies, and concerned provincial officials.

### ***Deliverables***

- Draft quantification report for malaria health commodities
- Activity report (Huambo and Luanda warehouse management support)

### ***Partner contributions***

- DPS Huambo and Luanda: Facilitation and collaboration in the reorganization of the provincial warehouses.
- CECOMA: Revision of the terms of reference for the consultant.
- Imperial Health Service: A sub-contracted institution providing technical assistance to CECOMA. Challenge: delays in finalizing the contractor's contract due to internal administrative procedures.

### ***Constraints to progress***

Insufficient and/or unreliable data for the quantification of malaria and HIV medicines, leading to the use of many assumptions. There is need to regularly review and validate different assumptions to align the estimations with reality. SIAPS is advocating for the nomination of a national working group for quantification that will be trained and supported to conduct these reviews regularly.

Very old and/or small warehouses at the provincial level that are too small and unsanitary to be suitable for products. CECOMA is building new warehouses in different provinces. SIAPS will assist in standardizing processes and procedures in the new warehouses.

## **Bangladesh**

***Goal: Improved availability of quality pharmaceuticals and effective pharmaceutical services to achieve desired health outcomes***

***Objective 1: Supply chain management systems of the MoHFW and component procuring entities strengthened***

SIAPS facilitated a two-day exercise on procurement planning using the online system in June 2013. This was done in follow up to a day-long workshop for staff from the Procurement and Logistics Management Cell and 32 Line Directors and Desk Officers from the MoHFW to acquaint staff with the online system.

SIAPS assisted the Directorate General of Family Planning (DGFP) to launch its new Procurement Procedures Manual (PPM). Based on the success of PPM, the project encouraged the MoHFW to develop a manual for the entire Ministry; to this end, a workshop was held in April 2013 to launch the development process. SIAPS facilitated monthly Procurement and Supply Chain Management meetings for the DGFP and the Directorate General of Health Services (DGHS). Participants discussed the procurement and supply chain status of all DGFP and DGHS procurement packages and addressed obstacles.

SIAPS staff embedded in the Procurement and Logistics Management Cell (PLMC) continued providing expert opinions on the procurement of goods and services to ensure timely and appropriate procurement processes. During this quarter, 20 written opinions were provided on procurement files.

As part of the capacity building initiative, SIAPS developed a competency gap matrix, based on the most recent training needs assessment report, to identify the way forward to bridge the knowledge gap of procurement and logistics-related staff in the DGFP and DGHS. SIAPS organized a training on Procurement Post-Review and Audit Trail for the desk officers and procurement assistants in the DGFP Logistics and Supply Unit. Desk officers are now acquainted with the system; immediately after the training, the audit filing was initiated by the Logistics and Supply Unit. SIAPS also organized a five-day training in May 2013 for the Procurement Desk Officers of the MoHFW, through the Central Procurement Training Unit and the Engineering Staff College Bangladesh, and incorporated materials on Supply Chain Management Portal. To support National TB Program, SIAPS facilitated to develop final draft of SOP for managing TB drugs and supplies.

### ***Deliverables***

- Workshop report on development of procurement plans for FY 13-14 for 32 operational plans
- Workshop report on the launch of the MoHFW Procurement Procedures Manual
- Report on training for Desk Officers and Procurement Assistants on procurement post-review and audit trail
- Training report on five-days basic training on procurement

- Competency gap matrix on supply chain
- Draft assessment report on the review of the existing DGHS logistics reporting system and storage guidelines
- Draft final SOP for Managing TB Drugs and Supplies
- Meeting minutes of the Procurement, Supply, and Management Unit Monthly Procurement and Supply Chain Management meetings for the DGFP and the DGHS
- Forecasting and quantification reports for reproductive health, maternal and neonatal child health, and TB

### ***Partner contributions***

The DGFP met regularly with the L&S Unit to successfully complete procurement by the end of the government's fiscal year. Due to regular follow up by DGFP officials, timely reporting of monthly logistics reports significantly increased.

The Central Medical Store Depot high officials and concerned staff played an enthusiastic and supportive role collecting data and completing the assessment report— “Reviewing Existing Logistics Reporting Systems and/or Storage Guidelines/Manual on Logistics Management in DGHS.” The head of the depot even spent holidays conducting joint monitoring visits as part of his cooperation. The technical committee formed by the NTP made major contributions to the update of the SOP.

### ***Constraints to progress***

- Key DGFP officials were busy with procurement and other financial issues as it was the last quarter of the Government of Bangladesh fiscal year.
- Political unrest and strikes in Bangladesh.
- Less interest on the part of government officials in disposing of obsolete equipment and expired commodities activities.
- Overlap of different training programs and engagement of NTP personnel in regional programs delayed the partners' meeting.
- Unavailability of secondary information for the quantification of MNCH commodities.

### ***Objective 2: Transparent and evidence-based decision making increased***

SIAPS seeks to strengthen the information management system at all levels and make data on reproductive health, TB, and other health commodities available for decision making. This involves building the capacity of DGFP and NTP staff who use SIAPS-supported software tools, especially the Upazila Inventory Management System, Warehouse Inventory Management System, DGFP Supply Chain Information Portal, and e-TB Manager. Since a wealth of data are generated by these tools, it is important to examine the quality of information coming from service delivery points to ensure that decisions are based on accurate, verifiable, and reliable data.

SIAPS actively worked to adapt a routine data quality assessment tool for use with DGFP and NTP databases and prepared a data quality management plan. The tools are now under review.

The e-TB Manager is currently functioning in 106 sites in 35 districts under the NTP, including at four MDR-TB treatment facilities. Basic trainings in the e-TB Manager were given to field- and managerial-level MDR-TB staff. Also, e-TB Manager training was provided to an additional 59 facilities at the Upazila Health Complex level.

SIAPS continued to facilitate the preparation and dissemination of the DGFP stock status report, TB stock status report, PPM Report, and other reports that enable policy makers to make sound, evidence-based decisions.

With support from SIAPS, DGFP Master Trainers successfully provided assistance to their peers to optimize use of the Upazila Inventory Management System. The system is currently functional in all 488 sites, and approximately 80% of all sites are directly uploading logistics data into the central DGFP Supply Chain Information Portal/LMIS.

Several publications were developed during this quarter, including—

- Posters for SIAPS Global Meeting
- Abstract for International Family Planning Conference
- Country brief paper for University Health Coverage meeting
- Regular quarterly newsletter
- Presentation for the Women Deliver workshop

### ***Next steps***

- e-TB Manager drug management module/LMIS presentation and training
- e-TB Manager desktop version presentation and training
- Implement data quality assessment tools
- Introduce TB LMIS

### ***Deliverables***

- Monthly DGFP stock status report, and Procurement Planning and Monitoring Report, and Monthly TB Stock Status Report
- e-TB Manager training report
- Draft RDQA tool for the DGFP and NTP
- Data backup on UIMS installation
- Posters for SIAPS Global Meeting
- Abstract for International Family Planning Conference
- Country brief paper for UHC
- Newsletter

### ***Partner contributions***

In comparison to previous years, GOB officials are now taking more initiative in

completing all procurements. Experts from the NTP, BRAC, and the Damien Foundation co-facilitated the e-TB Manager trainings.

### ***Constraints to progress***

- Political unrest and strikes.
- The GOB's fiscal year ends in June. Many counterparts were completing end-of-year tasks and were not available.
- Internet interruptions during training when the venue was not the SIAPS Bangladesh office.

### ***Objective 3: Pharmaceutical regulatory capacity and medicine safety strengthened***

The Directorate General of Drug Administration (DGDA) is the only drug regulatory authority under the MoHFW. It has no effective system to regulate licensing, registration, and reporting processes. An adverse drug reaction and pharmacovigilance system is the other emerging issue for the DGDA. Pharmadex, the online regulatory management system, is in the final stage of introduction at the DGDA. Several committees have been formed to accelerate the development of the regulatory system and considerable effort has been made to make the committees functional. Upon the completion of the regulatory system assessment report, further technical discussions were held on the proposed Pharmadex system. An initial draft version of the Pharmadex was demonstrated to the DGDA officials, including the Director General himself. Various recommendations were made to adapt Pharmadex to the Bangladesh regulatory and licensing system. After the demonstration, an action plan was prepared, with a time frame of launching Pharmadex by the end of December.

Two Adverse Drug Reaction Monitoring Cell meetings were held to assist the cell to finalize their organogram and terms of reference. The terms of reference for the ADRMC and the structure of the Adverse Drug Reaction Advisory Committee were approved by the MoHFW. The ADR reporting form was finalized and sent to the advisory committee for approval. As part of the regulatory and pharmacovigilance system assessment recommendations, SIAPS is supporting the DGDA to develop national pharmacovigilance guidelines; the draft version has been finalized and is now under review. SIAPS is also assisting the DGDA to join the WHO Uppsala Monitoring Centre International Drug Monitoring Program as an associate member and is taking the first steps to become an official member.

At the request of the DGDA, SIAPS supported the upgrading of the DGDA website. Pricing information on drugs is being collected and will be available on the website for use in post-marketing surveillance.

Next steps—

- Strengthen existing DGDA committees and improve governance of regulatory activities.
- Support the DGDA to conduct post-marketing surveillance to ensure drug quality.



- Strengthen the Adverse Drug Reaction Monitoring Cell of the DGDA.
- Assist the DGDA to join the WHO Uppsala Monitoring Center International Drug Monitoring Program as an associate member.

***Deliverables***

- Adverse Drug Reaction form
- Adverse Drug Reaction Monitoring Cell meeting minutes
- Draft pharmacovigilance guidelines
- Adverse Drug Reaction Advisory Committee notification
- Organogram of the Adverse Drug Reaction Monitoring Cell

## **Burundi**

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

**Objective 1: Organizational structure, governance, and accountability of PNILP and DPML improved**

SIAPS works with two key MoH institutions: the National Malaria Control Program (PNILP) and the Directorate of Pharmacies, Medicines and Laboratories (DPML), to improve the PNILP's leadership and governance, as well as to support the DPML to develop efficient and transparent pharmaceutical management systems.

During the quarter, SIAPS continued to support the development of the PNILP strategic plan for 2013–2017. The PNILP is using findings from the Malaria Indicators Survey and other recent surveys to formulate a new plan for 2013–2017, which will be in line with the National Development Health Plan for 2011–2015. Interventions that have been identified aim to strengthen the health system over the long-term. The fourth draft of the strategic plan is available. It defines objectives, key strategic interventions, activities, indicators, means of verification, budgets, and potential funding sources. In June, SIAPS funded the participation of the PNILP Director in a session to finalize the Malaria Indicators Survey report. Once the report is finalized, it will be disseminated to a large group of stakeholders to guide future planning and implementation.

To assist the PNILP to improve its organizational and managerial structure, SIAPS provided an opportunity for a PNILP staff member to attend the regional training course on Monitoring and Evaluation of Malaria Programs organized by the USAID-funded Measure Evaluation Project in Ouagadougou, Burkina Faso, in June. Following the training, the PNILP staff member will organize a session to share knowledge gained with other staff at the PNILP to build capacity and strengthen the PNILP's M&E system.

### **Plans for the next quarter**

- Plan for local training courses for PNILP and DPML staff.
- Roll Back Malaria Initiative quarterly meeting to track progress towards achievement of the PNILP 2013 work plan objectives. Highlight achievements and adapt the plan for July to December period.
- Finalize and validate the PNILP strategic plan.
- Initiate the development of intermittent preventive treatment of pregnant women policy.
- Continue to strengthen the organizational structure of the PNILP and managerial skills of its staff.

### **Deliverables**

- Trip report to finalize the MIS report

- Training report for the M&E training course
- Fourth draft of the PNILP strategic plan for 2013–2017

***Objective 2: Pharmaceutical capacity of PNILP, CAMEBU, DPML, and health districts strengthened***

During the quarter, SIAPS continued to support the DPML to organize the thematic group on medicine meetings to improve coordination of all stakeholders involved in the pharmaceutical sector. Three monthly meetings were held, focusing on supportive supervision and quantification of health commodities. As far as formative supervision is concerned, the MTG recommended that a supervisor profile be clearly defined, supervision plans be jointly elaborated by stakeholders under the coordination of the DPML, refresher trainings on supervision techniques for supervisors be held, and the pharmaceutical management supervision tool be updated. For quantification, the MTG suggested that SOPs on quantification for all essential medicines be developed to guide central level staff.

To strengthen the supply chain management of essential medicines and, in collaboration with SCMS, SIAPS is supporting the DPML to develop an integrated LMIS from central to peripheral levels. The first step, a mapping exercise of stakeholders involved in supply chain functions and structures, is ongoing. As a second step, the review of pharmaceutical management tools that are currently used at the peripheral level is underway. To this end, the technical group appointed by the DPML for this task has collected and reviewed all pharmaceutical management tools, including tools developed by vertical programs. The LMIS system and revised tools will be validated with stakeholders through a consensus meeting in July. During this quarter, in collaboration with the PNILP and Secretariat Executif Permanent/Conseil National de Lutte contre le Sida (Permanent Executive Secretariat/National AIDS Council) -Malaria, SIAPS completed a pipeline analysis of malaria commodities using the PPMRm for the period April through June 2013. This quarterly pipeline analysis showed the quantities of each commodity to be procured to cover needs through the end of the 2013. USAID/PMI and the Global Fund have started procuring the estimated quantities of ACTs and RDTs.

Planned activities for the next quarter—

- Continue to support the DPML to organize the thematic group on medicine meetings to improve coordination of all stakeholders involved in the pharmaceutical sector.
- Assist the DPML in an evidence-based review of its strategic plan for 2013-2017 and its alignment with the NHDP. A desk review of all existing documentation related to the management of the pharmaceutical sector is ongoing.
- Through formative supervision visits, continue to support the districts to improve supervision of pharmaceutical management activities, with an emphasis on malaria commodities.
- Support the PNILP, DPML, and other stakeholders to organize a meeting with peripheral and central level institutions to discuss data, assess problems with management of malaria commodities, and adopt appropriate strategies to address the problems.

### ***Deliverables***

- PPRMm files
- Reports of the monthly thematic group on medicine meetings

### ***Objective 3: Pharmaceutical management information is available and used for decision making***

SIAPS organized working sessions with the PNILP, SEP/CNLS Global Fund recipient, and the Department of National Health Information System to prepare: revised malaria case definitions; a list of core indicators to be routinely monitored at health facility and community levels and the best approach for their integration into the current health information system. The meeting analyzed root causes of inconsistency in reported data, such as: (1) staff workload at the facility level and lack of time to report in a timely manner; (2) multiple management tools used at the health facility level that can result in confusion; and (3) errors in transcription of data on the reporting tools due to the lack of compilation forms. At the end of the meeting, a list of stakeholders to invite to the review meeting was identified and a review plan developed. This activity will start in July with dissemination of the new STG at the facility level, which clearly states the definition of a malaria case. The next step will be to update management and reporting tools for the new STG and train all data managers.

### ***Plans for the next quarter***

- Develop a list of core indicators for routine data collection for malaria, integrate the list into the existing health management information system, and adapt reporting tools accordingly.
- Advocate to the PFC management cell and the Direction de l'Offre et de la Demande des Services about reviewing criteria to evaluate the performance of facilities in malaria case management; the existing criteria are based on quantity and not quality.
- Organize a coordination meeting of stakeholders to analyze the root causes of the resurgence of malaria in Burundi, and adopt appropriate strategies to address the expected increase in malaria cases during the next peak epidemiological season in October.

### ***Deliverables***

- Report on the support to Giteranyi district
- Database on the supervision and baseline report

### ***Constraints to progress***

- Inappropriate use of tools for the management of essentials medicines at the health center level.
- Lack of sufficient and qualified professional staff working in district pharmacies. Only one person in the pharmacy is responsible for all supply chain management activities.

**Objective 4: Pharmaceutical services improved to ensure best practices in malaria case management**

SIAPS continued to support the implementation of a pilot malaria community-based case management project, called PEDACOM, in two districts (Gahombo, Gashoho). A supervision checklist for use by district teams to supervise health centers on PEDACOM was developed and validated during a consensus meeting organized in June with representatives from provincial and district health offices and health centers. During the meeting, participants jointly analyzed errors often found in the monthly reports. At the end of the meeting, a plan for supervising CHWs was developed by each health center, as well as recommendations to improve the data reporting system.

SIAPS continued to support the PNILP to prepare the final evaluation of the pilot malaria community case management (CCM) projects. The terms of reference for the evaluation were reviewed and validated by the technical committee appointed by the MoH. The recruitment of consultants to conduct the evaluation was started. The cost of the evaluation will be shared between SIAPS and Concern Worldwide Burundi, a nongovernmental organization that is implementing a similar intervention in Mabayi district of Cibitoke province. The results of the evaluation are expected to be available by the end of August and will guide future scale up of CMM nationwide.

As a result of SIAPS support to the CCM—

- 8,304 children under five years with fever accessed CHW services during April and May. Among them, 7,211 accessed services within 24 hours.
- Of the 8,157 children tested for malaria, 5,325 were diagnosed positive using a RDT.
- 5,147 malaria cases were treated with ACTs, with 4,725 treated within 24 hours.

During this quarter, SIAPS assisted the DPML and the national pharmacovigilance technical committee to finalize a short-term action plan for the reactivation of an operational pharmacovigilance system. The action plan describes the legal framework needed, including guidelines for the system with clear roles and responsibilities of key actors at different levels.

Activities planned for the next quarter—

- Supervise the dissemination of the new malaria STG and train health care providers at the facility level.
- Continue to support the implementation of the CCM in two districts.
- Conduct the final evaluation of the CCM in two districts and disseminate findings to support next steps.
- Assist the DPML and the national pharmacovigilance technical committee in developing pharmacovigilance guidelines.

***Deliverables***

- Meeting reports
- Supervision checklist for CHWs
- Plan of action for the reactivation of pharmacovigilance activities

***Constraints to progress***

Newly elected CHWs were elected by the MoH throughout the country. Ten CHWs in charge of the CCM for malaria were not re-elected. The newly elected CHWs will need to be trained and oriented on CCM.

## Cameroon

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

### **Objective 1. Pharmaceutical sector governance strengthened**

This quarter was challenged by a new episode of stock out of first-line ARVs. This was primarily due to the fact that the Government of Cameroon was not able to provide their contribution for the procurement of HIV and AIDS commodities to allow proper planning and avoid stock outs. This situation has led SIAPS to focus most of its time supporting the National AIDS Control Committee (NACC) to reconsider patient projections, stock levels and pipelines, and the funding gap and facilitating communication with donors and key stakeholders.

Good governance requires systems and procedures to provide oversight, effective coordination mechanisms, and hold entities and staff accountable for their performance. These mechanisms must have adequate capacity and funding to function effectively. To improve medicines policies, legislation, regulations, norms, and standards, SIAPS collaborated with MoH/DPM to support the development of standards, procedures, and guidelines to govern various components of the pharmaceutical system and improve access to quality medicines and services. SIAPS will support the finalization of SOPs for HIV and AIDS commodities management at health facilities.

Governance structures promote stakeholder involvement, coordination, and oversight to ensure availability and accessibility of medicines at all levels of the health system. This includes implementing systems for overseeing the procurement process, in particular activities linked to supply planning and forecasting, and for auditing warehouse operations to identify theft or mismanagement. These pharmaceutical management systems must also be transparent and accountable. SIAPS provided technical assistance to the NACC and DPM to establish coordinated mechanisms for quantification, forecasting, and supply planning to improve availability of HIV and AIDS medicines. SIAPS collaborated with other partners, mainly Esther Aid and Clinton HIV/AIDS Initiative (CHAI).

### **Deliverables**

SIAPS supported the Commission Nationale de Lutte Contre le SIDA (CNLS) in partnership with CHAI to—

- Update the quantification of HIV and AIDS commodities needed to place the second order through the Global Fund Round 10 Phase 1. In agreement among GF, PEPFAR, and the NACC, this emergency order of first-line ARVs was placed using the emergency commodity funds mechanism to allow the country to immediately face the stock out. Data reviewed were ART patient projections, ART regimen, and stock.
- Estimate the ARV funding gap for 2013 and 2014 necessary to spur national discussion held during the PEPFAR technical working group visit and GF team visit in June 2013.

- Estimate HIV and AIDS commodities and the budget breakdown to place the order through the GF New Funding Model (budget of USD 10 million).
- Support CNLS to conduct onsite data verification of patients and stocks in 10 regions of Cameroon; 53 ART health facilities were targeted, which represents 67% of the total population on ART in the country.

### ***Constraints to progress***

- No progress was made this quarter on sector policies, guidelines, strategies, and SOPs developed or updated and submitted for adoption because the team did not work on this during the quarter.
- Finalization of SOPs to be implemented with trainings in ART health facilities was postponed due to the national stock out of ARVs.

### ***Objective 2. Capacity for pharmaceutical supply management and services increased and enhanced***

There are frequent complaints from CAPRs about CENAME's inability to satisfy orders placed. Interventions under this objective will focus on improving the functioning of CAPRs so that high-quality commodities can be available at distribution points and so that coordination and information-sharing between CENAME and CAPRs is improved.

During quarter of FY12, SIAPS assessed the CENAME and CAPR warehouses in all of Cameroon's provinces to identify gaps and weaknesses that hampered optimal management. SIAPS facilitated workshops to disseminate the findings of the warehouse assessments and to share, discuss, and finalize the draft action plan. SIAPS also initiated the process of purchasing equipment for warehouses to improve storage practices.

SIAPS also continued to support the reorganization of products in warehouses in the USAID focus regions by using good storages practices; to support training and the capacity building plan in supply chain management for pharmaceutical managers; to provide technical assistance to the national disease control departments for neglected tropical diseases, HIV and AIDS, malaria, tuberculosis, and reproductive health and to the Regional Délégué to improve the management of medicines.

During this quarter, SIAPS—

- Continued to implement action plan recommendations designated as being the responsibility of SIAPS, thereby directly assisting warehouses in USAID-focused provinces to make improvements in inventory management and storage practices
- Conducted training of trainers (TOT) for regional Ministry of Health Staff (Regional Délégué); this TOT focused on on-the-job training and supportive supervision to community dispensers ("commis")
- Supported training and implementation of SOPs for drug management for health facilities

SIAPS also received partial equipment orders from vendors and started to distribute them in the



CAPRs in late June 2013. The distribution will continue in early July and official handover will be organized through the Ministry of Health with the local administration representatives in the regions.

SIAPS supported CNLS to initiate the development of the HIV and AIDS commodities pharmaceutical management training materials and training guides that will be used for the first TOT for the CNLS regional coordinators (GTR) and regional M&E staff; CENAME and CAPR warehouse staff; and pharmacy managers at ART health facilities.

### ***Constraints to progress***

Training on inventory management and reporting tools has been postponed because of the stock out faced by ART health facilities.

### ***Objective 3: Utilization of information for decision making***

Information for timely and informed decision-making is critical for successfully managing pharmaceutical systems. The quality of consumption and stock level data for both vertical programs and those responsible for preparing orders at the regional and central levels is as important as their availability.

During its first year of operation, SIAPS supported CNLS in meeting the Global Fund Round 10 grant requirements or conditions precedents to first disbursement by developing a plan to improve the management of pharmaceutical information on the basis of stakeholders' consensus of what Cameroon's health system should look like. The plan focuses on improving the monitoring system for ARVS, HIV, and AIDS commodities to better track stock levels at the central and peripheral levels, including physically verifying stock levels and reconciling stock levels with the number of targets and patients on treatment.

### ***Deliverables***

- SIAPS participated in the first coordination meeting with CHAI and CENAME to share data and analyze HIV and AIDS commodities stock at CENAME.
- In May 2013, SIAPS supported CNLS to conduct onsite data verification related to patients and stocks in 10 regions of Cameroon; 53 ART health facilities were targeted, which represents 67% of the total population on ART in the country.

### ***Objective 4: Financing strategies and mechanisms to improve access to medicines strengthened***

During FY12, SIAPS assistance to CNLS facilitated fulfillment of the procurement and supply management-related conditions for Round 10 and disbursement of the Global Fund Phase 1 money for the procurement of HIV and AIDS commodities. SIAPS will continue with these activities.

Under FY13, SIAPS—

- Collaborated with Cameroon’s CCM, CNLS, and relevant stakeholders to monitor implementation of the action plan from SIAPS’s assessment of CAPR and CENAME conducted in June/July 2012
- Responded to ad-hoc requests from CNLS for technical assistance with pharmaceutical management-related implementation of Cameroon’s Global Fund Round 10 grant
- Estimated HIV and AIDS commodities quantities and budget breakdown to place the order through the Global Fund New Funding Model for a budget of USD 10 million to face the current stock out episode.
- Supported the NACC to make available to a PEPFAR/Washington treatment working group a funding gap analysis by reviewing patients projections and 20132014 needs versus existing funds available.

## Democratic Republic of the Congo

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

The provincial essential medicines lists (EML) initiated by SIAPS in the 4 USAID-supported provinces, through the provincial medicines committees have been completed in 3 provinces, and is in draft form under review in the 4th province. The 3 have been submitted to the national level. In the absence of EML from the other 7 provinces, the MoH has decided to compile the national EML based on these 4 EMLs only.

SIAPS still coordinated data collection and analysis of information from all partners on the availability of pharmaceutical management information on essential medicines by preparing stock status reports for Malaria and Family Planning Commodities. Provincial Medicines Committees have been able to redistribute medicines and other commodities at risk of expiry within health zones. At MoH's request, and in agreement with the DRC USAID Mission, SIAPS successfully dispatched PMI malaria commodities (overstock and near expiry) from 2 provinces to another newly adopted PMI province, on behalf of another USAID project, PMI-EXPANSION. SIAPS contributed to joint supportive supervisory visits with MoH provincial authorities and IHP in 27 USAID-supported health zones to improve pharmaceutical management capacity with a focus on data collection. These visits were an opportunity for the MoH provincial staff to make pertinent and real time decisions to correct the weaknesses encountered.

SIAPS trained staff from all PEPFAR implementing partners in pharmaceutical management. At the request of the MoH, the implementation of the Electronic Dispensing Tool (EDT) has continued in Katanga province to support the Mission's expansion of PMTCT program to this province. Procurement Planning and Monitoring Reports for malaria and contraceptives were produced with more involvement of the MoH, and submitted on-time to USAID Washington. Extensive MoH/IHP/SIAPS joint supportive visits to 27 health zones allowed many useful correctives measures to be taken.

Through the Provincial Authorities, SIAPS has assisted one province to harmonize and standardize the cost of health services to patients in all health facilities in the entire province, such that all health facilities in this province are the same.

### **Objective 1: Pharmaceutical sector governance strengthened**

The Directorate of Pharmacy and Medicines (DPM) has taken over full ownership of the registration process. This quarter, SIAPS provided reduced financial assistance for the quarterly Drug Regulatory Authority (DRA) registration session, during which 273 files were examined. From this examination, 173 new medicines were registered, including artesunate/lumefantrine combination, a medicine recently adopted by the National Malaria Control Program as another first-line drug for the treatment of uncomplicated malaria. The total number of registered medicines is 1,479 as of the end of June 2013, as against the target of 1,200 for the fiscal year ending September 2013. This represents a 123% achievement for the year. The DRA continues

to publish the list of medicines submitted for registration before registration, and the list of medicines registered within 15 days after registration. There is no longer a backlog of applications. The number of files to be processed at future sessions now depends solely on the number of new applications for registration.

The DRA accepted SIAPS' proposal to extend membership on the registration committee to individuals from outside the DPM (universities, professional societies, etc.). This will improve transparency and credibility of the registration process. From a stage where SIAPS wrote the SOPs for the registration process and was a member of the DRA registration committee with a big presence at the meetings to today, SIAPS' physical presence is no longer needed during these meetings. SIAPS' technical assistance is now provided to the DRA on demand. The financial assistance provided by SIAPS has also been reduced to token support for the members during the registration sessions.

At the provincial level, the provincial medicines committees continued to coordinate pharmaceutical activities in the provinces. Three provinces managed to complete their EML.

As agreed with the MoH, SIAPS' support to the MoH for strengthening governance in the pharmaceutical sector will continue to focus more on updating their internal procedures in project year 3.

### ***Deliverables***

- Quarterly Medicines Registration Report
- Provincial EML for three provinces (Sud Kivu, Kasai Occidental, Kasai Oriental)
- Report on the transfer of malaria commodities to Kisangani in Province Orientale

### ***Constraints to progress***

- The coordination of schedules among the MoH, WHO, and SIAPS for the joint training of 30 inspectors in inspection techniques has been challenging. This training is now planned for September 2013.
- For the EML, all needed resources to support the non-USAID provinces were not available.
- MoH counterparts were not available for the dissemination of the Maternal and Child Health Guidelines, produced with SIAPS' leadership and financial support.
- The limited number of SIAPS staff in the provinces has been a concern as SIAPS now has to follow up pharmaceuticals down to the health facility level in partnership with the IHP Project. Hiring more staff is under discussion with the USAID Mission.

**Objective 2: Capacity for pharmaceutical supply management increased and enhanced**

Sud Kivu is the only province in the Democratic Republic of the Congo (DRC) without a Regional Distribution Center (CDR), while other provinces have up to four. Sud Kivu has only three private depots. The provincial health authorities have been working with SIAPS to establish a CDR in Bukavu for the Sud Kivu province. The provincial government provided land. With SIAPS technical and financial assistance, the Sud Kivu provincial medicines committees has finalized the terms of reference for the whole structure, organization, and functions of the board of directors and the staff of the new CDR.

In April 2012, USAID commissioned an evaluation of three structures in the national pharmaceutical supply system (SNAME)—the National Federation of Central Essential Medicine Stores (FEDECAME), the Regional Association for the Supply of Essential Medicines (ASRAMES), and Central Essential Medicines Supply and Distribution Organization for Kananga (CADIMEK). SIAPS was charged with the responsibility of assisting CADIMEK to address the recommendations from this evaluation. From June 21 to 23, SIAPS assisted CADIMEK to implement recommendations in preparation for the upcoming second assessment by USAID.

SIAPS assisted CDR staff to update the standard operating procedures they developed to meet the requirements of good distribution practices. The updated SOPs were submitted for CADIMEK Board of Directors' approval, which is expected on July 14, 2013.

Last year, the USAID Mission decided to start PMTCT activities in Kisangani (Province Orientale) where SIAPS does not have any office or staff. As a matter of priority, the Mission requested SIAPS to assess the Kisangani Central Essential Medicines Supply and Distribution Organization (CAMEKIS) and provide recommendations prior to its use for storage of PMTCT commodities.

This quarter, at the request of USAID Mission, SIAPS and the provincial health ministry of Province Orientale visited the CAMEKIS to follow up on the recommendations provided during a previous assessment. A few points were noted, such as insufficient palettes and shelves, lack of software for pharmaceutical management, and incorrect organization of the available space. These are currently being addressed by SIAPS to improve the performance of this CDR.

**Deliverables**

- Terms of reference for Sud Kivu warehouse (CDR)
- Report on the evaluation mission for CAMEKIS
- Report on the evaluation mission for CADIMEK
- Swaziland trip report
- External TB Program review
- EDT implementation report

### **Partner contributions**

WHO, USAID, and IHP contributed financial support and expertise in TB.

### **Constraints to progress**

- Because of major changes in the management teams of all national programs, all trainings planned for the National Malaria Control Program (NMCP), HIV and AIDS and TB programs could not start because the new management teams had other priorities to address.
- The external review of the TB Program put all other activities in the program on hold.
- The National Malaria and Reproductive Health Programs have just started taking full ownership and leadership of the Procurement Planning and Monitoring Report on malaria and reproductive health commodities. In the meantime, SIAPS had to coordinate these activities.

### **Objective 3: Pharmaceutical management information available and used for decision making**

PPMR reports for malaria and for contraceptives have been completed, providing progressively improved information on stock levels on hand, in the pipeline, and to some extent, the consumption of malaria and contraceptives commodities in the country, and recommendations about future orders. Other partners have started providing data in a timelier manner.

During the quarter, SIAPS adapted the existing supervision tool, oriented IHP and provincial MoH staff on its use, and provided financial assistance to the MoH in the joint supervision of 27 IHP health zones using the adapted supervision tool. During the supervision visits, information gathered allowed the joint team to achieve the following—

- Medicine budgets were allocated to all health facilities within each health zone.
- Thirty percent of the value of medicines charged to the patient is supposed to be recovered by CDRs and credited back to the health zone account at the CDR for future medicine purchases for the health zone. Many aspects of the system are obsolete. SIAPS assisted by making several updates to the mechanism, e.g., taking into account that PMI medicines are distributed free of charge.
- Assessment of medicine storage conditions at health zones.
- Briefing MoH and IHP staff on the health zone monthly reporting tool on pharmaceuticals management.
- Distribution of medicines to health facilities that were stored at health zone offices.
- Reallocation of close-to-expiry malaria RDTs to other health zones in need.
- Health zones used to allocate medicines to health facilities following an arbitrary system that caused overstocks and stock outs. SIAPS assisted by providing with a simple Excel tool that allows health zones to determine the quantity of medicines to be distributed to health facilities within the health zone, based on the demographic characteristics of the health facilities and their patient attendance rates. Grants were signed between IHP and health zones that oblige health zones to collect and submit to health districts and IHP coordination offices monthly data on pharmaceuticals from the health centers. As a result,

the commodity stock status and consumption reporting is expected to improve to some extent.

- Detection of unexplained losses of drugs recently delivered to some health zones; an investigation was launched.

### ***Deliverables***

- PPMRm
- Procurement Planning and Monitoring Report for Contraceptives
- Trip reports

### ***Constraints to progress***

The limited number of SIAPS staff in the provinces.

### ***Objective 4: Financing strategies and mechanisms strengthened to improve access to medicines***

From a pilot medicines-costing exercise conducted in five health zones in Kasai Occidental with SIAPS technical and financial assistance, SIAPS led the Kasai Occidental provincial medicines committees to scale up the pilot to all 44 health zones. SIAPS assisted the provincial medicines committees to make minor adjustments for a number of health zones based on specific information, such as the existence in the health zone of subsidized medicines from partner organizations. This standardization of the cost of health care in Kasai Occidental is expected to increase the population's access to health services in health zones where the fee charged to patients was originally higher.

As part of improving the pharmaceutical management of ARVs and other HIV commodities under the Global Fund Rounds 7 and 8, and at the request of Sante Rurale (a Global Fund principal recipient), SIAPS trained 22 managers from CDRs (pharmacists, Directors), April 22–27, 2013 in Kinshasa on ARV and HIV commodities quantification. The evaluation of the CDR staff's performance is measured by the National Drug Supply Program PNAM and presented at the yearly meeting of all CDRs, planned for August 2013.

SIAPS also assisted the Katanga provincial medicines committee to conduct a gap analysis of medicines needs in the entire province. The results show that the financial contributions to health of all partners in 2012 covered only 20% of the total need for medicines. The contribution of USAID through IHP was equivalent to 8% of the total partners' contribution. The provincial health authority now knows the level of partners' contributions to health services in Katanga.

Following a series of National Medicine Committee meetings conducted with technical and financial support from SIAPS, and after the Minister of Health had created a task force (that included SIAPS) charged with quantifying essential medicines for 65 health zones, for the first time in decades the MoH provided more than USD 1.5 million from its own funds for SNAME, through FEDECAME, to purchase a six-month supply of essential medicines for the 65 health zones that are considered to have no support from partners.

### **Deliverables**

- Training report
- Gap analysis for Katanga Province

### **Objective 5: Pharmaceutical services improved to achieve desired health outcomes**

From May 20 to June 4, a medical doctor from the National Pharmacovigilance Centre (CNPV) participated in the 15th International Pharmacovigilance Course at Uppsala Monitoring Centre in Sweden, with full support from SIAPS. He is the second CNPV member to be formally trained out of 21 active members. The presence of this staff member at Uppsala allowed the UMC to analyze the DRC's pharmacovigilance system and to identify its strengths and weaknesses.

This year, DRC had the world's best completeness rate for reporting adverse drug events (ADE). Hospitals with Medicine and Therapeutic Committees (MTCs) established by SIAPS contributed greatly to increasing the number of ADE notifications submitted to the Uppsala Monitoring Center.

Although the MoH has standard guidelines for only a few diseases, they are not organized into one document and are seldom available when and where needed. In response to recommendations of the baseline study conducted in eight health zone referral hospitals, SIAPS supported the development of STGs to serve as a pilot tool in hospitals with MTC.

SIAPS assisted in updating the formulary list of Tshiamala Referral Hospital (Kasai Oriental), which was developed two years ago. SIAPS also assisted the Katana Referral Hospital MTC (Sud Kivu province) to develop its first formulary list. MTCs have submitted 44 ADE notifications to the CNPV during this quarter.

The CNPV also worked with the MTCs and saved the lives of two children from severe medicine reactions.

Next Steps: Conduct a survey on indicators of rational prescribing in all general referral hospitals with MTCs to measure the impact of corrective actions following the 2012 baseline study.

### **Deliverables**

- Updated formulary list of Tshiamala Referral Hospital (Kasai Oriental)
- First formulary list for Katana referral hospital MTC (Sud Kivu province)



## **Dominican Republic**

***Goal: Increase the availability of critical medicines and diagnostic materials, including ones used for HIV and AIDS and tuberculosis, through the implementation of the different elements of the SUGEMI system and building the capacity of national counterparts to effectively and efficiently operate the integrated system***

### ***Objective 1: Pharmaceutical sector governance strengthened***

SIAPS continued to provide technical assistance to the National Pharmaceutical Unit for the development of technical documents. Through two short-term consultants, SIAPS continues to support the unit's operations

SIAPS participated in a working group for the analysis of ARV pharmaceutical management. The group agreed to a roadmap to improve the availability of ARVs in the Dominican Republic.

#### ***Partner contributions***

All national counterparts and cooperating agencies, including USAID, participated in the preparation of the roadmap.

#### ***Deliverables***

Roadmap to improve the availability of ARVs

### ***Objective 2: Capacity for pharmaceutical supply management and services increased and enhanced***

The certified course on pharmaceutical management was completed with the graduation of 30 professionals. SIAPS shared the results of the final evaluation with university professors and authorities.

#### ***Partner contributions***

Certified course was organized by the Santo Domingo Autonomous University. USAID and public and private institutions paid the tuition fees.

#### ***Deliverables***

Final evaluation of the certified course on pharmaceutical management

**Objective 3: Pharmaceutical management information available and used for decision making at different levels of the DR health system**

The national pharmaceutical management system (SUGEMI) electronic tool was adjusted to facilitate the consolidation of information in the Regional Pharmaceutical Units, and the integration of indicators to monitor the performance of SUGEMI.

The regional and facility supervision forms were validated in a field test, and indicators to be used to monitor the SUGEMI performance were revised and validated by counterparts.

**Deliverables**

Final version of the supervision form and SOP

**Objective 4: Pharmaceutical services improved to achieve desired health outcomes**

SIAPS supported MoH initiatives to mobilize resources from foreign donors to improve the current conditions of regional warehouses. SIAPS also assessed the conditions of DCP central warehouses.

SIAPS supported the estimation of needs for a pooled procurement of medicines and supplies for all public institutions, and the estimation of needs for the DCP (TB, HIV and AIDS, maternal and child health, and protected disease which are clinical interventions (cancer treatment, kidney transplant, and dialysis financed directly by the MoH ). It is estimated that the government will save USD 32 million through the implementation of the pooled procurement mechanism.

**Partner contributions**

All public institutions participated in the programming exercise. The workshop was co-financed by the national HIV/AIDS council.

**Deliverables**

Technical reports on the results of the estimation of needs for the 2014 national pooled procurement of medicines and supplies

## Ethiopia

**Goal: Build the capacity of Ethiopian health institutions to assure the availability of efficient and effective pharmacy services that will lead to improved health objectives.**

The second round of training on clinical pharmacy for the plan year was successfully carried out and 26 pharmacists (20 males and 6 females) were trained. The trainees were drawn from 18 hospitals from Tigray, Amhara, Addis Ababa, Dire Dawa, Harari, Oromia and SNNP regions. The achievement accounts for 51% of the target set for the plan year after 25 pharmacists were trained in the last quarter. Considering the importance of this training for better health outcomes, it is planned to collaborate with PFSA, Jimma and Gondar universities to review curricula and training materials to conduct in-service trainings that will be financed by PFSA and the health facilities. The status of implementation of clinical pharmacy service in the 30 beneficiary hospitals was assessed and found to be encouraging as witnessed by the introduction of ward rounds morning sessions and keeping of medication records. In addition, supportive supervisions were made by trainers to support trained pharmacists and advise them how to improve clinical pharmacy services. There was also an assessment conducted at Gondar University Hospital to see its capabilities in hosting one of the next trainings on clinical pharmacy, For this purpose, two clinical pharmacists from Gondar University were sent to Jimma University to acquire experience in conducting in-service trainings in clinical pharmacy, including the overall organization and conduction of the class-based as well as ward-based components of the training.

In the reporting quarter, a total of 302 professionals attended the in-service training events—close to 30% of attendees were females. The majority of trainees were drawn from Amhara (43.7%) and Addis Ababa (20.5%).

During the quarter supportive supervision and mentoring were provided to 57 health facilities and provided on-the-job training for 49 dispensers, 5 data clerks and other staffs on real time dispensing; staff were trained on how to manage patient and pharmaceutical information by using Electronic Dispensing Tool and using the outputs of the tool. For this purpose, 2 computers and 22 external backup drives have been distributed during the last quarter. Likewise, PMIS format were distributed for 133 health facilities to strengthening the pharmaceutical information recording and reporting activities. A draft CRMS report and a EUV report has been produced and shared with partners and concerned bodies, two monthly antimalarial stock statuses were collected, aggregated and reported to Oromia regional health bureau and partners as well.

Onsite training and mentoring on APTS was given to six hospitals (five hospitals in Amhara (Finote selam, Debark, Motta, Metema and Bahirdar/Felegehiwot and one in Harari region (Jugel))and one health center in Harari region (Jinella health center). The above facilities are establishing APTS as a system and ensured transparency and accountability.

USAID/SIAPS/Ethiopia set a target to establish model sites of APTS at eight hospitals. So far, APTS has been implemented at 7 hospitals, which is 87.5% of the plan for the year.

### **Objective 1: Pharmaceutical sector governance strengthened**

This objective is a blend of specific interventions that lead to the improvement of pharmaceutical sector governance. The interventions are: Pharmacy Administration; Auditable Pharmaceutical Transactions and Services (APTS); health facility standards; Health Regulatory Information Center (HRIC); FY (2012) follow-on activities, such as STG revision, leadership training, and medicines waste management; and emerging activities, like the development of the social insurance medicines list.

**Pharmacy Administration:** Under this activity, preparation of a concept note on the institutionalization of appropriate pharmacy administration at both federal and regional levels is planned to facilitate improvements in access to medicines and the quality of pharmacy services. The concept note will be disseminated to stakeholders through the Ethiopian Pharmaceutical Association. Development of the concept note is underway, informed by a desk review and analysis of existing experiences.

**APTS:** This package of interventions, developed by SIAPS in collaboration with the Amhara Regional Health Bureau, requires the passage of new legislation for its effective implementation and ownership. Accordingly, SIAPS plans to support other regions in the development of legislative documents. Federal Ministry of Health has requested such assistance through the pharmaceutical fund and supply agency. A draft legislative document, which will be enriched by legal experts and other concerned stakeholders, is being prepared. No progress was made in the development of the draft legislation during this quarter. The Harari Regional Health Bureau committed to preparing a regional directive for the implementation of APTS. SIAPS is planning to provide technical assistance.

**Standards:** Health facility standards, which address pharmaceutical service standards at different levels, need to be printed. The Food, Medicines and Health Care Administration and Control Authority (FMHACA) issued a tender for this purpose. SIAPS was asked to finance the printing of standards for specialty centers, general hospitals, and specialized hospitals. The FMHACA recently modified its request for assistance. SIAPS issued a tender to select the printing house for the production of standards for primary hospitals, specialized hospitals, specialty clinics, and specialty centers. For training on the standards, the curriculum is under development. The implementation of the standards was launched by H.E the Minister, Dr. Kesetebirhan Tadesse, of the Federal Ministry of Health (FMoH) in a ceremony held in Hawassa in the presence of regional health bureaus and relevant stakeholders. MSH was awarded a certificate of merit; one of its staff received a gold medal for his immense contribution.

**HRIC:** FMHACA submitted a proposal for the establishment of Health Regulatory Information Center (HRIC). SIAPS considered the proposal in this budget year. After a consultative meeting with the AIDS Resource Center, FMHACA developed a new proposal, modified to accommodate appropriate technology, development of operating procedures, furnishing the center, development of a database, staffing, and training. The FMHACA has submitted this proposal and the SIAPS procurement unit is managing this request.

STG (follow-on activity): The consulting firm, Bethel Teaching Hospital, submitted the first draft, and two consecutive meetings have been conducted to discuss the way forward. The materials are ready for a national consultative workshop. SIAPS is organizing this workshop.

Leadership training (follow-on activity): This training was long delayed due to stakeholders' busy schedules. The training was delivered June 6–8, 2013 in Addis Ababa by JETHRO Training Institute. Twenty-three mid-level managers took part in the training.

### ***Deliverables***

- Draft STGs for health centers, primary hospitals, and general hospital
- Leadership training report
- HRIC material and system requirements
- Draft pharmacy administration model for Amhara Regional Health Bureau
- Draft federal APTS regulation in Amharic is available

### ***Partner contributions***

- FMHACA actively led the development of the new HRIC proposal and technical requirements.

### ***Constraints to progress***

- Ownership (lack of appropriate stakeholders)
- Coordination of stakeholders is a challenge as there is no responsible focal unit at the federal level

### ***Objective 2: Capacity for pharmaceutical supply management and services increased***

The FMoH, Pharmaceutical Fund and Supply Agency (PFSA), regional health bureaus (RHB), and SIAPS staff were given orientation training on the principles of clinical pharmacy followed by an APTS training at the head office of SIAPS/Ethiopia. A total of 37 people were trained.

These activities have contributed to ownership of the program at PFSA and RHB levels, and better technical assistance to health facilities by PFSA, RHBs, and SIAPS. The training will enable these actors to effectively carry out supportive activities on APTS for health facilities, including on-site trainings.

SIAPS coordinated the provision of on-site supportive supervision centered on clinical pharmacy activities to three hospitals in Oromia, four hospitals in Amhara, three hospitals in Addis Ababa, and one hospital in Harari region. A supportive supervision team was established with personnel from the Jimma University School of Pharmacy, PFSA, and SIAPS. The

supportive supervision was performed by use of a standard checklist. The team was involved in morning sessions, ward rounds, review of patient charts, observation of documentation, and discussions with the trained pharmacists, the head of pharmacy, and hospital management to gather information and discuss future action points. Technical support was provided to the trained pharmacists and management staff. Major findings and reports are included in the supportive supervision report.

To build the capacity of the Oromia Regional Health Bureau to coordinate its work and manage supportive supervision on good prescribing, dispensing practices, and other malaria-related activities, support was provided to develop a supportive supervision checklist for assessing the availability and rational use of antimalarial medicines during the outbreak of epidemics in some of the malaria endemic areas in the region. Supportive supervision visits were conducted in June 2013 to six zones (West Arsi, South West Shoa, West Shoa, Jimma, Illuababora, and Kellef Wollega). Twelve health centers and health posts, and twelve district health offices were supported technically and managerially during the supervision visits. The supervision aimed at assessing the availability, storage, and dispensing of AMDs at the target health facilities, and providing onsite comments and recommendations, in addition to managerial interventions. The rational use of antimalarial drugs during an epidemic has been a high priority of supervision. Proper recommendations have been provided on adherence to the National Malaria Treatment Guidelines (NMTGs).

It has been frequently observed that medicines may expire in one health facility, while the neighboring health facility is facing a stock-out of the same medicines. To address management challenges with antimalarial medicines at the facility level, redistributing excess stock has been promoted during the regular supportive supervision visits conducted by the team from Oromia RHB and the SIAPS/PMI-anti-malaria drugs management (AMDM) program in June 2013.

Technical support on the selection and quantification was provided to the Oromia RHB and PFSA during the drug selection and quantification workshop for health centers in Oromia Region, organized by PFSA in collaboration with Oromia Regional Health Bureau and TB CARE I. During the workshop, it was mentioned that drug selection and proper quantification significantly contribute to appropriate financial expenditure, avoidance of waste, increased access, and assurance that the drugs are properly used. It was also shown that proper drug management results in financial savings that can then be devoted to other health needs, particularly of disadvantaged populations. This makes it possible to have improved health outcomes without the need for additional expenditure.

SIAPS supported PFSA and the FMOH in the preparation and distribution of kits for the ICCM program. During the quarter, 2,000 kits, consisting of basic supplies for the ICCM program, including antimalarial products, were prepared and distributed to 2,000 health posts.

### ***Deliverables***

- Supportive supervision report
- Training report

### **Partner contributions**

Partners/stakeholders who have been participating in the clinical pharmacy service/training initiative include—

- PFSA: centrally coordinating the planning, organization, invitation of trainees, supportive supervision of clinical pharmacy service, and training.
- Jimma University: involved in the planning, training manual revision and facilitation of the training by providing venues, trainers, and its clinical wards.
- The Oromia RHB malaria and pharmacy units took a lead role during the supportive supervision to assess the AMDM challenges at the health facilities and provide technical and managerial support.

### **Constraints to progress**

- The inadequate number of pharmacy workers continues to hamper the implementation of services, such as clinical pharmacy at selected health facilities in Oromia Region.
- The turnover of trained pharmacists has also adversely affected the service.

### **Objective 3: Utilization of information for decision-making increased**

SIAPS/Ethiopia produced a bimonthly report providing information on progress and trends in patient uptake of and ARV medicines use throughout the country. It was shared with USAID and other relevant stakeholders.

Supportive supervision and mentoring were provided to 57 health facilities. Onsite training on real-time dispensing was provided to forty-nine dispensers, five data clerks, and other staff, showing them how to manage patient and pharmaceutical information using the Electronic Dispensing Tool and the outputs of the tool. For this purpose, two computers and twenty-two external backup drives were distributed. Likewise, the PMIS format was distributed to 133 health facilities to strengthen pharmaceutical recording and reporting activities. Hardware and software maintenance support was provided to 18 health facilities, including Kaspersky antivirus software installed in 29 computers.

A working group composed of the PMIS team, regional technical associates, and the IT Unit of MSH was formed and started preparing documents to develop a comprehensive dispensing tool.

To provide mentoring in the generation and compilation of quarterly Continuous Result Monitoring System (CRMS)-related data on AMDM to meet PMI information requirements in Oromia, CRMS data was collected from the PMI sentinel sites. Based on this data, one CRMS quarterly report was provided to partner organizations and to PMI headquarters. Likewise, one EUV report as well as two stock status reports were shared with relevant partners and stakeholders.

CRMS findings were presented and discussed with health facility DTCs, such as the ones conducted at Shashemene Hospital, Wonji Hospital, and Wolenchiti health center. Hospital directors, pharmacy heads, and different facility staff attended the presentations, raised questions, and provided feedback to improve the provision of antimalarials to patients, how to follow up ADRs related to antimalarials and other pharmaceuticals, rational prescribing, dispensing, and patient use. In most health facilities, patient education is initiated and pharmacy personnel are actively involved in providing pharmaceutical-related information directly to patients. Further discussions were held at the Oromia RHB, East Shoa Zone, and Shashemene town health offices and the health facilities on future strategies to institutionalize the CRMS at the health facility level to support DTCs with pharmaceutical management.

To collaborate with USAID and CDC implementing partners on PMIS training for pharmacy personnel, the Standard Operating Procedure (SOP) Manual was revised; finalization is expected shortly. The SOP Training Exercise Package was also revised to reflect current developments in ART services and to coincide with the revision of the SOP Manual. SOP trainings were provided to pharmacy personnel in ART. The trainings were organized by partners. Two SOP trainings were conducted, with sixty-two pharmacy personnel trained.

### ***Deliverables***

- One bimonthly patient uptake report
- Draft CRMS Report (being reviewed at headquarters)
- End-user verification report
- Field visit reports on EDT maintenance and on-the-job trainings
- CRMS review meeting reports

### ***Partner contributions***

Health facilities produce monthly AMDM reports regularly.

### ***Constraints to progress***

- There are frequent power interruptions at some health facilities making it difficult to implement real-time dispensing and to encourage the use of computers for information recording.
- Frequent computer failures and delays in monthly reports at some health facilities.

### ***Objective 4: Financing strategies and mechanisms to improve access to medicines strengthened***

Working with hospital DTCs, SIAPS/Ethiopia is providing technical assistance to implement the Pharmacy Chapter of the Ethiopian Hospital Reform Implementation Guideline (EHRIG), which includes patient-oriented pharmacy services and APTS. This has created transparency and accountability for the procurement process at these sites. Implementation of APTS requires that: all medicines received by a health facility from suppliers and issued to clients are accounted for; the sale of medicines and turnover rates are closely monitored; loss and/or



waste is properly documented; and the availability of medicines, patient load, and client satisfaction with services provided are closely monitored.

In collaboration with the RHBs, SIAPS/Ethiopia planned to implement APTS in eight hospitals—Dire Dawa (1), Harar (1), Southern Nations, Nationalities, and Peoples' Region (1), Amhara (3), and Tigray (2). To date, work has been done in seven hospitals (87.5%). As a result of this intervention, gross profits from medicines increased due to improved internal efficiency (bin location system, vital, essential, or nonessential medicine (VEN) selection, minimal wastage (expiry), and pharmaceuticals sales financial management).

APTS have already been enacted by a regulation in two regions, Amhara and Diredawa. The Tigray regional state government passed an agreement to implement APTS in two sites before the approval of the APTS regulation in the region. A directive for Harari region was drafted this past quarter. These regional health bureaus and SIAPS have come a long way in implementing APTS, thereby ensuring transparency, improving affordability and efficiency of financial management, and increasing financial gains from the sale of pharmaceuticals, and thus, increasing access to medicines.

No errors were seen in the daily summaries prepared by the pharmacy accountant when APTS was initiated on May 17, 2013, in Woldia Hospital. There were no voided receipts or deleted raw data in any of the APTS registers. Within just three days, dispensers were able to detect a number of medication errors, the majority of which were problems of indication and sometimes of duration of therapy. Much effort was made to encourage dispensers to make evidence-based decisions to safeguard their credibility on the medical team. They were mentored to use STGs, which they have on hand.

At the time of the USAID Mission visit to Woldia General Hospital on June 20, 2013, the APTS service was observed to be effectively running and staff were delivering a very stable and promising service. The pharmacy accountant's workload observed at the beginning has been resolved with the hiring of an additional pharmacy accountant by the hospital.

Onsite training and mentoring on APTS was given in six hospitals and one health center, the first health center to be mentored and trained on APTS in the reporting quarter. Five hospitals in Amhara (Finote selam, Debark, Motta, Metema, and Bahirdar/Felegehiwot) and one hospital and one health center in Harari region (Jugel Hospital, Jinella Health Center) were involved. These facilities are establishing APTS as a system to ensure transparency and accountability.

### ***Deliverables***

- Monthly financial and service reports from sites implementing APTS
- Training reports
- Summary report on the implementation of APTS in Woldia Hospital

### **Partner contributions**

- Amhara regional state health bureau supported the reform process by conducting discussions with hospital staff on the importance of APTS implementation.
- Woldia Hospital fully deployed the manpower needed for the efficient and speedy establishment of APTS.

### **Constraints to progress**

- The number of pharmacy accountants is very low.
- The existing infrastructure is not conducive to the introduction of APTS.

### **Objective 5: Pharmaceutical services improved to achieve desired health outcomes**

To implement EHRIG pharmacy standards at target facilities, supportive supervision visits were made to four hospitals in Oromia and four hospitals in the SNNP region. During the visits, the status of implementation of EHRIG pharmacy standards and functioning of the DTC, Drug Information Service (DIS), and clinical pharmacy (in three hospitals) were reviewed and discussed. The status of facility-specific drugs list, activities related to ADR monitoring and reporting AMR containment, APTS, and other standards were reviewed, and guidance was provided to the respective hospitals' pharmacy staff. The findings and recommendations were discussed with the respective hospitals' management (CEO, Medical Director, and Pharmacy Head).

SIAPS/Ethiopia provided mentoring and on-site training to conduct ABC value analysis and ABC/VEN reconciliation activities in six hospitals (Jugel, Butajira, Dilla, St. Peter, Axum, and Debre Markos). An additional four hospitals (Mizan Aman, Hossana, Dilchora, and Felegehiwot Hospitals) were also mentored. Based on the mentoring and onsite training it received, Butajira Hospital finalized ABC and ABC/VEN reconciliation and is now conducting a stock status analysis. Dil-Chora Hospital in Dire Dawa region completed a five-year aggregate ABC analysis and reported to hospital management for further analysis of drug use evaluation. VEN/ABC matrix and stock status analysis were likewise done by Felegehiwot Hospital in the Amhara region

SIAPS/Ethiopia also facilitated one-day Drug Use Evaluation workshops for Dessie and Debre Berhan Hospitals, and attended the Dessie Hospital's Drug Use Evaluation workshop. A similar workshop was organized by the regional technical associate at Debre Berhan Hospital.

To provide SOPs/guidelines and referral materials to scale up the establishment and operation of DIS, SIAPS facilitated the DIS inauguration ceremony at Gandhi Memorial Hospital. As a result of this event, 46 DIS sites are in operation.

In collaboration with facility DTCs, SIAPS/Ethiopia organized face-to-face discussions on how to identify, prevent, and report ADRs at four health facilities (Woreda 8 health centers,

Addis Hiwot, International Cardiac Center, and Yordanos private hospital). A total of 72 health providers from the four facilities participated in the discussion. Fifty-four reports were entered into the national database and WHO Vigiflow.

A consultative workshop was organized on June 20, 2013 at the FMHACA conference hall for teaching institutions to discuss challenges faced in teaching pharmacovigilance.

Technical and material assistance to the Prevention and Containment of AMR, Quality Assurance Meeting with Journalists on Prevention and Containment of Antimicrobial Resistance and Rational Medicines Use: Twenty-six journalists working on the health programs of different federal and regional government and private radio programs, television programs, and print media participated in this meeting. Almost all of the journalists reported on rational medicine use and antimicrobial resistance following the training. Some of them reported live and with active involvement of the end users. However, some of the journalists mentioned that they are generalists, i.e., working on a wide variety of topics rather than health programs solely, which challenges their capacity to report on the issue.

Promoting rational prescribing, dispensing, and client use of medicines through educational, managerial, and regulatory interventions: SIAPS continued to distribute Good Medicines Prescribing and Dispensing Manuals and Pediatric ARVs Prescribing and Dispensing Aids IEC materials to end users.

### ***Deliverables***

- Workshop and meeting reports
- Report of the consultative workshop with the teaching institutions
- Summary of ADE reports for the year 2005 E.C

### ***Partner contributions***

- Facilities provided their valuable time and rooms for face-to-face discussions at the International Cardiac Center and Yordanos Hospital
- FMHACA experts' contributions
- Academic institutions are one of the major partners in pharmacovigilance. During the workshop, they suggested challenges and recommendations for further activities to include in pharmacovigilance instruction.

### ***Constraints to progress***

Turnover of staff is always a problem faced by facilities when trying to make the drug safety monitoring activity sustainable. As a solution, SIAPS/Ethiopia started selecting two focal persons per health facility. They are responsible and may support one another to carry out the activities.

## Guinea

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

The past quarter has seen major progress made toward meeting Objective 3 by making pharmaceutical management information available for decision making at the national level. SIAPS Guinea and its in-country partners, the National Malaria Control Program (PNLP) and the National Health Information System (BSD/SNIS), worked together to finalize preparations for launching a new monthly report template for malaria at the health district and facility level. This new reporting template—along with another tool, a new comprehensive product order and delivery form for antimalarials—are the results of two SIAPS workshops and multiple working sessions with a wide range of partners over the past six months. In late June, SIAPS, PNL, and Bureau de Strategie et du Development (BSD) organized a first training for all health centers, hospitals, and district-level data managers and pharmacists in Conakry to officially introduce the new reporting tools. The training is being repeated in all 19 districts of the PMI zone through early July. The new malaria reporting template includes a detailed section on drug management, including stock status and monthly consumption at the facility level. Coordination with Global Fund implementing partners has ensured that the new reporting template will also be scaled-up to the other 19 districts of the country.

To encourage reporting at higher rates and on time, especially for drug management, SIAPS had proposed a series of concrete strategies that were validated by all Regional and District Health Directors in March. For example, reporting by e-mail to a generic PNL address, using a standardized Excel template, from the District level directly to the Central level, has already started to show results even before the official launch. To achieve this goal, SIAPS is distributing internet connection keys to the 19 PMI Districts. A quarterly reporting competition has also been established among Districts and will result in institutional prizes that are related to reporting activities, such as laptops, printers, and additional internet credit.

A second EUV survey was conducted on April at 23 facilities in PMI zones, in collaboration with the major SIAPS in-country partners and national, regional, and district-level supervisors. The survey found good availability of ACTs and other antimalarial products at the facility level, mainly due to the distribution of a new arrival of PMI products which was conducted by SIAPS in March.

### ***Objective 1: Pharmaceutical sector governance strengthened***

During this quarter, there were some setbacks and delays in meeting Objective 1. Reforms at the Central Pharmacy of Guinea (PCG) are still awaited and the change of its legal status has been de-prioritized by PCG (this is an activity that was deemed important last year and therefore was included in the SIAPS scope of work). Following recent discussions between the PMI Washington and Guinea teams as well as the Directors of PCG, PNL, and SIAPS in late June, it has become clear that PCG must speed up its reforms and show transparency to benefit from PMI assistance, but also that PCG is in need of political rather than technical support at this stage. This is a critical issue, as PCG is an autonomous entity and therefore

does not benefit from Government of Guinea funds but needs funding to distribute drugs to the regions. High-level discussions will continue via the PMI Washington and Guinea teams, but also via SIAPS which will support whatever process is being decided upon for drug distribution in country.

Activities regarding the implementation plan of the National Pharmaceutical Policy are also delayed at the moment due to competing priorities at the national regulatory authority (DNPL). The SIAPS Country Project Director has had several meetings with DNPL and has extended technical and financial support for two central-level workshops that will help revise the National Pharmaceutical Policy and draft an implementation plan. The activity has been initiated and will continue based on the partners' availability.

Drug registration activities are currently on hold due to budgetary constraints and will require the help of an international consultant.

### ***Constraints to progress***

The MOU detailing the terms and costs of the regular distribution of antimalarial products supplied by PMI now exists, but it requires governance reforms at the Central Pharmacy before it can be funded by PMI. PCG has appeared to re-engage in the process following the PMI Washington's visit to Guinea.

Competing priorities of the major MoH partners (PNLP and DNPL) often derail activity timelines which have been agreed upon; however, SIAPS is working closely with the partners to manage significant delays in implementing key activities.

### ***Deliverables***

The European Union performed an audit of the PCG and its results will be used by the PMI team to make recommendations to Central Pharmacy. Based on progress toward the recommendations, PMI will be able to assess whether or not it can fund the MOU between PNLN and PCG for internal drug distribution in Guinea.

### ***Partner contributions***

SIAPS had several rounds of discussions with PNLN, PCG, and the USAID/PMI in-country representatives on finding a long-term solution to the problem of PMI products not reaching the regional warehouses (and ultimately, the health facilities) on a regular basis. SIAPS is ready to support whatever mechanism is being decided upon for internal distribution.

### ***Objective 2: Capacity for pharmaceutical supply management and services increased and enhanced***

A SIAPS sub-objective in Guinea is to strengthen inventory and pharmaceutical management capacity of individuals and institutions. Toward this goal, SIAPS and its partners (PNLP, PCG, and others) developed and launched a new Product Order and Delivery form for

antimalarial products, replacing three different forms. The introduction of this new form provided the opportunity to train all the heads of health centers and the District pharmacists on good stock management practices including physical inventories, record keeping and stock cards, computing methods for the average monthly consumption of medicines (especially in an environment of frequent stock-outs), minimum and maximum levels of stock, and quantities to order.

During the trainings taking place in all PMI districts in late June/early July, facilities are notified that they should no longer wait for an allocation of antimalarial products from the national level, but rather should submit quarterly product orders based on consumption to reduce the likelihood of running out of stock. The circuit of product orders and deliveries has also been made more efficient and transparent—the product orders of individual health facilities will be sent to the District, then the Regional level for validation, and finally to the Regional warehouses which will deliver the products. Product orders no longer have to arrive at the national level (PNLP) which would cause delays in delivery and increase costs. In addition, Districts will no longer combine the health facilities' orders, but rather each facility's request will be addressed separately. The new product order and delivery form will take effect in the next quarter (October 2013) and facilities have received the necessary forms to use for a period of approximately 3 years.

Observations made at the facility level during the two EUV surveys have also been incorporated into the training in order to provide reminders about good stock management practices.

### ***Constraints to progress***

Since the issue of a continuous distribution system for PMI products to the regions has not yet been solved, PNLN is planning another one-off distribution to facilities country-wide in July. However, since not all facilities have been submitting the old stock management monthly reports, PNLN has decided to do this distribution in a “push” fashion (using PMI, Global Fund, and Islamic Bank of Development (Banque Islamique de Development) products), rather than the “pull” system that has been advocated since last year. This problem should be corrected going forward with consistent-email reporting which will ensure more timely information for decision making and the new system of quarterly product orders from facilities.

### ***Deliverables***

Booklets containing four copies each of the new product order and delivery forms) along with clear instructions about the new system have been issued to all health facilities and district pharmacists in PMI zones.

### ***Partner contributions***

SIAPS worked closely with PNLN, PCG, and other partners toward developing the new form and providing trainings.

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

A key objective for this year's work plan is to ensure that pharmaceutical management data is available and used for quantification and procurement planning. This past quarter marks a landmark towards strengthening Guinea's pharmaceutical management information system (PMIS) with the launch of the new monthly malaria report which now includes a section on stock status, consumption data, and stock-outs.

The new malaria report (which includes both patient and product data) will be completed in hard copy at the facility level, but will be incorporated into a standardized Excel template (with built-in formulas) at the District level. Starting August 1, it will be sent by e-mail to PNLP, the National Health Information System (BSD/SNIS), and the Regional level. BSD's platform can import the Excel file (which is easier to use by data managers at the District level). SIAPS ensured the coordination of reporting requirements with both PNLP, BSD/SNIS and for scale-up purposes with USAID and Global Fund implementing partners, MCHIP, Faisons Ensemble, and Christian Relief Services).

The heads of health facilities and data managers at the District level are currently receiving hands-on trainings in the PMI zones. The first training took place in Conakry on June 27 and was organized by SIAPS with trainers from PNLP, PCG, and BSD.

SIAPS and PNLP are also in the process of organizing the second quarterly review meetings with the Regional and District Health Directors. The first meeting took place in Conakry in March 2013. The July meetings will take place at the regional level and will include a review of the monthly malaria reports to date.

To support basic information technology needs, particularly for reporting purposes, all 19 PMI districts data managers have received an internet connection key with a limited monthly subscription. PNLP has also received 2 internet keys, 2 laptops, and 2 printers designated for the Pharmacy and M&E teams. SIAPS is in the process of distributing additional laptops and printers to PCG, DNPL, and to the Districts as part of the newly-establishing quarterly reporting contest.

A second EUV survey was conducted in PMI zones in April 2013 in collaboration with PNLP; SNIS; DNPL; national, regional and district level supervisors; and USAID partners MCHIP and Faisons Ensemble. The survey included some additional questions reflecting new SIAPS outcome indicators and lessons learned from the first survey of December 2013. SIAPS and PNLP entered the data into a database and analyzed it; a presentation of the results has been drafted to be discussed at the regional quarterly meetings in July 2013. The next EUV survey is scheduled for late August 2013.

**Constraints to progress**

Because of other ongoing activities at PNLP, including a mass distribution campaign of bed

nets in Global Fund zones, the introduction of the new malaria reporting template (and the associated trainings at the health facility and District level) were delayed by a couple of months, but are now underway.

The only constraint experienced for the second EUV study was that the teams did not receive approval to work at the two Central Pharmacy warehouses in Conakry, although they were able to conduct the study at two regional warehouses. This was due to the lack of a convention between PNLN and PCG at the time.

### ***Deliverables***

A final version of the new monthly malaria report template along with instructions in booklet form (for facilities) and as a standard Excel file with built-in (protected) formulas for the District level

Two reports are available for the second EUV survey: a summary report in English for PMI/USAID, and a full-length presentation in French for in-country partners

### ***Partner contributions***

Both the report trainings and EUV survey included a wide-range of in-country partners.

### ***Objective 4: Pharmaceutical services improved to achieve desired health outcomes***

The April EUV survey found good availability of PMI products at the facility level. All facilities (100%) visited had artesunate/amodiaquine (AS/AQ) for small children and adults in stock; 95% had AS-AQ for adolescents; 85% AS-AQ for infants; 83% SP; 91% injectable quinine and 87% RDTs, although the quantity of rapid diagnostic tests available in country was minimal at the time. The good availability of products was because of another one-off distribution conducted by SIAPS in March 2013.

While discussions continue between PMI/USAID, PCG and PNLN regarding the draft convention for in-country distribution of PMI products, SIAPS has been asked to ensure that all remaining products currently stored at the PCG are distributed to the regions as soon as possible (in July 2013). In the past weeks, PNLN drafted a distribution plan based on allocation (rather than product orders based on consumption). SIAPS and PNLN will work together to find a quick yet efficient way to distribute the products to the regions.

### ***Constraints to progress***

PNLN still favors distributions by allocation, in part because of incomplete consumption data they have received from the Districts so far. However, many of the Districts have begun providing their reports by e-mail and therefore PNLN should take this data into account for future distributions.



In the absence of a funded agreement between PNLN and PCG, the challenge remains how to fund another distribution of products to the regions in July 2013 before facilities begin to experience stock-outs.

***Deliverables***

A database summarizing the consumption data from PMI zones over the past quarter along with the product distribution list from March 2013, by health district and by facility

***Partner contributions***

PNLN, PCG, and SIAPS worked together (on a technical and logistical level) to organize the distribution of PMI products at the Health Directors' meeting in March 2013.

## Latin American Countries Amazon Malaria Initiative

**Goal: By the end of 2013, Amazon Malaria Initiatives countries will have institutionalized national and regional mechanisms to assure a continuous supply of antimalarials as the key malaria control strategy, particularly in low incidence areas.**

Most of the targets were met. The finalization of research protocols, and therefore the implementation of studies, has been delayed due to conflicting agendas of the principal researchers. The closure of the USAID mission in Bolivia imposed additional restrictions in the implementation of the work plan.

### **Objective 1: Pharmaceutical sector governance strengthened**

The antimalarial requisition and dispatch forms and e-tools elaborated for Honduras were adjusted, considering the new MoH administrative structure.

SIAPS visited Bogota, Colombia, in June 2013 to assess the progress in implementing pharmaceutical management activities supported by AMI. The requisition and dispatch electronic application (in MS Excel) for malaria medicines and commodities has been implemented in all relevant departments. The reliability of the information and opportunity of the report is still low.

SIAPS consultants visited Paramaribo, Suriname, on May 2013, for a follow-up on the pharmaceutical management activities supported by AMI. Responding to the request of national counterpart, SIAPS had the study “Bottlenecks in the Procurement through the PAHO Strategic Fund” translated to English and distributed to AMI English-speaking countries and shared storage manuals and pharmaceutical guidelines for the primary health level. SIAPS also collected data to assess the feasibility of a knowledge, attitude, and practice study that focused on the access and use of medicines in the mining areas.

The malaria pharmaceutical management guidelines for primary health facilities were finalized and validated in Colombia and Bolivia. SIAPS couldn’t support the printing and distribution of these guidelines in Bolivia because of the closure of the USAID Mission in that country.

SIAPS distributed Spanish and English version of “Criteria for Programing and Distributing Antimalarials in Low Incidence Areas.” The final reports 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.

The next AMI steering committee meeting is scheduled for September 2013.

### **Deliverables**

- E-application and procedures for dispatch and requisition of antimalarials in Honduras
- E-application and procedures for dispatch and requisition of antimalarials in Colombia

- Pharmaceutical guidelines for primary health facilities in Colombia
- E-application for the consolidation of supervision forms in Guyana

**Objective 2: Pharmaceutical management information available and used for decision making at different health system levels**

IAPS used the Centers for Disease Control’s Epi Info™ software tool to consolidate the information generated by the malaria supervision system in Guyana.

DIGEMID and SIAPS transferred the coordination of the malaria regional stock monitoring system to the PAHO Strategic Fund. Through its national consultants, SIAPS supported national counterparts in the collection of information. The first quarter bulletin (January–March 2013) was distributed by the PAHO/SF in May 2013. Ten countries (including some in Central America) provided data.

SIAPS is still processing the information to finalize the performance assessments of malaria control strategies (using an adequacy approach) for three Central American countries.

**Deliverables**

The first quarter (January–March 2013) regional bulletin on monitoring of antimalarial stocks in AMI countries

**Partner contributions**

The coordination for the quarter monitoring bulletin of antimalarial stocks in AMI countries was transferred to PAHO.

**Objective 3: Pharmaceutical services improved to achieve desired health outcomes**

The USAID/AMI diagnosis of the structural conditions of the department medial stores in Honduras could not be completed because two remote stores were not evaluated due to the lack of local resources for transportation.

SIAPS consultants completed the collection of data for the study on access and use of antimalarials in Brazilian gold mining areas (garimpos).

In Suriname, SIAPS collected data to assess the feasibility of a knowledge, attitude and practice study that focused on the access and use of medicines in mining areas.

**Deliverables**

Progress report: Implementation of criteria for programing and distributing antimalarials in low-incidence areas

## Lesotho

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

No significant progress has been achieved in strengthening pharmaceutical sector governance. There have been delays in finalizing the STGs that are to be used to ensure that performance indicators for objective 1 are met, including setting of baselines and targets. SIAPS is working through concerted communication and advocacy efforts to pharmaceutical directorate to ensure that technical assistance for implementation of STGs and EML is accomplished. Quality assurance mechanisms for ARVs and other HIV-related commodities have been partially implemented. The Minilab™ was procured under the SPS Program to initiate commodity testing. SIAPS then procured the quality assurance testing standards for National Drug Service Organization (NDSO). However, the standards cannot be located and there are questions as to whether they have expired or not. Therefore quality assurance testing of commodities has not been conducted. SIAPS is currently establishing what might have happened to these standards at NDSO.

The second performance objective is to enhance and increase capacity for pharmaceutical supply management and services. The performance indicators for this objective will be measured once the Supply Chain Options Analysis (SCOA), scheduled for completion in the next quarter, is finished. The draft protocol and the data collection tools have been developed and data collection will commence in the next quarter. The procurement process for pallets, shelves, and refrigerators has been initiated to support 16 health centers and one hospital. The curriculum review process at the National Health Training Centre (NHTC) has already started and a consultant was engaged by the end of the quarter. The reviewed curriculum and the report will be available by the end of the next quarter.

SIAPS has made considerable progress to ensure that information use for pharmaceutical and laboratory decision-making is increased across all levels of the Lesotho health system (objective 3 in the work plan). ART PMIS and laboratory LMIS information has been analyzed with stock status reported through technical reports that have indicator information for the Supportive Supervision and Mentoring (SSM) program. This information will further be published on the SIAPS Supply Chain newsletter pending approval. RxSolution system implementation has been extended to a total of 13 hospitals where the system is available. Implementation of mHealth and ePMIS have been scheduled to the next quarter. The ePMIS portal has already been registered with Econet telecom Lesotho and testing of the system has already commenced.

The last objective in the current work plan is strengthened financing and procurement mechanisms to improve access to health commodities, but the baseline and targets for performance indicators for this objective have yet to be established. This will be done once the SCOA is completed. The NDSO costing analysis report, which will also inform the targets for this objective, has been approved and sent to editorial before printing while a draft protocol and data collection tools have been developed for SCOA. The study will run in the next quarter but planning stages were initiated during this reporting period.

### **Objective 1: Pharmaceutical sector governance strengthened**

The two performance indicators tracked under this objective in the work plan are—

- Percentage of prescriptions that contain an antibiotic
- Percentage of prescriptions in compliance with STGs

There are three sub-objective level indicators tracked, and these are—

- Percent of facilities that have a copy of the revised STGs and EML
- Number of pharmaceutical policies, guidelines and strategies and SOPs developed or updated and submitted for adoption
- Percentage of batches of ARVs that underwent quality checks at NDSO

The aim of the first objective-level indicator is to achieve minimal prescriptions containing antibiotics. There has not been any progress toward achieving either indicator result. Once the STGs are finalized, SIAPS will then provide assistance with editing and formatting after which SIAPS will also provide support for printing the document.

SIAPS predecessor program SPS had procured a Minilab for NDSO, to ensure that the quality of medicines such as ARVs and anti-TB and opportunistic infections (OIs) medicines circulating in the country is assured. However, there has been a delay in implementing the Minilab quality assurance mechanisms for ARVs and other HIV-related commodities.

#### **Constraints to progress**

Despite attempts by SIAPS to advocate for fast tracking STGs approval, this has not happened. SIAPS Supply Chain Management Advisor embedded at the MoH, is working with the new pharmaceutical directorate director to try and expedite the approval process. Furthermore, there has not been any testing of commodities to assure quality of medicines circulating in the country due to unavailability of quality assurance testing standards.

### **Objective 2: Capacity for pharmaceutical supply management and services increased and enhanced**

This objective intends to increase and enhance capacity for pharmaceutical supply management and services in the country. The performance measurements for this objective are—

- The percentage of public sector personnel working in the pharmacy that know how to order according to Lesotho Standard Operating Procedure Hospital Order 04 (LeSOP HOSP ORD 04). This is a procedure used for routine ordering of pharmaceutical products and medical supplies from NDSO for hospitals and DHMTs

- The percentage of public sector personnel working in the pharmacy that order according to LeSOP HOSP ORD 04.

Remarkable progress has been achieved on this objective. The SSM team (Supply Chain Management (SCM) Advisor, Supportive Supervision and Mentoring Coordinators (SSMCs), and District Logistics Officers (DLOs) visited the facilities to support inventory management and ensure that optimum stock levels are maintained. Within the five SIAPS-supported districts, sixteen health facilities have been identified to receive a capacity building package inclusive of refrigerators and pallets. The procurement process is already ongoing and handing over will be done in the next quarter. SIAPS is also supporting installation of shelves at Berea Government Hospital. SIAPS is working with the MoH's Estate Management Unit in finalizing the specifications for the additional shelves. The shelves will be put in during the next quarter. This will increase capacity of the pharmacy store to maintain pharmaceutical commodities under good conditions.

The in-service training program, which is embedded in the SSM program, will continue in the next quarter. It is expected that the performance output for this activity will surpass the set target by the end of this FY. Data from the paper-based PMIS system dating back from October 2012 has been analyzed to show stock levels per ART regimens against the number of patients for the specific regimens.

There has not been any SCM technical working group meetings because of competing priorities within the Pharmaceutical Directorate. The meeting has been scheduled in the next quarter and SIAPS will continue to offer support.

A consultant has been engaged to start work on review of the pharmacy curriculum at NHTC. The team will consist of the consultant and two short-term advisors from HQ to revise the NHTC diploma in pharmacy technology curriculum. This activity will involve extensive engagements and consultations with stakeholders. The final product is expected to be submitted to NHTC by the end of next quarter.

### ***Constraints to progress***

The accreditation process of Millennium Challenge Account-Lesotho constructed health facilities has hindered the SIAPS process of acquisition and installation of pallets, shelves, and refrigerators, as the handover of facilities was delayed. However, a list of accredited sites has been issued by estate management department of MoH and the procurement process is already in progress. Another constraint has been the need for continuously outsourcing transport to conduct SSM visits, which delays the activity. The process of initiating procurement has been done; the purchase request has been raised, request for quotation has been sent to eligible vendors, vendor selection justification has also been done, and request for approval has also been sent to USAID. The expectation is to have the vehicles towards the end of next quarter. Motor vehicles are considered restricted assets and that is why their procurement and approval processes are lengthy.

### ***Deliverables***

- Supportive Supervision and Mentoring technical report— Mafeteng district
- Supportive Supervision and Mentoring technical report—Maseru district

**Objective 3: Use of information for pharmaceutical and laboratory decision making increased across all levels of the Lesotho health system**

Under this performance objective, SIAPS supports increased information use for pharmaceutical and laboratory decision making across all levels of Lesotho health system. This objective is measured by three performance indicators—

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

These indicator targets have not been set yet. Once MoH has approved the SSM program baseline report, these performance measurements will be implemented. The SSM baseline report has not been approved yet; however, there has been significant progress towards achieving this objective.

The SSM program team have been routinely collecting and analyzing data from both the laboratory LMIS and the PMIS. A two-pager analysis form for both the laboratory LMIS and ART PMIS have been developed to inform stock levels, and advise the MoH on possible threats to stock-outs. These analysis documents will be shared in the SIAPS quarterly supply chain newsletter which has been developed and awaiting approval before publication. The newsletter will show the stock status for both laboratory LMIS and ART PMIS over the reporting period. The information generated from the two-pagers shall also be published on SIAPS website and shared among the facilities, MoH headquarters, and other relevant stakeholders. Feedback will be provided to the facilities regularly as denoted in the cross-sectional information flow chart for the National ART program. There is a need to print these flow charts to display at all SIAPS supported facilities and five DHMTs. The purchase request for the printing has already been done and sent for approval. The team is already compiling comprehensive quarterly PMIS and LMIS reports from the data that has been collected since October 2012. These reports detail performance on inventory and information management indicators. Continued support has been extended to facilities for management of both paper-based (laboratory LMIS and ART PMIS) and RxSolution systems.

RxSolution has been implemented in 13 hospitals inclusive of supervision and mentoring. Implementation of the system in Quthing hospital has been scheduled in the next quarter which will also include piloting of the system at Berea DHMT. Installation of requisition module was completed at NDSO following the release of the NDSO IT personnel. The IT personnel is intended to support implementation of the system at NDSO. Both the mHealth

and ePMIS establishment processes are ongoing and their full implementation is scheduled in the next quarter. The ePMIS portal has already been registered with Econet telecom Lesotho and testing of the system has already commenced.

Support has been extended for close monitoring of the laboratory LMIS system. Routine analysis including documentation review have been effected to improve the quality of data and information reported from laboratory LMIS. SIAPS and MoH have compiled two abstracts depicting the work SIAPS has been doing to support MoH in information management for PMIS and laboratory LMIS. These abstracts have been accepted for poster presentation at the Seventh IAS HIV and AIDS Pathogenesis, Treatment, and Prevention Conference in Kuala Lumpur, Malaysia. Despite unavailability of funding for the trip, the abstracts will be shared among the participants at the conference. This will be an ideal platform to share communities of practice at international level as part of knowledge management initiatives by SIAPS.

### ***Constraints to progress***

Staff shortages continue to pose a threat in the consistent use of RxSolution. SIAPS has since encouraged hospitals to ensure that all pharmacy staff are trained to increase system-user pool. This approach will play a significant convenience during staff rotations or while another user is on leave.

There has been a slow response towards implementation of laboratory LMIS especially from the laboratory directorate side. The laboratory logistics coordinator has been slow in implementing the laboratory LMIS despite support that she has been receiving from SIAPS has sought to take over the management of laboratory LMIS program—leading to the two-page analyses.

### ***Deliverables***

- Data salvation/recovery trip report
- Lab LMIS two-pagers and ART PMIS two-pagers
- Two trip reports for support of ART PMIS (RxSolution)
- One trip report in support of laboratory LMIS implementation
- Supply Chain Newsletter draft

### ***Objective 4: Financing and procurement mechanisms strengthened to improved access to health commodities***

In this objective, SIAPS supports the strengthening of financing and procurement mechanisms to improve access to health commodities. The performance measurements for this objective are—

- Value of expired and wasted stock last quarter
- Number of activities to reduce out-of-pocket expenses implemented



- US dollar value of cost efficiencies achieved through targeted SIAPS activities

The baselines and targets for these performance indicators are yet to be established through the Supply Chain Options Analysis (SCOA) and the NDSO Costing Analysis reports. The Costing Analysis report has been approved by NDSO and it has been sent to editorial at HQ for final editing before printing. On the other hand, the draft protocol for the SCOA, and the data collection tools have been developed and data collection will commence in the next quarter. The recommendations from these studies shall be used to improve the supply chain system performance and maximize efficiency.

### ***Constraints to progress***

There have been delays in the process of initiating data collection for the SCOA. However, the draft protocol and data collection tools for the study are available. The study is expected to start in August.

### ***Deliverables***

- Draft protocol for SCOA study
- NDSO Costing Analysis Report

## **Liberia**

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

To improve the availability and use of pharmaceutical information for decision making, SIAPS Liberia in collaboration with the National Malaria Control Program (NMCP) conducted End Use Verification exercises in two counties—Bomi and Cape Mount. These exercises were to monitor the use and availability of malaria commodities in the public sector and to enhance the availability of information for decision making. A total of 24 facilities were visited during this data collection period. A draft report has been ready and has been shared with the USAID. A dissemination meeting has been set up in collaboration with the NMCP for key stakeholders on July 12, 2013, to obtain stakeholder input and buy in for county-level corrective action for gaps identified during the End Use Verification (EUV) exercise. The report will be finalized after the stakeholder meeting.

The USAID Mission requested SIAPS to focus on supporting EUV activities only. This request was captured in the revised work plan which was resubmitted and has received approval from the Mission. SIAPS Liberia office developed a close-out matrix to guide the office close-out in September 2013.

***Objective 1: Capacity for pharmaceutical supply management and services increased and enhanced***

SIAPS concluded its support to the national private sector ACT Technical Working Group coordination activities with technical inputs on the overall design and common reporting tools for rollout of the private sector ACT program. SIAPS worked with the NMCP and the technical working group to finalize the monitoring and supervision strategies and the client referral forms needed for the private sector malaria program.

### ***Constraints to progress***

The results of the recent feasibility study conducted on the RDTs and ACTS for the private sector showed clearly that there was a need to introduce price incentives at the retailer level to encourage the use of rapid diagnostic tests prior to sale of ACTS in the community. The gap between NMCP's position of continuing with the initial set of prices and USAID's position on the need to revise these prices to introduce necessary incentives for retailers remained which led to the Mission's decision to withdraw SIAPS support to the private sector effort in Liberia.

### ***Deliverables***

- Finalized feasibility report
- Meeting reports from ACT technical working group

**Objective 2: Make pharmaceutical information available for decision making**

To make pharmaceutical information available for decision making, SIAPS Liberia conducted End Use Verification exercises in two counties—Bomi and Cape Mount. The total of 24 facilities (2 hospitals, 2 health centers, 2 county drug depots, and 18 clinics) were visited during the data collection period. The report has been drafted and is being reviewed for inputs and editing.

**Constraints to progress**

The EUV exercise was implemented to monitor the use and availability of malaria commodities in the public sector and to enhance the availability of information for decision-making purposes. It requires the review of inventory records and patients' records. Poor quality data which included missing information, incomplete information, and out-of-date records was a challenge to the exercise.

**Deliverables:**

Draft EUV Report

**Partner contributions**

The MoH NMCP collaborated with SIAPS for data collection and analysis.

**Objective 3: Pharmaceutical services improved to achieve desired health outcomes improved**

SIAPS finalized an MOU for engaging the National Drug Service/Community Operated Pharmacy 1 and the private sector outlets for the rollout of ACTs and RDTS during this quarter.

**Constraints to progress:**

Because of several iterations of the private sector plan, the NMCP position not to adopt the feasibility survey results, the activities under this objective were advisedly halted after discussions with the mission.

## Mali

***Goal: Assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes—overall quarter progress***

In PY2/Q3, SIAPS Mali, achieved some activities started during the second quarter and implemented those planned for the third one.

Progress was made on objectives 1, 2, and 3.

According to the IR 1, SIAPS provided technical assistance to the MoH to strengthen pharmaceutical governance. During this quarter, SIAPS proposed, discussed, and validated with the MoH Directorate of Pharmacy and Medicines (DPM) a statement of work and budget for the dissemination of the SDADME (the national guidelines for procurement and distribution of essential medicines) in five regions of the south of Mali. The SDADME describes Mali's supply chain and all the tools, such as forms and registers, that pharmaceutical sector personnel have to use to manage and track pharmaceuticals. During the first year, SIAPS provided technical and financial assistance to the DPM to disseminate the SDADME at the health system's central level. Still remaining is to disseminate the revised SDADME to lower levels of the health system to ensure that it is completely understood and ultimately adhered to by key personnel at the regional, district, health center, and community levels of the health system. This dissemination will occur during the next quarter.

During this quarter, SIAPS also continued to support the DPM to strengthen the existing mechanism(s) for quantification, procurement planning, and monitoring of key health commodities (e.g., malaria commodities and reproductive health commodities), with a view to establishing a regular, sustainable mechanism for these activities. On June 14, 2013, SIAPS assisted the MoH to organize the first meeting of the national technical committee. Regarding IR 2, SIAPS Mali provided financial and technical support to the MoH with a view of increasing and enhancing capacity for pharmaceutical supply management and services.

In collaboration with the National Malaria Control Program (NMCP), a training workshop was organized to train key personnel in approaches to quantifying malaria commodities. During this training, recently developed quantification guides and tools were introduced to be used in quantification to promote consistency, efficiency, and transparency. SIAPS also supported the training of four national managers for one week in Burkina Faso. This training focused on organizing and managing logistics management information systems (LMIS) for medicines. It is anticipated that since knowledge acquired at the training will make DPM, Central Medical Stores (Pharmacie Populaire du Mali), and NMCP managers more comfortable with LMIS concepts, they will be more inclined to participate fully in implementing the redesigned LMIS for health commodities

In addition, SIAPS provided assistance in quantifying and developing a procurement and distribution plan of contraceptives for more than almost 900 primary health care clinics (Centres de Santé Communautaire [CSCOMs]) of Mali for the six upcoming months. This particular

process has not involved the government according to the restriction on family planning commodities that occurred after the coup d'état.

Many activities were conducted during this quarter under IR 3 to support the pharmaceutical management information systems (PMIS) for decision making.

1 PPMRM was submitted, 1 EUV was conducted, and the new LMIS SOPs manual was validated.

***Objective 1: Pharmaceutical sector governance strengthened***

During this quarter, SIAPS provided technical assistance to DPM, NMPC, and PPM to promote good governance in pharmaceutical sector by disseminate the SDAME, a policy document at regional level and building individual and institutional capacity.

The SDAME describes Mali's supply chain and all the tools, such as forms and registers that the pharmaceutical sector personnel have to use to manage and track pharmaceuticals. SIAPS provided technical and financial assistance to the DPM to disseminate the SDADME at the central level of the health system. In this FY, SIAPS planned to disseminate the revised SDADME to lower levels of the health system to ensure that it is completely understood and ultimately adhered to by key personnel at the regional, district, health center, and community levels of the health system. After discussions with SIAPS, the DPM during this quarter adopted the scope of work and budget of the dissemination workshops for the SDADME at the regional, district, and facilities levels. The five regions of south Mali will hold these workshops on July 2013.

In Mali, inadequate coordination exists among stakeholders in the pharmaceutical sector. Lack of information sharing that accompanied this poor coordination has resulted inaccurate quantification and inadequate supply plan monitoring.

The existing technical committees for the coordination of commodities chaired by the DPM (for contraceptives) or the PNLP (for malaria commodities) do not have well-defined terms of reference and do not meeting on regular basis. Furthermore, key actors involved in the Malian supply chain are not invited to these meetings.

According to the recent LMIS assessment conducted during the first year of SIAPS activities, SIAPS assisted the DPM to create an overarching mechanism to coordinate quantification, forecasting, distribution, and corrective actions for health commodities supply.

The first meeting of this pharmaceutical commodities quantification technical committee was called by the DPM on June 14, 2013. During this meeting, the terms of reference for these mechanisms were updated, the roles and responsibilities of the members were clarified, and a calendar of activities was established (which includes quarterly coordination meetings) to ensure that the work of the mechanism is implemented.

SIAPS will provide technical support during quarterly meeting in which the stock levels of malaria commodities, family planning commodities, and key MCH commodities will be reviewed and decisions made concerning corrective actions to take in response to identified supply chain problems.

At the request of USAID Mission, SIAPS provided technical assistance to develop a supply plan for the next six months for contraceptives after an estimation exercise of contraceptive needs. During this quarterly, SIAPS also assisted the PNLN in the elaboration of distribution plans for malaria commodities (ART) delivered by USAID/JSI in May– June 2013.

A distribution plan for more than 900 CSCOMs was also developed by SIAPS for contraceptives commodities delivered by USAID to PSI warehouses. The distribution will be done by ATN plus.

### ***Deliverables***

- Scope of work for the National Committee of Coordination and monitoring of health commodities was adopted
- An action plan to improve quantification process was adopted.
- Supply plan for contraceptive developed and implemented
- Distribution plans for malaria commodities and contraceptives developed and implemented

### ***Partner contributions***

- DPM, PKCII, NMCP, PSI, and WHO contributed to validating the scope of work for the National Committee for Coordination and Monitoring of Health Commodities
- NMCP and PPM participated in developing a malaria commodities distribution plan

### ***Objective 2: Capacity for pharmaceutical supply management and services increased and enhanced***

The second SIAPS objective in Mali is to improve the capacity of key stakeholders at central and peripheral level in pharmaceutical management, to improve the distribution system of products at the peripheral level, and to support supervision of system monitoring.

With the goal of improving quantification to ensure the constant availability of antimalarials in care centers, SIAPS assisted the NMCP to organize a training workshop to strengthen the capacity of the principal stakeholders involved in the needs forecasting exercise at Hotel Columbus on May 7–9, 2013. This workshop was attended by executives (pharmacists and other staff) from the central and regional levels, as well as certain non-governmental organizations involved in the management of antimalarials. The participation of regional stakeholders allowed them to better grasp the necessity of collecting and transmitting information: this has been a major challenge to the quantification activity. During the three days of the training on the new developed manual, the participants learned about principle methods, necessary data, and the formulation of assumptions. At the end of this workshop, a national quantification improvement plan was developed by the participants. They recognized the necessity to create a national

coordination committee to monitor data inputs into the national level quantification. The introduction of tools such as Quantimed to be used for quantification was also adopted.

In April, SIAPS supported the training of four national managers (2 DPM managers, 1 PNL manager, and 1 PPM manager) for one week in Burkina Faso during a training program provided by Bioforce. This training focused on the organization and management of logistics management systems for medicines. It is anticipated that since knowledge acquired at the training will make DPM, PPM and NMCP managers more comfortable with LMIS concepts, they will be more inclined to participate fully in the functionality of the Mali's LMIS for health commodities.

During this quarter, SIAPS provided technical assistance to support contraceptives quantification for the next six months. SIAPS supported the contraceptives needs estimate for the private and public sectors. The quantification method was based on morbidity data, the statistical data having been collected through epidemiological documents review. Private sector needs were estimated using historical consumption data for a period of six months; the public sector estimate was done using utilization rates for each contraceptive method for a period of three months.

To ensure the continuous availability of contraceptives at the community level in the context of sociopolitical crisis in Mali a contingency plan was put in place by the USAID/Mali mission through its implementing projects (Population Services International [PSI], Assistance Technique National Plus [ATN], Projet Keneya Ciwara II [PKC], and SIAPS); this plan set up a provisional supply chain to make contraceptives available to communities through donations made directly to the community health centers.

SIAPS played a critical role in the provisional supply chain success by gathering the necessary data and quantifying adequately the quantity of products to be procured by USAID and distributed to cover the needs of the population at the community level and in the private sector in Mali.

SIAPS collaborated closely with the other implementing projects to provide necessary technical support for warehousing, storage, and distribution of the procured products. For the time being, the provisional supply chain is guaranteeing access to contraceptives for the population until the governmental crisis has abated and the US Government can directly provide aid for family planning commodities.

### ***Deliverables***

The contraceptives needs estimate for public and private sectors

### ***Partner contributions***

- DPM, NMPC, and PPM participated in the LMIS training
- USAID, ATN, PKC, and PSI participated in the contraceptive needs validation.
- NMCP, DPM, PSI, President's Malaria Initiative, DNS, and six regional health directors (Directeurs Régional de Santé) attended the training on malaria commodities quantification.

**Objective 3: Pharmaceutical management information available and used for decision making at different levels of the Malian health system**

In Mali, key weaknesses in the pharmaceutical sector include unavailability of regular, reliable pharmaceutical management information for decision making and an inadequate and fragmented logistics system which doesn't take the community level into account regarding stock management tools and inventory systems. As a result, stock-outs of life-saving commodities are frequent at all health service delivery points.

During this quarter, SIAPS worked with the PPM and the NMCP to produce and submit the quarterly Procurement Planning and Monitoring Report for malaria (PPMRm). The PPMRm focused on the availability of malaria commodities at the Central Medical Stores (PPM).

The PPMRm reports along with ACT and RDT needs estimation were submitted on April 2013. These data collected through PPMRm were shared with decision makers to facilitate procurement decisions for malaria commodities and to help the NMCP to make distributions plans for malaria commodities (sulfadoxine-pyrimethamine and rapid diagnostic tests) received in the country.

SIAPS also coordinated and conducted with the NMCP an end user verification (EUV) survey by following the sampling protocol and the EUV guidance introduced by PMI in 2011. This process is used to assess the availability of malaria commodities at the end-user level. The end user verification process informs policy makers and planners on the effectiveness of the health system in making malaria commodities available to those who need them.

The technical assistance provided to the NMPC by SIAPS consisted of describing the protocol, organizing data collection, analyzing and using information to make decision at different level regarding commodities availability, storage, and medicine prescription. In July, a workshop will be held with NMPC to validate and share EUV results for decision making.

During the last quarter, SIAPS Mali focused on building on the LMIS assessment conducted in the first year of the project by supporting Mali's MoH in redesigning the LMIS to improve inventory management, record and transmit LMIS data, improve ordering and orders fulfillment, reduce stock-outs, and improve availability of health commodities at all health system levels.

SIAPS assisted the DPM (MoH) to organize a national workshop in March 2013 with the key actors of Malian supply chain from all level of the health system (central, regional, district, and community). USAID implementing partners such as PSI, ATN Plus, PSI, and PKCII also participated in this workshop in which, role and responsibilities regarding Malian logistic information system for pharmaceuticals were specified. All the participants agreed on tools, frequency and mechanisms to report logistic data from the community level to the central level.

The output of this workshop developing a standard operation procedure (SOPs) manual for the management of pharmaceuticals logistic information system in Mali.



During this quarter, SIAPS assisted the DPM to validate the new LMIS SOP manual. The next step of this process will be the TOT workshop planned for September.

***Deliverables***

- PPMRm report submitted
- ACT and RDT needs submitted
- Draft of EUV survey report
- LMIS SOPs validated manual

***Partner contributions***

- USAID, NMCP, PPM contributed to the elaboration and the validation of the PPMRm report, and to the ACT and RDT needs estimation
- NMCP, PPM, DRS, and CSCOM participated in the EUV survey
- NMCP, PPM, DPM, ATN, PSI, PKCII, and WHO contributed to the validation of the new LMIS SOPs manual

## Mozambique

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

### **Overall Quarter Progress**

Based on the gaps that have been identified in the pharmaceutical system in Mozambique, SIAPS has been focusing on supporting the pharmaceutical sector in the areas of policy, regulatory functions and pharmaceutical systems. This quarter, April through June 2013, SIAPS/Mozambique made significant progress towards meeting targets.

For this quarter, the SIAPS Senior Technical Advisor along with Dr. Orlas from the Pharmacy Department carried out a Pharmacy Department M&E framework and indicators assessment in June 2013. The effort introduced indicators which can be rolled up to measure progress across all PD sectors. These indicators and the framework will continue to be updated in collaboration with the PD. Further, the SIAPS Portfolio Manager visited Mozambique to follow-up on administrative and USAID/stakeholders communications. She also assisted the CPD on MSH office registration identifying the local law firm and finalizing the contractual paperwork. In addition, the SIAPS team continued discussion on harmonizing the SIAPS FY 14 work plan with the Pharmacy Department, Hospital Pharmacy Department, and USAID—this resulted in an initial list of activities for the next year work plan to be budgeted and further negotiated.

### **Objective 1: Governance in the pharmaceutical sector strengthened**

Activities under this objective emphasize the use and institutionalization of management processes that are transparent, participatory, and consensus-oriented. The expected outputs for this quarter were to continue the process of defining and revising the national Essential Medicines List (NEML), and to begin the process of revising and institutionalizing a monitoring and evaluation plan with appropriate, agreed-upon indicators linked to a results framework.

In an effort to streamline procurement activities, minimize institutional costs, and optimize patient care, SIAPS has been supporting the Pharmacy Department (PD) to revise and update the NEML. Building on work begun last quarter, SIAPS submitted a concept note, terms of reference (TOR) for the committee, as well as procedures and guidelines for updating and reviewing the NEML. These have now been approved by the PD and the MoH. Selection of committee members is under development. During the next quarter, the committee will begin the review process. The results of the committee meetings and review of the EML will be a list of all medicines approved for procurement and use in Mozambique's public health sector, providing the basis for the development of regional, hospital, and clinic formularies lists.

In June, SIAPS supported the PD to focus on key indicators that will provide useful information to improve effectiveness, accountability, and transparency in the PD. The first steps were to facilitate the definition of goals and objectives for the PD based on its priorities, and the standard goals and objectives for a functioning regulatory authority. SIAPS then began working with the PD to develop/adapt a results framework and a core set of performance metrics based on their

current M&E and data collection systems, in collaboration with and through in-depth interviews with the PD department sector heads. SIAPS presented the draft indicators and framework to the PD sector heads and is now in the process of updating them, based on feedback, for review and approval of the PD. Once they are agreed to, SIAPS will continue to build the capacity of designated staff to generate and report on these indicators, and to use and disseminate the information appropriately.

### ***Deliverables***

- NEML concept note, committee TOR, reviews and updated procedures and guidelines approved; nomination of committee members is in process
- M&E framework and indicators proposed for PD results reporting

### ***Constraints to progress***

- Approval of the NEML concept note took more than two months; it is expected that the nomination of committee members will take another month.
- The absence of an approved strategic plan for the PD limits the creation of a strong link from the plan to the framework and indicators. The PD team has little capacity and understanding of monitoring and evaluation. This is going to require quite a bit of training and continued reinforcement of M&E concepts and practical applications.

### ***Objective 2: Capacity in pharmaceutical management increased***

No activity planned for this quarter under this objective. Discussions have been held with the PD, Hospital Pharmacy Department (HPD), and USAID about activities for the next work plan year.

### ***Constraints to progress***

Two provincial-level pharmacovigilance centers have been established. However, the actual status of these units and their activities are not clear and there is no documentation.

### ***Objective 3: Utilization of strategic information for decision-making increased***

To improve the utilization of strategic information for decision-making, SIAPS continued to provide technical assistance to support the implementation of an electronic information system for the regulatory system, in particular, the automation of the registration process using the automated registration system, PHARMADEX. The support provided this quarter focused on further discussions surrounding the institutionalization and sustainability of the system and its future use in the regular functions of the PD. The proposed roadmap for developing and using the automated system has been approved and preparation for the implementation of the automated system has started, including the adoption of the common technical document system for all medicine registration forms. In addition, SIAPS customized the system (including translation). It is ready for testing by PD staff.

***Deliverables***

- Draft training and instructional materials to serve as references for users and maintenance providers  
Medicine automated registration review, workplan developed and agreed upon

***Constraints to progress***

- Storage of the registration files is not organized appropriately and needs a full reorganization and a proper storage/identification system to be able to identify application locations and content when it is not needed. The PD is currently looking for funding to support this reorganization.
- There is no IT support in the PD, which is essential for the successful automation of the registration process. SIAPS is working closely with the PD administration to identify solutions to overcome these limitations to a successfully automated registration system.

***Objective 4: Financing strategies and mechanisms strengthened to improve access to medicines***

The aim of this objective in the current and subsequent quarters is to assist the PD with the development of a price control system for medicines. SIAPS is working with the PD to propose a new roadmap for enforcing the price control system and to build staff capacity to properly control and enforce the system within the current pricing law. The draft assessment/roadmap report was developed this quarter and is currently being translated. A stakeholder meeting will then be conducted following discussion and review with the PD Head and Sector Leads. Continued technical assistance will allow for a more effective system to update and control prices at regular intervals and according to specific criteria.

***Deliverables***

Draft assessment/roadmap report, including best practice review and strategic plan for discussion that integrates the proposed pricing practices into the overarching selection and regulatory framework for health products in Mozambique

***Constraints to progress***

- There is only one, newly appointed pharmacist in charge of the pricing system, whereas at a minimum, there is need for two staff for pricing regulations and two staff for price-related inspection.
- There are no laws in Mozambique to empower the price control system and support its enforcement.

***Objective 5: Pharmaceutical services to achieve desired health outcomes improved***

SIAPS is working to improve pharmaceutical services so that medicines are not only available at service delivery points but are also prescribed and dispensed appropriately, used correctly by patients, and monitored for safety and efficacy with the aim of achieving desired health outcomes. The Department of Hospital Pharmacy at DNAM has identified the establishment of DTCs at hospitals as a priority intervention to improve the appropriate use of medicines at the hospital level. The MoH has already established DTCs in five hospitals, and another seven hospitals have started the process of establishing their DTCs. During this quarter, SIAPS also worked on the preparation of a workshop (to take place next quarter) to further develop DTCs at the hospital level and to review and update the TOR for these committees. The workshops will also focus on the preparation of a plan to build the capacity of related stakeholders at two pilot central hospitals' DTCs in Maputo province to identify any potential subject or issues (such as STGs or other rational drug use issues) they have in that particular hospital. In addition, the HPD has identified these two hospitals as pilot sites in Maputo city, as they are close to the HPD and SIAPS, allowing for close monitoring and capacity building of these hospitals to identify opportunities for rational drug use interventions.

***Deliverables***

TOR for DTCs for Twelve hospitals  
Inventory of existing STGs

***Partner contributions***

The HPD contributed time to help develop activities under this objective.

***Constraints to progress***

There has been some delay in getting the HPD fully engaged. There are only two staff members, including the Head of the Department. They have many competing priorities.

## Namibia

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

### **Objective 1: Pharmaceutical system governance strengthened**

Discussions between SIAPS headquarters and SIAPS Namibia on the implementation of the upgraded web-based Pharmadex continued. The implementation will take place in a modular fashion, where the registration module will be implemented first before the rest (quality control, inspection, and pharmacovigilance). Emphasis will be put first on the registration module that will be demonstrated to the NMRC in Q4, after which customization to suit NMRC will begin. A scope of work (SOW) detailing the technical assistance to implement the upgraded Pharmadex was completed and submitted to SIAPS headquarters for review and finalization; it is currently awaiting headquarters concurrence to initiate planned activities. About 10% progress has been made against the annual target of 75%.

During Q3, SIAPS supported NMRC to develop a data collection and reporting system for in-country post-marketing surveillance (PMS) of the quality of antiretroviral and other essential medicines. SIAPS also supported NMRC to draft a memo to encourage passive reporting of suspected poor quality medicines by health care workers. NMRC sent the memo to hospitals and the private sector, along with a form for reporting medicine quality issues. The activity is about 60% complete.

The Quality Surveillance Laboratory is liaising with the WHO-accredited Centre for Quality Assurance of Medicines, South Africa, to confirm the results from 3 tests of PMS samples that failed. The 3 samples came from 12 samples submitted for testing on the basis of 12 PMS reports in Q2.

SIAPS continued discussions with the Health Professions Council of Namibia (HPCNa) on streamlining processes to evaluate applications for registering pharmacy professionals. HPCNa constituted a technical working group (TWG) that will liaise with SIAPS Namibia on this activity. The first consultative planning meeting with the TWG was held with the members of the Education Committee of the Pharmacy Council. A scope of work (SOW) for this activity was completed, and SIAPS is currently searching for qualified consultants to undertake the planned tasks by July 2013. Development of the framework is expected to be completed by mid-August and training undertaken in mid-September. Activity is 20% complete.

SIAPS supported MoHSS in completing support supervision visits (SSVs) to the two remaining regions (Otjozondjupa and Khomas) during Q3. However, the SSV for Otjozondjupa couldn't be conducted because of the unavailability of key personnel from the National Medicines Policy Coordination (NMPC) sub-Division of MoHSS. SIAPS is supporting MoHSS in compiling the technical report which should be ready in Q4. The report will provide recommendations for improving the delivery of pharmaceutical services at health facilities. Otjozondjupa region will not be included in the report.

SIAPS provided financial support for the Essential Medicines List Committee (EMLC) meeting held on June 26 and 27, 2013, in Windhoek. This activity was transitioned to MoHSS in 2012; however, a request for support was received in May 2013 to facilitate this meeting. The meeting was held to review motivations for changes to the Nemlist and the STGs to reflect the latest cost-effective treatment options and to enable availability of the medicines recommended in the STGs.

***Deliverables and constraints to progress***

The SSV technical report is about 80% complete. Delays are due to the non-submission of data for some of the health facilities visited by the assigned MoHSS team-leaders. Follow-up with MoHSS counterparts is on-going.

Pharmadex implementation is lagging behind due to delayed support by the SIAPS headquarter technical team.

***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***

SIAPS linked University of Namibia School of Pharmacy (UNAM-SoP) to MoHSS's Division of Pharmaceutical Services for support in the induction of UNAM pharmacy students for rural workplace placements, a practice that enhances students' practical training. The four-week workplace placement provides the students with hands-on experience in providing pharmaceutical services at the health facilities. In preparing the students for the fieldwork, SIAPS provided the UNAM-SoP with data collection spreadsheets and oriented the students on how to collect, analyze and present data on key medicine use indicators for decision-making. The training was intended to build students' capacity to assess pharmaceutical service delivery and develop their pharmaceutical management competencies.

A total of 28 pharmacy assistants (PAs) graduated from the National Health Training Center (NHTC) on May 16, 2013. Their training was made possible through SIAPS' assistance to NHTC in the form of staff support, development of teaching materials, and improvements in classroom- and workplace-based learning, among other forms of assistance. Additionally, NHTC enrolled 34 students for the 2013/2014 PA course intake. Moreover, SIAPS supported the installation of IT equipment that was delivered in Q2. The equipment will help to virtualize the classroom environment and enable tutors to utilize a cost-effective, computerized local area network that comprises a server and dummy terminals (thin clients) in delivering lectures and electronically managing student assignments, assessments, and course work. SIAPS will continue supporting NHTC to strengthen the output and quality of PA training in the country to increase the pharmaceutical workforce size in a sustainable manner.

The UNAM-SoP is to develop a five-year strategic plan to guide the transition of the UNAM Department of Pharmacy to the School of Pharmacy (SoP) and ensure achievement of long-term objectives; a short-term consultant is being sought for the project.

SIAPS is in the process of identifying a consultant to support UNAM-SoP with compiling teaching materials focusing on pharmaceutical supply management for the pharmacy practice module. This material is intended for BPharm course and will be further customized for the NHTC PA course.

SIAPS helped coordinate the dissemination of results from the analysis of NIP data that TIPC conducted in Q2 at the Pharmaceutical Symposium that was held on June 22, 2013 at UNAM.

### ***Constraints to progress***

Staff shortages at NHTC delayed the commencement of studies of PAs enrolled for the 2013/2014 intake. SIAPS continued dialogue with USAID and MoHSS to find interim measures as a permanent solution is sought.

### ***Objective 3: Pharmaceutical metrics developed and the availability and use of data for making strategic, evidence-based decisions improved***

SIAPS staff together with MoHSS counterparts updated the Pharmaceutical Management Information System (PMIS) training materials to reflect changes made by the PMIS Review Task Force. Selected indicators were updated to guide improved and more useful data collection. The changes included defining HF1 (changed from a cross-sectional assessment of key items availability to longitudinal assessment), updating the calculation of HF15 (to improve accuracy of the indicator results, and adding indicator HF23 (annual pharmaceutical expenditure per patient visit; a case study was developed for this indicator). Preparations for two PMIS trainings scheduled for July 2013 were also made.

SIAPS assisted MoHSS with the comparison of Electronic Dispensing Tool (EDT) and the Electronic Patient Management System (ePMS) patient data for December 2012 and March 2013. This is a data quality assessment measure to ensure high-quality data for decision making. A summary of the findings were shared with MoHSS during the quarterly data validation meeting in May 2013.

In collaboration with the NMPC and Directorate of Special Programs (DSP) staff, two EDT mobile training workshops were conducted to improve ART data quality and stock management at ART Integrated Management of Adult and Adolescent Illness (IMAI) sites. EDT data is used for quarterly ART reporting, including detailed analyses of patient numbers, antiretroviral medicines, ART regimens, and HIV/DR resistance indicators. A total of 56 nurses, nurse supervisors and pharmacy assistants were trained on the use of the EDT mobile to ensure accurate and timely capturing and reporting of ART patient and stock data at IMAI sites. These sites have no pharmacy staff and currently use a manual (paper-based) system to manage their ART patient and stock data. The trained participants from Katima Mulilo, Rundu and Nankudu districts developed post-training implementation plans to use the EDT mobile starting in June 2013. Participants from Omusati, Ohangwena, Oshikoto, and Oshana regions developed post-training implementation plans for implementing the EDT mobile at IMAI sites. The Ministry is following up with the individuals who were trained to provide them with ongoing support. One post-training follow-up/support visit conducted to Caprivi region showed that the trainees had already started implementing activities, such as updating data records.



SIAPS technical staff participated in month-long trips to all health facilities to upgrade their EDT computers' hardware and software. The software upgrade included additional functionalities to facilitate implementation of the EDT mobile for ART data capturing and reporting at the primary health care level. The SIAPS technical team continued to provide advice to DSP on developing a plan for implementing a mobile phone-based short messaging service (sms) reminder system for patients who delay in their appointments for collecting their ARV medications from ART sites.

Together with SCMS staff, SIAPS assisted MoHSS' ART logistics pharmacist to aggregate and compile the ART patient data required for the annual WHO survey from the national database. The exercise was used to identify patient records having erroneous information. These records were extracted onto MS Excel sheets and will be sent to facility pharmacy staff to verify and update their EDT records.

### ***Deliverables***

EDT training report; a technical report showing notable improvement in ART data quality for Caprivi region, where the variance between EDT and ePMS data went down from 49% in December 2012 to 9% in March 2013. This analysis was a follow-up on the site visits that were conducted in February 2013 through SIAPS support by a joint team from MoHSS/RM&E and SIAPS.

### ***Partner contributions***

Collaboration with CDC Namibia on formulation of SMS reminder implementation plan for ART adherence

### ***Constraints to progress***

PMIS data collection and reporting at CMS and RMS is behind schedule. The matter was discussed at the last Project Steering Committee meeting held on June 12, 2013. MoHSS counterparts will take remedial action.

Because of pharmacy staff shortages in some parts of the country, EDT data for December 2012 for Ongha HC, Nankudu DH, Nkurenkuru HC, Rundu IH, and Okakarara DH was not available for the quarterly ART data verification exercise.

### ***Objective 4: Financing strategies and mechanisms to increase access to medicines strengthened***

The National Tuberculosis and Leprosy Programme (NTLP) provided concurrence for SIAPS to rollout the eTB Manager to the rest of the nine DR-TB treatment sites. A follow-up meeting was held with NTLP in May to discuss implementation of the tool rollout. Drafting the e-TB manager rollout plan and SOW for technical support was completed; both documents are currently under review for finalization and implementation in Q4.

**Objective 5: To strengthen pharmaceutical services delivery to improve adherence to HIV/TB treatment, enhance achievement of health outcomes, and contain antimicrobial resistance**

SIAPS technical advisors developed a concept note for implementation of adherence interventions that was discussed by the MoHSS' adherence technical working group (TWG) on May 31, 2013. A joint work plan for implementing activities by MoHSS and its partners was prepared.

SIAPS staff, together with members of the adherence TWG, drafted an implementation plan for use of SMS technology/reminder system to improve ART adherence. The adherence TWG identified community-based organizations that can partner with health facility staff to trace patients who are late, lost, or lost-to-follow-up to enhance retention on ART. Discussions are on-going to strengthen linkages between facility staff and the organizations.

SIAPS coordinated with TIPC to provide technical assistance for follow-up and analysis of data collected from a cohort of 453 patients currently enrolled in the active surveillance of ARV safety at Windhoek Central and Katutura State Hospitals. A statement of work for the University of Washington to support the activity was completed and signed-off by the university.

SIAPS supported training of 26 Project HOPE's TB field promoters in Kavango region to improve reporting of adverse reactions to TB/HIV medicines. SIAPS staff conducted a support visit to Project HOPE's office in Ongwediva and trained the clerk on how to enter data in the adverse medicine reaction spreadsheet. SIAPS collaborates with Project Hope to improve community-based pharmacovigilance focusing on anti-TB and ARV medicines.

SIAPS staff participated in advocacy for pharmacovigilance through a presentation made to health care workers in Ohangwena region during the region's monthly capacity building seminar that was attended by 27 medical officers and nurses.

Printing of the October 2012–March 2013 issue of TIPC's Namibia Medicine Watch is underway; dissemination will be done in Q4.

SIAPS staff prepared a briefer and a PowerPoint presentation on HIV drug-resistance early warning indicators (HIVDR EWIs) implementation in Namibia for presentation at the USAID Summits on the Air South Africa (SOTA) regional meeting in Johannesburg, May 5-10, 2013. The presentation highlighted lessons learned in using routine ART pharmacy data to monitor HIVDR EWIs. Also, a meeting of MoHSS/ Response Monitoring & Evaluation (RM&E) sub-Division, Tufts University and SIAPS agreed on the way forward on EWI data validation and compilation of the HIVDR-EWI technical report as well as the implementation of suitable public health interventions for containing HIV drug resistance. Routine EWI data validation, which had been pending since October 2012, was restarted with assistance from Tufts University.

SIAPS staff participated in meetings held June 12-14, 2013, to develop a comprehensive HIVDR monitoring and prevention strategy for Namibia. In addition, SIAPS staff participated in a meeting held on June 24, 2013, to disseminate results of HIVDR EWI data abstraction and

analysis as well as HIVDR prospective survey findings. At this meeting, SIAPS staff made a presentation on the EWI component.

SIAPS continued providing technical assistance to Namibians Against Antibiotic Resistance (NAAR), a multidisciplinary coalition that was jointly formed in 2012 by Windhoek Central and Katurura Hospitals. In April-June, SIAPS provided technical assistance through provision of manuals to guide strategic planning for NAAR activities as an organization. Two advocacy meetings were held. UNAM was introduced to NAAR to support NAAR in conducting operational research that generates evidence to inform policy and clinical guidelines decisions.

### ***Deliverables***

- Briefer (for USAID/Namibia) on HIVDR EWI implementation presented at the USAID SOTA regional meeting in Johannesburg in May 2013
- 1 medicines watch (Oct 12 – Mar 13) under print for dissemination in July 2013
- Article entitled “Antimicrobial Sensitivity Patterns of Cerebrospinal Fluid (CSF) Isolates in Namibia: Implications for Empirical Antibiotic Treatment of Meningitis” published in the *Journal of Pharmaceutical Policy and Practice*
- 2 abstracts submitted for presentation on ICASA 2013: “Effect of Change in CD4 Count Threshold for Initiation of Antiretroviral Therapy on Rates of Substitution from Nevirapine to a Protease Inhibitor in Namibia” and “Increase in Reports of Nevirapine-Associated Serious Adverse Events in Namibia: Is This Cause for Concern?”

### ***Partner contributions***

- Tufts University, Boston, USA, on EWI data validation and dissemination of HIVDR results
- Project Hope trained 26 TB field promoters for community pharmacovigilance

### ***Constraints to progress***

- Delays in the reproduction of the treatment literacy DVDs and flipcharts caused by misquoted pricing for production of the flipcharts and MoHSS’s withdrawal from production of the DVDs because of inability to access funds from the Global Fund
- Number of adverse event reports received is below the expected number based on WHO guidelines of 200 reports per 1 million people annually. More advocacy is needed to increase level of reporting of adverse events.
- Declining enthusiasm of NAAR members because of failure by NAAR to call regular meetings

## Philippines

**Goal: To strengthen key institutions in reducing the TB burden through increased access to quality and effective pharmaceutical and laboratory services.**

**Objective 1: Capacity for pharmaceutical and laboratory supply management improved**

To support the national TB program (NTP), SIAPS focuses on improving the capacity of the human resource management system for laboratories and pharmaceutical services for the program management of drug-resistant TB (PMDT).

To identify gaps in human resource management systems, an analysis of the situation in NTP laboratories and PMDT clinics across the country was started. Data collection methods include: a survey of group and organizational climate; a survey of group/organizational culture and teamwork; and key informant interviews.

To strengthen the capacity of health workers to lead and manage TB pharmaceutical services, SIAPS assisted the Quezon City Health Department to write an abstract reporting on their experiences strengthening grassroots TB program leadership and management in one of their urban poor communities (i.e., Payatas). The abstract was submitted to the 2013 UNION World Conference.

SIAPS continued to support the NTP and partners to ensure the smooth functioning of drug supply management for second-line anti-TB medicines. SIAPS worked with the NTP and partners to revise the forecast for second-line drugs based on the actual number of patients enrolled, rather than Global Fund targets. There is currently no critical danger of stock outs. Several drugs, such as p-amino salicylic acid (PAS), were ordered to ensure sufficient lead time for procurement. The team is closely monitoring other drugs for possible expiration due mainly to lower than anticipated patient enrollment.

SIAPS successfully coordinated the procurement of clofazimine, used for extensively drug-resistant TB treatment. The medicine was received and there was no interruption in the supply of this drug.

SIAPS implemented the Food and Drug Administration of the Philippines' (FDA) requirements for the registration process for second-line drugs. SIAPS ensured that the NTP appointed a focal person to follow up on registration with the FDA. Next steps will be to acquire the filing requirements from the manufacturers and to submit complete requirements to the Philippines' FDA.

SIAPS followed up on the possibility of changing the PAS formulation used by the program from one requiring a cold-chain to a room-temperature salt formulation. The decision is currently pending approval by the NTP technical working group.

The Department of Health's Materials Management Division and the NTP approved and are willing to collaborate on tracking TB medicines and commodities from the central level to peripheral stock storage levels.

A first draft of the Action-oriented Practical Guide for Pharmaceutical Management was developed. Consultations with stakeholders will be initiated to ensure applicability and usability of the document. Job aids to complement the Practical Guide will be developed upon its finalization. The adoption of guidelines, SOPs, or job aids in government systems requires approval and clearance by several government units. SIAPS developed terms of reference for approval by the NTP and Materials Management Division as a first step in this process. At the request of PMDT, SIAPS assisted in drafting and revising the PMDT pharmaceutical management monitoring form.

SIAPS initiated coordination of the GeneXpert supply from the Global Fund Principal Recipient (The Philippines Business for Social Progress [PBSP]) to the National TB Reference Laboratory (NTRL).

Management of laboratory supplies is still a problem. SIAPS is coordinating with the NTRL to conduct training and offer support in this technical area.

### ***Deliverables***

- Draft action-oriented guidelines (under peer review)
- Draft PMDT monitoring form
- Request and terms of reference for adoption of the above-mentioned documents
- Abstract on TB Grassroots Leadership and Management in Payatas (Quezon City)

### ***Constraints to progress***

- Ad hoc requests from NTP national managers to support their activities are competing with planned activities. Responses to the ad hoc requests were approved by USAID/Philippines.
- Difficulty in setting up a schedule with the NTRL for laboratory supplies management work.
- The decision to change the PAS formulation has to pass through TWG approval, but the TWG will not meet until July 2013.

### ***Objective 2: Capacity for transparent and evidence-based decision making increased***

All components of the current TB information system need to be strengthened, from data collection processes to the generation, dissemination, and utilization of reports and other products to inform program managers and decision makers.

SIAPS is supporting the NTP to develop a plan to strengthen the NTP information system. SIAPS is currently leading the situation analysis of the NTP information system in preparation for the planning process. Data collection for the situation analysis is ongoing.

SIAPS helped the NTP to write and finalize the NTP country surveillance report (the TB Profile of the Philippines) that was published in April–June 2013 issue of the WHO Western Pacific Surveillance and Response Journal.

To increase the availability of quality TB data and the use of data for decision making, SIAPS is supporting the Department of Health in moving to migrate data from e-TB Manager to the department's information management systems. This quarter, SIAPS worked with the Department of Health to finalize the plan for Phase II data migration from e-TB Manager to the system, extracted TB patient and diagnostic data from the e-TB Manager database for migration to ITIS, and drafted a data migration report. In collaboration with the NTP, the Department of Health Information Management Services Unit, and other stakeholders, SIAPS participated in the Health Information Management forum.

### ***Deliverables***

NTP country surveillance report

### ***Constraints to progress***

- Difficulties in coordinating schedules with program managers, particularly at the national level, because of current activities for the revision of the Philippine strategic plan for TB control, revision of the NTP's Manual of Procedures, and preparation of the Global Fund concept note.
- Ad hoc requests from NTP national managers to support their activities related to the development of national strategic plans/policies and guidelines are competing with planned activities. Responses to the ad hoc requests were approved by the USAID Mission.
- Shifting timelines of partners.

### ***Objective 3: Pharmaceutical services strengthened for improved outcomes in TB case management***

SIAPS supported the NTP in the development of NTP strategic plans, policies, and guidelines, which will help improve leadership, management, and governance of the program.

As technical lead in the laboratory working group, SIAPS supported the NTRL to develop the NTP laboratory strategic plan that aims to improve the laboratory services' effectiveness and quality, accessibility, management systems and leadership, and ensure the sustainability of services. The plan also forms part of the foundation for new Global Fund support to the Philippines. The strategic plan was presented and approved by the DOH's TB TWG. It was also presented for comment to key stakeholders, including laboratory and program managers at regional and local government unit levels, patient groups, and other partners.

Working with the NTP working group (NTRL, USAID-funded IMPACT project, NTP, PMDT), SIAPS provides ongoing technical assistance to the NTP for the revision of the NTP Manual of Procedures. SIAPS support includes: review and revision of policies and procedures for TB diagnosis and treatment; preparation of technical briefs on the incorporation of new diagnostics

in NTP case finding; revised policies and procedures for monitoring, evaluation, and supervision, recording and reporting, including revision of indicators; and procedures for PhilHealth (the Philippines's national health insurance corporation) DOTS accreditation and for the management of adverse drug reactions. SIAPS wrote the draft for the NTP Manual of Procedures section on Management of Medicines and Laboratory Supplies.

SIAPS is a key member of the working group for the revision of the NTP strategic plan (PhilPACT) and for the preparation of the country's concept note for the Global Fund's New Funding Model. The project provided technical input for the analysis of PhilPACT's status and the formulation of revised performance targets and key activities. These are now being used to guide the preparation of the concept note for the Global Fund.

Pharmacovigilance activities will be covered during the next quarter.

### ***Deliverables***

- Draft NTP Laboratory Network Strategic Plan
- Technical brief for the diagnosis of smear negative TB
- Technical brief for the allocation of GeneXpert in the Philippines
- Draft NTP-MOP section on management of medicines and laboratory supplies

### ***Partner contributions***

- USAID-funded IMPACT project acted as secretariat and provided logistical support to the laboratory working group for the development of the laboratory strategic plan.
- With guidance from SIAPS, the NTRL provided overall leadership in the planning process.
- The NTP organized and led the working groups for the NTP-MOP revision, PhilPACT revision, and development of the Global Fund concept note, with funds from the Global Fund principal recipient. Technical partners from the WHO, other development projects, and community-based groups, including patient organizations, as well as local and national government offices provided additional technical advice.

### ***Constraints to progress***

Ad hoc requests from NTP national managers to support their activities are competing with planned activities. Responses to the ad hoc requests were approved by USAID/Philippines.

## South Africa

**Goal: Strengthen the capacity of pharmaceutical systems at all levels to support the South African Government's priority health programs and initiatives to improve health outcomes**

### **Objective 1: Pharmaceutical sector governance strengthened**

The consultant contracted to support the review of the Pharmacy Act 53 of 1974 submitted draft “Regulations relating to Pharmacy Education and Training” and “Regulations relating to Pharmacy Practice” to the relevant committees of the South African Pharmacy Council (SAPC) for review. Work is ongoing on the amendments to the “Regulations relating to the Registration of Persons and the Maintenance of Registers.” The first draft of proposed amendments to the Pharmacy Act has also been submitted to the SAPC.

The Director-General of the National Department of Health (NDoH), as part of planning for enactment of National Health Insurance (NHI), has directed that an Essential Medicines List (EML) linked to the items and pack sizes on national contracts be developed. SIAPS provided technical assistance in the compilation of all contract information and prices, and categorization of all items into therapeutic classes according to the Adult Hospital EML 2012. The linked list was published and circulated by the NDoH and is a first step towards the establishment of a national contracts database.

Work commenced on the development of an electronic version of the Adult Hospital EML 2012 with a mobile phone application to support prescribing in compliance with STGs. The application will enable prescribers to access the Adult Hospital EML 2012 on their smart phone, thus making the information instantly available when a prescriber is deciding on therapy for an individual patient. The user requirements for the application were finalized. The web-based application will be presented to NDoH in the following quarter.

Considerable progress was made in reviewing the remaining items on the Eastern Cape formulary. The Provincial PTC has identified 7% of the 720 items that require further attention to ensure compliance with the NEML. The review of the Gauteng provincial formulary is also at an advanced stage of completion. However, final publication of both of these formularies is on hold due to the delay in publication of the revised national Hospital Pediatric EML.

Assistance was provided to the Pharmaceutical Evaluations Directorate of the NDoH for the annual adjustment of the single exit price for medicines and scheduled substances.

SIAPS continued support to the NDoH to strengthen governance in the issuing of licences for pharmacies, issuing of licences to doctors and nurses authorised to dispense medicines, as well as the issuing of permits which enable nurses to prescribe, and certain entities to supply medicine, including yellow fever vaccines. An analysis of the South African legislation that governs pharmacy ownership and licensing was undertaken. Following consultation with officials in the Licensing Unit of the NDoH, the approach currently used to award pharmacy licenses was drafted into a set of criteria and provided to senior management for input. The next step will be to develop a revised set of criteria to improve access of communities to pharmaceutical services,



particularly in underserved areas. It is also anticipated that the revised criteria will be more robust and in line with the principles of good governance, thus reducing the number of legal challenges faced by the NDoH. A literature review of approaches used in other countries to assess the need for establishing a pharmacy was completed and provided to the NDoH. Current procedures followed in the consideration of applications for pharmacy licences and licences for dispensing doctors were mapped. Work was also done on the application forms used by persons and entities wanting to administer yellow fever vaccines.

SIAPS has provided support in the preparation and advertising of eight surgical sundry tenders since the start of 2013. Bids for the bandages and dressings contract closed at the end of March and SIAPS support was provided in the evaluation of samples in two provinces. Samples are currently being tested by the quality standards authority. Further technical assistance was provided in the preparation of documents, review of estimates, and the bid evaluation process of three pharmaceutical tenders for family planning agents, antibiotics, and TB medicines. The process for awarding the TB and antibiotic tenders is at an advanced stage of completion. It is expected that these two tenders will be published within the 16-week target period. The family planning tender is also on track. SIAPS is supporting the development of checklists for each step of the tender management process to streamline procedures, build capacity within the Directorate for Affordable Medicine, and provide oversight. A draft supplier performance reporting tool has been implemented and suppliers are rated on their performance against the contract. Weekly activity tables and progress reports per tender have been implemented, as up to 10 tenders are at various stages of award.

It was planned that, by FY2, two service-level agreements (SLA) between provincial depots and their clients would be accepted. In the Free State, the SLA is still awaiting the signature of the Head of Health of the province (delays are a result of a change in leadership in the province). In the Eastern Cape, a consultative stakeholder workshop was held in May to work on and develop suggested amendments and required annexures. The draft SLA will be submitted to management for signature in the next quarter. Work was also done on SLAs in Northern Cape and North West, where draft SLAs have been provided to stakeholders for comment. Each SLA contains a set of indicators to monitor performance in areas such as medicine availability, compliance with ordering and delivery schedules, and completeness of orders processed by the relevant depot.

One of the challenges facing pharmaceutical services is the lack of standardized policies and guidelines for pharmacy infrastructure, resulting in the design/acquisition of inappropriate and/or inadequate buildings. Particular challenging is the availability of sufficient storage space for medicines in primary health care clinics, as a result of increasing numbers of patients seeking treatment at lower levels of care. One of the activities included in the FY2 work plan is the provision of support to the Directorate of Affordable Medicine for the Infrastructure Unit Support Systems (IUSS) project. The aim of this joint project of the NDoH, the Council for Scientific and Industrial Research (CSIR), and the Development Bank of South Africa is to develop norms and standards for the infrastructure of all sections of health care establishments. During this reporting period, a meeting was held with representatives of the NDoH and the CSIR's architect to prepare a concept document.

SIAPS support to the National Office of Standards Compliance continued. Input was provided by SIAPS on the draft of a guide for facilities that explains how to conduct a self-assessment of

compliance with NCS. At the request of one of the consultants providing support to the Office of Standards Compliance (OSC), a proposal to provide Leadership Development Program (LDP) workshops to the newly appointed inspectors of the OSC was prepared, although it was subsequently decided that the inspectorate was not yet ready for the training.

SIAPS continued to support quality in service delivery through initiatives aimed at improving compliance with NCS. Through the Pharmaceutical Leadership Development Program (PLDP), a team of pharmacists in Umzinyathi district in KwaZulu-Natal achieved an average 13% increase in compliance with NCS measures for eight primary health care clinics. Interventions included revising medicine supply management policies and SOPs. Nurses (42) at primary health care clinics were also trained on EML and STGs.

As reported in the previous quarter, SIAPS was requested to partner with the Free State province to support implementation of the NCS in community health centers and primary health care clinics. A plan was developed by the province to improve compliance with NCS and was presented to the Provincial Quality Assurance meeting in May. SIAPS made a presentation on how the LDP approach could be used to improve the quality of care at facilities in the province. A meeting was subsequently held with the provincial counterpart and SA Sure, a local partner, to discuss possible collaboration in supporting the NHI priority district Thabo Mofutsanyana in improving compliance with NCS. This possibility will be followed up in the next quarter.

### ***Deliverables***

Presentation on LDP approach to Free State QA meeting

### ***Partner contributions***

SA Sure partnering in Free State on NCS compliance (potential)

### ***Constraints to progress***

- Final publication of formularies in Gauteng and Eastern Cape was put on hold due to the delay in the publication of the Hospital Pediatric EML (publication date changed from July 2013 to October 2013)
- Delays in progressing with licensing work with NDoH because of the busy schedule and conflicting priorities of the counterpart

### ***Objective 2: Capacity for pharmaceutical supply management and services enhanced***

In the previous quarter, technical assistance was provided to the SAPC in the finalization of criteria for the review of curricula for the BPharm programs because a new qualification has been introduced in the country. A workshop of subject specialists was facilitated where curricula for eight pharmacy schools were evaluated. The curriculum of only one of the pharmacy schools was found to comply with the criteria. The other schools were requested to provide further information or reexamine their curricula. A second workshop of subject experts was facilitated by SIAPS in May where the resubmissions by the pharmacy schools were evaluated. The next

step will be onsite inspections of the schools to verify aspects of the curriculum, including the processes used to assess students.

As reported in the previous quarter, SIAPS planned to support the SAPC in the development of the qualification for the pharmacy general assistant (PGA), curricula for five categories of specialist pharmacists, and the curriculum for authorized pharmacist prescribers (APPs). During this reporting period, the draft qualification for three specialist pharmacists, namely, clinical pharmacist, radio-pharmacist, and pharmaceutical public health specialist, were submitted to the SAPC for review. The APP curriculum outline was finalized by the Education Committee and approved by the SAPC in June. In the previous quarter, it was reported that the SAPC had put the work on the PGA qualification on hold because of various challenges relating to the National Qualifications Framework (NQF). During this quarter, the SAPC resolved that the draft qualification would need to be revised to meet the requirements of the Quality Council for Trades and Occupations.

At the end of June, a landmark National Pharmacy Conference was organized by the SAPC and attended by 660 delegates from all sectors of the pharmacy profession. The aim of the conference was to set a strategic direction for the profession in preparing for NHI. SIAPS made an important contribution to the conference by sponsoring the attendance of the Heads of Pharmaceutical Services of the provinces and some of the Metros. Attendance of one of the international speakers was also supported. A presentation entitled “Re-Engineering the Pharmacy Internship in South Africa” was well received. SIAPS also facilitated development of a shared vision for the pharmacy profession as a whole. Agreement was reached on a vision - “Quality pharmacy services for improved health outcomes – always, everywhere, for all” which was accepted by the plenary session at the conclusion of the conference. The next step will be the development of a mission and core values for the profession.

SIAPS continued to provide the Pharmaceutical Leadership Development Program (PLDP). Since its inception, 96 pharmacists and 11 facility managers have completed the program; during the quarter, 20 pharmacists from KwaZulu-Natal completed it. The final presentation of the quality improvement projects took place in Pietermaritzburg in May 2013. Three of the five teams achieved their desired measurable results. Those teams that did not achieve their result are moving forward with implementation of the quality improvement plans to achieve the desired results. The results achieved by the teams in KZN are summarized below:

- The percentage of medicine packs pre-dispensed from Northdale Hospital for collection from Bangalore Road Clinic increased by 10.5% over a 6-month period.
- The percentage of uncollected pre-dispensed medicine packs was reduced from 34% to 15% over a 4-month period at Umzinto primary health care clinic in the Ugu district.
- An average 13% increase in compliance with NCS measures relating to availability of medicines and supplies was achieved at 8 primary health care clinics in Umzinyathi district. The facility scores improved from a range of 65–79% in March 2013 to 80–93% in April 2013.
- An overall 53% reduction was observed in chronic repeat prescriptions containing inappropriately prescribed medications at Imbalenhle Community Health Centre.

Inappropriate prescription was defined as medicine prescribed for an acute condition or not in accordance with the recorded diagnosis.

- The value of expired stock was reduced from 3.4% to less than 0.5% of stock held in 6 of 11 clinics in Sisonke district.

In Western Cape, 12 pairs of pharmacists and facility managers from the Northern Tygerberg Suburbs Substructure (NTSS) completed the LDP and presented the results of their quality improvement initiatives to senior management in Cape Town. Challenges addressed included the reduction of waiting times, improving prescribing practices, facilitating access to medicines by creating alternate medicine collection points, and improving medicine supply management practices. For example, at Kraaifontein Community Health Centre, the average patient waiting time was reduced from an average of 41 minutes to 19 minutes over a 6-month period. SIAPS was subsequently informed that three of the projects would be rolled out across the whole substructure. There was also a request for SIAPS support in sustaining all 12 projects for an additional 12 months. The PLDP continued to demonstrate significant measureable improvements to pharmaceutical services at health facilities that implement the program.

Two abstracts entitled “Reducing Patient Waiting Times at Kraaifontein Community Health Centre” and “Building Sustainable Capacity and Improving the Quality of Pharmaceutical Services through Leadership Development in South Africa” were submitted for the Public Health Association of South Africa (PHASA) conference scheduled for September 2013.

In KwaZulu-Natal, an independent consultant had been contracted by the province to do a business systems analysis of processes in the province that affect availability of medicines. SIAPS was requested to assist with the development of a remedial action plan to address challenges identified in the report. A workshop attended by the Provincial Head Office staff, the manager and staff of the Provincial Pharmaceutical Supply Depot (PPSD), and district pharmacy managers was subsequently facilitated. During the workshop, the annual review of reports against the indicators for routine monitoring of pharmaceutical services (developed with the help of SPS in 2010) was undertaken. Challenges identified during this annual review were consolidated with those arising from the business systems analysis. It was agreed that the PLDP participants would be encouraged to take on some of the challenges as part of the PLDP. Furthermore, one of the PLDP participants would be working with PPSD to address challenges at the depot. Following the workshop, an abstract describing the M&E system in KZN to monitor pharmaceutical services was prepared and submitted for presentation at the PHASA conference in September 2013.

M&E workshops were carried out to develop results frameworks and related indicators for pharmaceutical services in Eastern Cape and Limpopo provinces during the quarter. As a part of this process, a compendium of indicators was drafted incorporating measures for pharmaceutical services from various provinces. Once finalized, it is envisaged that the compendium will be a valuable reference tool for routine monitoring of pharmaceutical services in the country. A follow-up workshop was held for pharmacists in Limpopo to refine indicators.

### **Deliverables**

- Three abstracts for PHASA: Reducing Patient Waiting Times at Kraaifontein Community Health Centre; Building Sustainable Capacity and Improving the Quality of Pharmaceutical Services through Leadership Development in South Africa; Improving Effectiveness of a Health System through Implementing a Framework for Monitoring Pharmaceutical Services in KwaZulu-Natal
- Five posters and presentations developed and presented by the KwaZulu-Natal PLDP teams
- 12 presentations to senior management by the NTSS LDP teams in the Western Cape
- “Reengineering the Pharmacy Internship in South Africa” presented at the National Pharmacy Conference
- Poster for the SIAPS Global Retreat: Building Capacity and Improving the Quality of Pharmaceutical Services through Leadership Development in South Africa

### **Constraints to progress**

There is a considerable increase in demand for the PLDP/LDP program which entails facilitation of workshops and provision of support and coaching visits. Steps are underway to increase the capacity of the PLDP team to be able to meet the increasing demand.

### **Objective 3: Use of information for decision making in pharmaceutical services improved**

One of the activities included in the work plan was to develop a national data warehouse. As a step towards the establishment of such a warehouse, SIAPS is supporting the NDoH to improve visibility of provincial depot information by using Infomaker®. Infomaker is currently installed to generate reports from the provincial depots that use the MEDSAS inventory management system. A catalogue of 55 standard reports has been developed to facilitate generation of information from the 5 provincial depots where Infomaker is installed.

In South Africa, 224 facilities are currently using one or more of the stock management, batch management, and dispensing modules of RxSolution. During this quarter, revised criteria were developed to assess the level of usage of RxSolution at sites where it is installed. An initial analysis of data collected from 94 of these sites revealed that 74% showed a defined level of usage based on a threshold number of transactions for orders, receipts, requisitions & prescriptions for the period April 2012 to March 2013. This data collection exercise is being conducted in tandem with the upgrade of RxSolution sites to the new version finalized in the previous quarter.

Promoting the use of information on pharmaceutical services at the facility level is another objective to which SIAPS is committed. During this quarter, for example, technical assistance was provided to a pharmacist at Chatty Clinic in the Eastern Cape to determine the level of excess stock held at the facility. This determination was made with the batch management module in RxSolution to identify short-dated stock that was likely to expire according to the average consumption history for the previous six months. All identified stock was distributed to other facilities within the province for use. With assistance from Nelson Mandela Metropolitan

University (NMMU), data obtained from RxSolution from Andries Vosloo Hospital in the Eastern Cape was analyzed and submitted to the facility for consideration by the PTC. The opportunity to work closely with NMMU in the analysis of data from RxSolution will be explored further in the next quarter.

SIAPS worked in collaboration with the Eastern Cape Department of Health to develop an RxSolution Disaster Recovery Plan for the province. The plan, which was approved for implementation during the quarter, requires that all RxSolution databases be backed up to a central location on a weekly basis to facilitate data recovery in the event of a server malfunction.

### ***Deliverables***

Poster for SIAPS Global Meeting

### ***Constraints to progress***

Differing levels of usage of RxSolution at facilities complicates the establishment of provincial data warehouses as provided for in the work plan

### ***Objective 4: Access to medicine improved by implementing new strategies***

In Limpopo, the first batches of direct deliveries for ARVs and oncology agents were made to 41 hospitals with support from the Provincial Procurement Unit (PMPU). SIAPS worked with NDoH and other PEPFAR partners including SCMS to implement the PMPU as a means of strengthening the Limpopo pharmaceutical supply chain. SIAPS provided technical assistance in finalizing the list which details the products that may be ordered by a facility based on the level of patient care provided at that facility. Technical assistance was also provided in the allocation of order codes for products on tender that are being managed through the PMPU. A customized version of RxSolution was developed and, as of this quarter, is being used to manage direct deliveries to 40 hospitals in Limpopo. The software enables the PMPU to routinely monitor supplier performance with respect to quantities and values of orders processed. Since May 5, a total of 939 orders have been captured for the hospitals supported by the PMPU.

SIAPS is part of the Goods Procurement Sub-Committee of the NHI Ministerial Task Team, whose goal is to develop a suitable procurement model for pharmaceutical services to support universal health coverage. No meetings were held by the team during the last three quarters because of delays in providing letters of authority to team members. The letters were issued towards the end of the quarter and work can now proceed. A meeting has been arranged with NDoH to discuss future support of NHI activities by SIAPS.

The NDoH is in the initial phases of establishing NHI. In preparation for possible contracting of private pharmacies, NDoH requested SIAPS to investigate geo-mapping of all pharmacies in the country to identify private pharmacies located in close proximity to public sector facilities. SIAPS is waiting for a response from NDoH regarding the next step in the mapping exercise. SIAPS also continued to support to a group of pharmacists meeting under the theme “NHI value

proposition for pharmacy.” The group is investigating public-private partnerships between government and community pharmacists.

### **Constraints to progress**

Delays with provision of letters by NDoH to members of the Goods Procurement Sub-Committee of NHI Ministerial Task Team

### **Objective 5: Improved medicine availability**

The South African antiretroviral tender (effective January 2013) was the first to include fixed dose combination (FDC) agents for use in public health care facilities. SIAPS continued to support a phased approach to replace current single agents through the national quantification task team. Quantification models were developed in a team effort with CHAI according to the requirements of the NDoH. Because of challenges in quantification for switching patients to FDCs, only 3 of the 18 routinely stock items (17%) are forecast within the target margins of 80-120% accuracy. The discrepancy is largely attributed to suppliers not keeping up with program roll-out requirements. Bi-weekly meetings are held with all stakeholders to review stock levels and order status. The roll-out quantification tool is reviewed on an on-going basis in light of the information obtained during these meetings.

SIAPS continued to provide technical assistance in preparing public pharmaceutical depots for licensing by the Medicines Control Council (MCC). In the North West, SOPs for depot functions were finalized and incorporated in the draft compliance report for the MCC. SIAPS worked with the acting manager of the Mpumalanga Depot and other stakeholders to develop an action plan for addressing other gaps towards compliance with the MCC requirements.

In Limpopo, SIAPS was part of the committee that evaluated 38 applicants for the contract to distribute medicines from the provincial depot to health care facilities in the province. None of the applicants met the requirements to be awarded the tender.

SIAPS continued to work with partners to implement a quality improvement approach to medicine supply management training in the Eastern Cape. In the model being used, the actual training is provided in collaboration with partners and counterparts using SIAPS material. Partners will play a key role in the performance of post-training quality improvement interventions at the facility level. In this province, 9 workshops were held where 234 pharmacists, pharmacist’s assistants, operational managers, and other personnel were trained with a series of one-day presentations on the principles of medicine supply management and ordering, receipt, and distribution of medicines. The training focused on the use of the NCS questionnaires and checklists. A clinic visit was incorporated in the training to demonstrate the tools. The purpose of this approach is to capacitate personnel to undertake self-assessments and develop quality improvement plans for their facilities or programs. It was agreed that clinic supervisors would utilize the NCS questionnaires and checklists to conduct self-assessments by the end of June 2013. These assessments will inform the need for further technical assistance and support for quality improvement initiatives in these facilities.

In Limpopo, further training on medicine supply management was provided for 183 pharmacists, pharmacist's assistants, and nurses in Capricorn, Mopani, Sekhukhune, Vhembe, and Waterberg districts. These training sessions were held in partnership with ANOVA Institute and the provincial department of health. TOT workshops were held in Gauteng (24) and North-West (29) for pharmacy managers.

### ***Deliverables***

Poster for SIAPS Global Meeting

### ***Objective 6: Improved rational use of medicine and patient safety***

SIAPS is committed to supporting the rational use of medicines by strengthening the governance and functionality of Pharmaceutical and Therapeutic Committees (PTCs) at the provincial, district, and institutional levels. In FY12, SIAPS had a target to provide technical assistance to four PTCs. To date, PTCs for Limpopo, Eastern Cape, and Gauteng provinces and Sedibeng district have documented resolutions that will contribute to improvement in medicine use. Following a cost analysis, the Eastern Cape Provincial PTC adopted a resolution to use enalapril as the ACE inhibitor of choice. The guidelines for changing adult patients from perindopril to enalapril tablets have been drafted and will be circulated, once approved by the PTC. Further technical assistance on cost analysis provided to the Gauteng Provincial PTC resulted in the committee adopting the following resolutions, which are anticipated to reduce treatment cost.

- Enalapril will be the preferred ACE inhibitor of choice in the province
- Amlodipine will be the preferred calcium channel blocker of choice in the province
- Surfactant 4 mL and 8 mL will be used in preference to 1.5 mL and 3 mL, respectively
- The cost-effective use of prefilled insulin syringes will be improved
- Safe and cost-effective use of intravenous phenytoin will be promoted

Circulars for implementation of the above resolutions have been approved by the Provincial PTC and are awaiting the Head of Department's signature prior to dissemination.

During the quarter, SIAPS also provided technical assistance to Steve Biko Academic Hospital, Rahima Moosa Mother and Child Hospital, Helen Joseph Hospital, and Leratong Hospital to improve medicine use through ABC analysis and expenditure analyses per ATC class.

SIAPS continued to support the Gauteng Provincial PTC in its efforts to harmonize PTC functions within the province. The document *Guidelines for Implementation of PTCs in Gauteng Province* was approved by the Gauteng Provincial PTC. Final edits are currently underway.

Technical support was provided to the NEML Committee to perform a national ABC analysis per ATC class. For each of the top 11 ATC classes, the expenditure was disaggregated per province and presented in relation to population and burden of disease when available. The results were presented to the provincial Heads of Pharmaceutical Services during the National Health Council Pharmacy Sub-committee meeting in June. The presentation aimed at raising awareness on the need for provincial PTCs to improve medicine use.



The findings from the study entitled: *What are the Reasons for Switching Adult Patients to Second-Line ART Regimen in Public Healthcare Facilities in Gauteng Province* were presented to the Gauteng Department of Health during a workshop held in June. The research report was finalized and has been disseminated to the Gauteng Department of Health and National Essential Medicine List Program. Some results (namely the finding that only in 49.4% of cases are patients switched to second-line ART in compliance with the applicable guideline) were presented at the 6th South African AIDS conference. An abstract entitled “Understanding the Factors Influencing the Duration of First-Line Regimens in an Ageing Antiretroviral Treatment Programme” has been submitted for the 17th International Conference on AIDS and STIs in Africa scheduled for December 2013.

SIAPS continued to provide support to the NDoH Pharmacovigilance Centre (NPC) in implementing the decentralized pharmacovigilance system. Of the 26 clusters targeted, 20 are actively reporting ADR to the NPC. Plans are currently being developed for implementation of the decentralized model for pharmacovigilance in two districts in the North West province.

During this quarter, SIAPS worked with NTP managers and USAID to develop a work plan based on the recommendations of the pharmaceutical management of TB assessment report. All the stakeholders agreed that SIAPS will support the NDoH to:

- Build capacity of health care professionals on medicine supply management of TB medicines using a combination of medicine supply management training and mentorship
- Conduct an assessment of the pharmaceutical management of TB in the Department of Correctional Services
- Increase compliance with STGs in the treatment of TB
- Develop and implement a system for monitoring TB ADRs in conjunction with the Pharmacovigilance Unit at the NDoH
- Increase knowledge and literacy levels of TB of patients and clients
- Conduct drug utilization reviews of second-line TB medicines

SIAPS is also working to enhance patient rights by increasing their knowledge of medicine therapy. During the quarter, a poster and flyers were developed to promote patients’ understanding and knowledge about generic medicines in preparation for the annual Pharmacy Week campaign. This work is done in partnership with the NDoH, the Pharmaceutical Society of South Africa, and the SAPC.

Formal training on infection prevention control and the use of the Infection Control Assessment Tool was conducted for 36 nurses in Northern Cape. Training was also conducted for 18 community service pharmacists on pharmaceutical waste management.

### ***Deliverables***

- Abstracts and presentations: Programmatic Implications of Irrational Switching of Patients onto Second-Line ART; Understanding the Factors Influencing the Duration of First-Line Regimens in an Ageing Antiretroviral Treatment Programme

- *Guidelines for Implementation of PTCs in Gauteng Province*
- Research report: What are the reasons for switching adult patients to second line ART regimen in public healthcare facilities in Gauteng Province?
- Poster for SIAPS Global Retreat: Study Highlights Implications of Irrational Switching of Patients to Second-Line ART in Gauteng, South Africa

***Constraints to progress***

The post of senior technical advisor for pharmacovigilance under SIAPS is still vacant because no identified candidates accepted the position. Recruitment is still on-going for this post.

## South Sudan

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

**Objective 1: Pharmaceutical services improved to achieve desired health outcomes**

SIAPS provided responses to inquiries regarding the Emergency Medicines Fund (EMF) procurement from USAID | DELIVER through several consultations with the MoH/Directorate of Pharmaceuticals and Equipment (DP&E). The project also supported DELIVER to understand the country's needs and requirements. Several issues regarding the EMF supplies were also discussed to see how gaps could be filled and commodity security in the country ensured. This led to DELIVER procuring the products requested by the MoH and to DELIVER facilitating an early shipment of ACTs to avoid stock outs.

SIAPS worked with UNICEF and the State MoH to renovate the state MoH medical store in Juba. The project is waiting for final approval before the contractor may begin renovation work. It is expected that this warehouse will ease the pressure on the Central Medical Store (CMS) and ensure that commodities, including malaria and family planning commodities, are kept in good storage conditions.

As part of its activities in the CES and with NMCP and Population Services International (PSI), SIAPS visited Juba Teaching Hospital (JTH) and El-Sabah Hospital and a few PHCCs around Juba (Munuki, Nyakuron, Kimu, and Gurei). These visits revealed actual ACT needs at El Sabaah and the Primary Health Care Centers (PHCCs). The team supported the supply of ACTs and RDTs to the facilities, except JTH, which had enough stock of both items. SIAPS and the M&E team from the NMCP and PSI will work closely with the facilities to ensure accurate reporting of consumption data using the government reporting tool printed by SIAPS with funding from USAID and distributed to facilities in the Central Equatoria State and Western Equatoria State.

SIAPS provided technical assistance to health partners, including NGOs, in making requests for quantities of ACTs from the CMS, for about 400,000 doses of ACTs from USAID and about 1.2 million doses from PSI, to be used as buffer stock during the rainy season and for other emergency/humanitarian situations.

### **Deliverables**

- Quotation for the renovation of the CES warehouse
- Letter of Understanding between MSH, UNICEF, and the MoH in CES
- Minimum list of essential medicines and medical supplies vital for primary health care
- Quantification data sheet for EMF supplies

### **Constraints to progress**

The recruitment process for the Malaria Advisor and Pharmaceutical Advisor has taken time and delayed some of the activities planned for the quarter. However, recruitment of these replacements has been finalized. The Malaria Advisor is onboard and the Pharmaceutical Advisor will start work in August at the latest. This will expedite activities in these areas.

SIAPS, with approval from the USAID, is currently exploring the possibility of re-engaging the former M&E specialist who left to pursue postgraduate studies

Continued delay in receipt of approval to conduct renovation work has the potential to adversely affect SIAPS' working relationship with the Central Equatoria State MoH. The work is expected to start at the end of July and be completed by September 2013.

Because of delayed disbursement, activities co-funded by the Global Fund and other partners could not be completed. For example, WHO provided initial funding for antimalarial efficacy studies and SIAPS worked with the NMCP and WHO to train health workers from the sentinel sites. But enrollment of study subjects could not be initiated because of the delayed release of funds from the Global Fund.

### **Objective 2: Capacity for pharmaceutical supply management and services increased and enhanced**

SIAPS shared the draft pharmaceutical training manual with MoH counterparts for their input before finalization. When completed, the training manual will serve as the national guide for all training in pharmaceutical management at facilities by all partners providing pharmaceutical management support in the country. This forms part of the MoH's harmonization strategy being rolled out with SIAPS support.

SIAPS trained 26 personnel from various disciplines in WES in its effort to strengthen pharmaceutical management and to establish a model county PMIS program in Tambura County. SIAPS conducted a three-day pharmaceutical management training for health workers at health facilities in Tambura County to refresh health worker knowledge on the pharmaceutical management information system and storage management.

As part of its capacity building efforts with the DP&E, SIAPS facilitated a procurement and supply management training course in Ethiopia. Two senior staff members (Director of Pharmaceuticals and Supplies, and Director of Quality Control) from the DP&E attended the training. It is expected that such training will expose senior leadership to best practices, thus making it easier to introduce changes to pharmaceutical management systems in the country. As part of its regular supportive supervision activities, SIAPS visited health facilities in Terekaka: Muni PHCC, Tukoro Primary Health Care Unit (PHCU), Wujungani PHCU, Meridi PHCU, Lokweni PHCU, and Nyikabur PHCU, helped them update their stock cards with maximum, minimum, and reorder levels, and oriented them on how to correctly place orders using the report and requisition voucher. This is part of SIAPS' strategy of introducing the pull system in selected counties and facilities.

SIAPS provided supportive supervision and on-the-job training for staff in Yei, Lanyia, and Morobo counties on how to correctly fill in the stock cards and dispensing registers to track consumption and to request new supplies based on consumption trends. This is likewise part of the plan to initiate the pull system. The project carried out these activities with MoH counterparts from the CES.

### ***Deliverables***

- Draft pharmaceutical management training manual
- Reports of supportive supervision trips to CES and WES facilities to provide on-the-job training.
- Regular supportive supervision visit reports in WES and CES.
- Trip report on visit to Mvolo and Mundri and team trip report for Yei, Lanyia, and Terekeka

### ***Constraints to progress***

- The lack of adequate HR capacity led to delays in the finalization of some critical documents, such as the pharmaceutical training manual, which involved input from the MoH.
- At lower levels, lack of HR capacity also impeded the roll-out strategy for expanding pharmaceutical management trainings and best practices.

### ***Objective 3: Information for decision-making challenge in the pharmaceutical sector addressed***

SIAPS provided information on the stock status of antimalarials through the PPMRm data request, by consolidating all procurements from partners and the MoH, including pipeline data. This information leads to decision making at the national level to ensure commodity security for antimalarial commodities. To further improve the availability of data, SIAPS will be working with James Kong and the MoH to obtain similar data at the county level on a monthly basis.

SIAPS currently serves as the secretariat to the National Pharmaceutical Technical Working Group. 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 the last quarter's TWG meeting, by supporting MoH to send out invitations to partners; and drafting technical presentation on quality assurance of medicines, and facilitating follow up actions from the TWG. In this quarter, PSI and DELIVER shared information of their procurement activities especially for ACTs which has led to action by the MoH to engage facilities to make request and receive them on time before the rainy seasons. SIAPS is currently working with the MoH to start collating county level data on stock status of much needed ACTs and other key essential medicines.

SIAPS began the roll out of the Logistics Management Unit and initiated a short- term contract for a data officer to facilitate the coordination and collection of data from county health departments.

Supportive supervision reports indicating gaps and challenges in pharmaceutical management systems in the Counties and facilities are shared with the State MoH for actions to be taken. Lanyia and Tereka have stockpiles of infusions; the MoH is taking steps to return them to the CMS for redistribution. In Lanyia, a stock out of ACTs was identified and steps have been taken to provide them with supplies.

### ***Deliverables***

- PPMRm Reports
- PTWG minutes and presentations
- Distribution list/ report for PMIS tools
- Correspondence among DELIVER, USAID, and MoH counterparts on issues relating to EMF supplies
- Meeting minutes with DELIVER and action points for EMF supplies

### ***Objective 4: Pharmaceutical sector governance strengthened***

SIAPS has begun the process of reviewing and updating the EML and STGs for the MoH. Official letters have been written to the DG for Pharmaceuticals through the Director of Policy and Pharmacy Practice to set up a committee to review the EML and the STGs. This is an MoH-led activity. SIAPS will provide technical assistance and coordination for the review and update of these important documents.

SIAPS has also allocated two office spaces in the NMCP building to facilitate the activities of the Drugs and Food Control Authority. This has enabled it to establish a working area to carry out daily activities. Some of the items provided are for temporary use (printers, furniture, and internet connection). SIAPS also initiated an in-depth analysis of the 2010-2012 Minilab data in collaboration with the DFCA

SIAPS facilitated a meeting organized by the Department of Pharmaceutical Services at the State MoH in WES to discuss the inspection of private pharmaceutical and medical premises. This meeting was needed because of the rapid expansion of private drug stores and influx of substandard medicines in the State.

### ***Deliverables***

- Draft Minilab report for 2010, 2011, and 2012
- Letters from the MoH for the establishment of a committee with Terms of Reference to undertake the revision of the EML and STGs.

### ***Objective 5: Scale up of malaria interventions better coordinated and documented***

SIAPS supported the NMCP in the organization of the 2013 World Malaria Day on April 25. The project provided technical and financial support on how to communicate their activities and procuring the venue, respectively. Several partners attended the event, including USAID, NGOs, and the MoH. The guest of honor was the Minister of Health.

The project participated in planning the 2013 Malaria Indicator Survey. Through SIAPS, USAID has obligated USD 150,000 to support the second Malaria Indicator Survey activities, which will be used for priority activities identified by the NMCP. The SIAPS Malaria Advisor will also provide continuous technical assistance to the NMCP in the implementation of the MIS activities.

SIAPS with NMCP and PSI visited Juba Teaching Hospital (JTH) and El-Sabah Hospital jointly and few PHCCs around Juba ( Munuki, Nyakuron, Kimu, and Gurei) and established their actual needs and agreed to supply them with ACTs and RDTs, except JTH which had enough stock of both items. SIAPS and the M&E team from both NMCP and PSI will work closely with the facilities to ensure accurate reporting on consumption data using the government reporting tool printed by SIAPS with funding from USAID and distributed to facilities in the CES and WES.

The project procured a Malaria Advisor to support the NMCP and enhance its human resource capacity for the implementation of activities. The recruitment process went through several steps, including a face-to-face interview with the proposed candidate by the MoH-NMCP, SIAPS, and USAID. The final decision was made and the candidate started work on June 2, 2013.

The Program had consultative meetings with the PMI technical lead from Washington, DC (George Geer), who visited the country as part of the MOP review and planning process. During his visit, he met with the USAID South Sudan Mission and other key partners, including the SIAPS project and NMCP. SIAPS presented its current and planned activities for the coming year, which are in line with PMI plans for the country while NMCP presented priority areas for PMI support. This led to a commitment of funding to the project for the 2013–2014 work plan to support malaria activities and for overall pharmaceutical systems strengthening in WES and CES.

### ***Deliverables***

- MIS planning meeting reports and presentations
- Meeting minutes with PMI technical lead
- SIAPS presentation to PMI technical lead

## Swaziland

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

During this quarter, SIAPS has actively worked with the MoH and partners to monitor stocks of essential health products at the HIV treatment sites. In this regard, SIAPS uses proven tools such as Pipeline, Quantimed and RxSolution to manage and plan for product requirements in the national AIDS program. Pipeline was used for the first time in this quarter at the national laboratory services to plan and adequately cost the laboratory commodities requirement for the 2013/14 procurement cycle. The procurement plan for laboratory as well as ARVs has been used to plan funds release by the Ministry of Finance. A TB medicines procurement plan was also completed and requirements shared with stakeholders such as MSF, and other TB partners in the country. The first procurement of TB medicines was done in this quarter based on the supply planning from Pipeline.

With the integrated storage of medicines at the National Medical Warehouse (Central Medical Stores), the space available was found to be inadequate. SIAPS worked with the MoH, National Emergency Response Council to HIV and AIDS (NERCHA) to secure additional, larger storage space for ARV, reproductive health commodities (including condoms) and anti-malarial agents. This new warehouse will ensure that all these essential products are stored safely and product quality is maintained.

There hasn't been a stock out of TB, ARVs and condoms in this reporting period and the average stock holding of the essential items have been between 2 to 4 months of stock. This is the average at national level while facilities mainly kept their stock level within the minimum limit of 3 months. The stock status of condoms has improved from 4 months of stock in the previous quarter to 18 months at the end of the quarter. This has been through a coordinated effort with SIAPS and other partners such as Population Services International (PSI), AIDS Healthcare Foundation (AHF), and local community-based organization. However, the 18 months of stock excludes condoms held by PSI. There is inadequate distribution of condoms within the country and the next steps are to improve this so as to ensure that condoms are available in facilities and communities in the country. SIAPS and PSI have worked with local volunteers from Peace Corps to assist in the distribution of condoms to rural communities.

### **Objective 1: Strengthen governance in the pharmaceutical sector**

An efficient policy environment sustained by good governance is essential to strengthening pharmaceutical systems that support priority health programs, such as HIV, TB, and malaria. SIAPS continuously provides technical support to strengthen governance in the pharmaceutical sector. SIAPS supported the development of the Medicine and Related Substances Control Bill (8 of 2012) and the Pharmacy Bill (7 of 2012). These bills were approved by the Cabinet and are due to be presented to Parliament in the fourth quarter.

SIAPS is working closely with key stakeholders to support the MoH's efforts to move the legislative activities along and strengthen governance in the pharmaceutical sector. Regarding



the Pharmacy Bill and Medicines Bill, one of the stakeholders is the Parliament Health Portfolio Committee and Senators. Supported by SIAPS and in collaboration with the Parliament Health Portfolio Committee, the MoH successfully conducted two advocacy workshops for the House of Assembly and the House of Senate. The workshop purpose was to present the content of the Bills so that legislators have more understanding and hence accelerate the process of passing both bills in Parliament. The MoH presented an overview of the pharmacy profession and the role of pharmacy personnel in the health care system. An overview of both bills was also presented, including the consultative method undertaken to develop the bills. The legislators had an opportunity to review both bills in more detail, with special attention given to potentially contentious issues, an exercise that the legislators hailed as necessary and crucial given the technical nature of the Bills. In total, 40 legislators from the House of Assembly and 22 from the House of Senate, respectively, participated in the workshops.

SIAPS and the MoH's Senior Pharmacist continue to work closely with the Clerk to Parliament to finalize the Health Portfolio Committee report on the two Bills to be presented to the House of Assembly for debate, a process which is envisaged to be less intensive given the advocacy workshops held with the legislators.

Pending the passage of the bills, SIAPS has developed draft regulations for the Medicines and Related Substances Control Act and the Pharmacy Bill.

The enactment of the Medicines and Related Substances Control Bill will lead to the establishment of the Medicines Regulatory Authority. SIAPS has provided technical leadership in drafting the implementation plan for establishing the authority, which is currently being reviewed by the MoH after having been reviewed internally. Having a Medicines Regulatory Authority will assist the country to enforce rules and regulations and issue guidelines to regulate drug registration, manufacturing, marketing, and labeling of pharmaceutical products.

Another key area of SIAPS/Swaziland work in good governance concerned the printing of the Swaziland Pharmaceutical Strategic Plan (SPSP, 2012– 2016) following its endorsement by MoH senior management, signing by the Principal Secretary and Minister, and approval by the Cabinet. The importance of this strategic plan cannot be over emphasized. The SPSP provides the overall roadmap for the development of pharmaceutical services in the health sector. Six hundred copies of the SPSP were printed. The next step is the dissemination of the document. The strategy is to make the SPSP available at every health facility and institution in the country. Once the SPSP has been rolled out, SIAPS will actively monitor its implementation on a quarterly basis.

### ***Deliverables***

- A technical report on the workshops for legislators on the Pharmacy Bill and the Medicines Bill
- Draft MRA establishment implementation plan
- Draft Pharmacy Bill and Medicines and Related Substances Control Bill regulations
- Printed 600 copies of the SPSP

### **Constraints to progress**

Securing dates for the workshops for legislators was a challenge; however, after MoH lobbying two Members of Parliament and a Senator, the two Houses of Parliament allocated time for the seminars.

### **Objective 2: Strengthen pharmaceutical supply management and services**

SIAPS has been actively involved in capacity building of health care workers, through both in-service and pre-service trainings. For the pre-service training, a total of 25 students are enrolled in the Pharmacy Certificate program currently offered by the Southern African Nazarene University (SANU). The students have just completed their first year; 64% will proceed to year two while 32% will have to sit for supplementary examinations. The students are expected to graduate in 2014. A new batch of 30 candidates has been offered places for August 2013. SIAPS has engaged a consultant to develop a curriculum for a Diploma in Pharmacy.

For in-service training, SIAPS conducted inventory management and LMIS training for 246 health personnel who work at laboratory and TB treatment facilities. The new LMIS was designed to support peripheral clinics to request supplies from the main laboratory monitoring sites. For TB treatment facilities, the new system will support them to send their reports and requests directly to the CMS every month to avoid stock outs and integrate the distribution system with that of the essential medicines. This helps facilities to not only complete their reports and order forms appropriately but also reduce the work load at the central level.

Another capacity building initiative used by SIAPS to transfer skills to health care providers responsible for pharmaceuticals at facilities is supportive supervision visits. During this quarter, 21 facilities in the Manzini region were visited. Pharmaceutical systems and services were assessed, gaps in the management of pharmaceuticals were identified, and possible interventions were implemented. The supportive supervision visits help identify training and mentorship needs at the health facilities and among health workers. SIAPS works closely with other partners such as CHAI, URC and EGPAF in conducting supportive supervision at facilities.

As another strategy for the transfer of skills and local capacity building, SIAPS participated in the Supply Chain Technical Working Group, for which SIAPS is currently serving as the secretariat. The working group meeting serves as a supply chain coordination mechanism. It facilitates the sharing of information on the current situation with supplies and systems, which helps identify interventions needed at the national level. During the meeting, current information about product availability and system implementation issues are discussed and documented. This includes advocacy for more funding and supply chain system implementation. Only one Supply Chain Technical Working Group meeting is scheduled per quarter.

Forecasting and supply planning exercises help the government budget and prepare tenders for procurement. SIAPS worked on promoting effective quantification and procurement systems for medicines and laboratory commodities. During this reporting period, SIAPS conducted quarterly supply planning for HIV commodities as well as for TB medicines (both first- and second-line), and family planning commodities, including condoms. SIAPS also facilitated meetings to revise

forecasts for TB and family planning commodities. SIAPS facilitated the preparation of the first quarterly supply plan for laboratory commodities using pipeline data. Pipeline is currently being implemented for laboratory commodities. SIAPS continues to provide technical assistance to relevant MoH staff on forecasting and quantification of health products. Due to SIAPS support for conducting regular and systematic quarterly supply planning, the first quarter procurement budget for ART products decreased by SZL 2,027,194.36 (6.44%). For family planning, owing to the revision of assumptions, considering the existing situation, and using currently available data for decision making, the total cost of these commodities decreased by SZL 18,420,978.68 (69.2%).

SIAPS has been supporting the MoH procurement unit in the development and implementation of procurement guidelines and SOPs. The SOP for laboratory warehouse management has been reviewed by National Clinical Laboratory Services management and is now being proofread before being formally signed and printed.

### ***Deliverables***

- Draft Laboratory Standardization (LMIS) report for HIV platform
- Supply planning report for ARVs and reproductive health commodities for the 2013/14 fiscal year. The budget requirement was reduced by 6.44% for ARVs (SZL2, 027,194) and 69.2% for reproductive health commodities (SZL18,420,978)
- Inventory management training and LMIS for 246 health workers from TB facilities and laboratories
- 16 pharmacy certificate students promoted to second year of the program while 8 are yet to sit for a supplementary exam

### ***Constraints to progress***

- Major constraints in this quarter related to reaching more facilities with mentoring and supportive supervision. The challenge is in part due to human resource shortages at the MoH. Also, the SIAPS technical team is not sufficient to reach more facilities
- Another constraint was the delay in awarding the 2013/14 tenders.
- Changes in laboratory equipment have also caused problems during the quantification of reagents and supplies.

### ***Objective 3: Address information for decision-making challenges in the pharmaceutical sector***

SIAPS has supported the innovative use of information technologies, such as an integrated Patient Management Information System (PMIS) for effective HIV and TB patient information management.

The APMR tool is linked to the RxSolution tool, which is a stock inventory tool used for stock management and dispensing. Having already established these electronic tools in the HIV program, the main focus is to improve the integration of pharmaceutical services and supply chain data collection, processing, and reporting of information to support staff at all levels of the

health system to make evidence-based decisions. SIAPS is committed to ensuring that all tools that provide a platform for tracking and managing patients or products are effectively integrated.

In line with the MoH's strategy to improve the monitoring and evaluation of clients on HIV and TB treatment, SIAPS engaged a local firm/contractor to redesign the APMR software to capture and monitor patient treatment outcomes for both HIV and TB. SIAPS continues to work with the MoH and the contractor in the redesign activity. Guidance has been given to the vendor on the System Requirements Specifications document and System Technical Design document. Although it may delay progress, the participation of the MoH in this process has proved worthwhile, especially in ensuring that the final product meets the client's requirements. The redesign has made significant strides as several reviews of the System Requirements Specifications and System Technical Design have been done, and recently a user requirements gathering workshop for stakeholders was hosted by Institution for Health Measurement (vendor).

Regarding RxSolution, the focus was to strengthen the use of the tool by currently supported sites to include all essential pharmaceutical commodities for inventory management. This initiative has seen SIAPS supporting PSI/Swaziland in the implementation of RxSolution, focusing on requisitions of their male circumcision commodities. All 38 sites using RxSolution are routinely supported by SIAPS to use the tool to improve inventory management and dispensing. Support also includes troubleshooting due to system or network failures, and assisting with the navigation of some reporting functions. A new version of RxSolution was launched this quarter. SIAPS is currently rolling out the upgraded version to sites using the tool.

SIAPS also supports the development of a logistics management information system (LMIS) such as the web-based Commodity Tracking System and the manual LMIS at the regional level to capture data on medicines and supplies, laboratory supplies. These tools are predominately used in tracking consumption of TB, HIV, malaria, and laboratory commodities. SIAPS continued to work to ensure functionality of the Commodity Tracking System by providing technical services and exploring interface options with existing tools. All health facilities are supported to use the LMIS form for ordering and reporting to the CMS Data Management Unit. The ART LMIS reporting rate has improved in the past quarter. The Data Management Unit has started capturing reproductive health and laboratory data. The data collected through the LMIS forms is important to inform product consumption assumptions and confounding factors when projections for quantities to be ordered are being made by the SCTWG on PIPELINE. Pipeline is another electronic tool supported by SIAPS and used when medicine procurements are done.

### ***Deliverables***

- Draft RxPMIS System Requirements Specifications document
- Draft RxPMIS Technical Design document
- New version of RxSolution available and implemented at sites

### **Constraints to progress**

- Delays in the implementation of the CTS. Continuous engagement with the MoH is at an advanced stage. The plan is to have the tool implemented by the CMS Data Management Unit during the next quarter.
- Computer hardware problems affect the smooth operation of the software (Rx-Solution and APMR).
- Delays in submission of approved deliverable by the RxPMIS redesign contractor.

### **Objective 4: Financing strategies and mechanisms strengthened to improve access to medicines**

SIAPS supports the MoH in the efficient use of warehouse storage space for priority health products. The storage space should be optimally utilized to ensure the quality and integrity of the products is maintained throughout the supply chain until it reaches the patient. SIAPS has assisted the MoH in identifying new warehouse storage space that will integrate the storage of all priority health products such as ARVs, Reproductive Health commodities and anti-malarial treated bed-nets. This integration will mean that MoH will gain extra space for expansion of warehouse storage and also proper oversight under one roof.

Wastage of medicines can cost the public health sector a lot of money which could have been used for other health interventions. The safe destruction of medicines is also an important process as medicines waste, not properly managed; can end up back in the supply chain system hence causing further public health concerns.

### **Deliverables**

- Approved CMS leadership organizational structure
- Draft waste management guidelines

### **Constraints to progress**

Delays in the approval of the CMS leadership organizational structure. The MoH eventually agreed to the recruitment of the Assistant Director to lead the CMS. SIAPS will assist with the recruitment for this position.

### **Objective 5: Improve pharmaceutical services to achieve desired health outcomes**

One of the key activities that SIAPS has conducted is orienting health care workers on how to use the STG /EML, essential in promoting appropriate and rational use of medicines STG/EML. With a high baseline of 89% for the EML prescription compliance rate noted in the pre-implementation phase, it will be interesting to observe any changes after implementation of the STG/EML.

To ensure appropriate and rational use of medicines, SIAPS continues to disseminate the STG /EML and orient health care workers on it. Optimal use of this document will ultimately standardize care, and improve the selection and use of essential medicines. During this reporting

period, SIAPS conducted an orientation meeting at the invitation of the Mbabane Hospital Clinicians Committee. The meeting served as an opportunity to provide guidance to the clinicians on submitting recommendations for changes to the STG/EML document. The meeting was attended by two specialist physicians, two pharmacists, thirteen medical officers, and three department nursing heads.

SIAPS continues to be actively involved in supporting the MoH on adherence monitoring for TB patients. In this quarter, reports for the months of April and May were received and analyzed. The average adherence rates for the two months were 90% and 93%, respectively.

Regarding issues of adverse events and adherence to ensure medicine safety and effectiveness, SIAPS has collaborated with the WHO/AFRO office in Swaziland to strengthen systems and improve ADR reporting for TB, ARV, and the Expanded Programme on Immunization (EPI). For some time, the MoH has relied on spontaneous reporting of ADRs, which is heavily dependent on the willingness of health workers to file the report. Development of a sustainable active surveillance system for the HIV/TB program will complement the spontaneous ADR reporting in the country. This system will provide local data on drug safety and generate safety signals for medicines used by HIV and TB patients. During this quarter, SIAPS finalized the active surveillance protocol, SOPs, and related training materials for implementation of the new system. Following the approval of the protocol, the TB/HIV active surveillance activity was launched. Soon after the launch, 34 health care workers were trained (4 medical doctors, 13 pharmacists, 6 data clerks, and 13 nurses). The training resulted in SIAPS supporting the MoH to install SASSA (the specialized database to capture the ADRs at facilities) at all six pilot sites, and conduct onsite mentorship on the documentation and reporting of ADRs to the CMS. The DCAT (a central data aggregation tool) was installed on the CMS server for the Pharmacovigilance unit. SIAPS will feature ADR reports in a consolidated quarter three and quarter four medicine safety watch newsletter.

### ***Deliverables***

- Swaziland Ethics Committee (SEC) approval of the implementation of the TB/HIV active surveillance activity
- Trip report and technical report on the launch of and training for the TB/HIV active surveillance activity
- TB management training
- Finalized protocol for the TB/HIV active surveillance protocol and draft SOPs
- ADR reports with the pharmacovigilance unit
- TB treatment Adherence reports for April and May

### ***Constraints to progress***

Champion to take up the STG / EML task team chairperson role

## **Turkmenistan/Uzbekistan**

***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.***

SIAPS in Uzbekistan and Turkmenistan is focused on strengthening the national TB programs and improving the decision making and managerial practices, which impact rates of MDR-TB, through the provision of technical assistance and implementation of e-TB Manager. Efforts continued to move forward this quarter, April to June 2013. In addition, at the request of the USAID Central Regional Mission, SIAPS will support the TB pharmaceutical management system in Tajikistan and has been obligated USD USD 428,000 for this work. As agreed with the Mission, SIAPS will submit a revised work plan for Uzbekistan, Turkmenistan, and Tajikistan during the FY 14 SIAPS work planning cycle.

In Uzbekistan, the main constraint in moving forward is with Uzmedinfo. SIAPS, along with WHO/Europe and country counterparts, has put together and sent the requested documents and they are awaiting feedback form the MoH. In Turkmenistan, SIAPS continues to work closely with WHO/Europe and country counterparts towards the goal of initiating a pilot of e-TB Manager in Ashgabat and Mary Regions.

As agreed with the USIAD Central Asia regional Mission, the SIAPS principal advisor and senior technical advisor traveled to Tajikistan in late May. They met with national and international stakeholders to identify gaps in TB pharmaceutical management and discuss and agree on the SIAPS interventions to improve TB pharmaceutical management in Tajikistan. The focus will be providing support to the National TB Program (NTP) through an embedded technical advisor, improving the existing LMIS, developing human resource capacity within the NTP, and collaborating with the MoH to revise the course curricula for a variety health care workers and pharmacists to include up to date information on pharmaceutical management of TB drugs. The SIAPS senior technical advisor will return to Tajikistan in mid-July to participate in the WHO/Europe Tajikistan TB program evaluation and the Global Drug Facility (GDF) country monitoring mission, as well as provide TA to the country in pharmaceutical management of anti-TB drugs as needed and work on planning of the activities of SIAPS Tajikistan for FY2014.

***Objective 1: Strengthen the National TB Program of Uzbekistan through improving the TB management information system countrywide***

This quarter, April to June 2013, SIAPS has been in discussions with the USAID Central Asia Regional Mission on the stalled efforts in moving e-TB Manager forward, as well as the Mission's interest in conducting an assessment of the TB pharmaceutical management system. It has been agreed that in September, 2013, SIAPS's principle technical advisor and senior technical advisor will travel to Uzbekistan. They will meet, plan, and discuss this assessment with the national counterparts, as well as identify which national partners will be involved. In regards to e-TB Manager, SIAPS continues to coordinate with WHO/Europe and the MoH in Uzbekistan to move forward with e-TB Manager. As previously reported, the implementation of e-TB Manager in Uzbekistan has been suspended since the summer of 2012. Uzmedinfo, the

eHealth Development Center, a structural unit of the MoH of Uzbekistan, requested the DOTS Center (the main national counterpart of SIAPS in implementation of e-TB manager) not to use e-TB manager until further decision and referred to certain regulations of health information systems. Uzmedinfo finally provided the formal clarification of the exact documentation needed for the approval the beginning of April, 2013 (despite many attempts from SIAPS and WHO to get the clarification, as well as a trip and meetings in Uzbekistan among all partners and counterparts).

Uzmedinfo provided a set of standards from the Soviet era as a guide for preparation of the documents needed for approval of e-TB Manager. SIAPS, in collaboration with WHO and the national counterparts, prepared the set of the documents according to the corresponding standards. The documents were officially submitted to the MoH in mid-May. To date, SIAPS and its partners are awaiting feedback from the MoH on the submitted documents. SIAPS continues to be engaged and working through WHO and MoH TB counterparts to advocate for and address any concerns regarding e-TB Managers approval.

As soon as the MoH allows implementation and use of e-TB Manager, the following steps will need to be taken—

- An updated review of the status of the Uzbekistan version of e-TB Manager (information entered in the system on the piloting stage, needs for further customization, etc.)
- Assessment of the current status of the human capacity developed during the piloting process of e-TB Manager;
- Assessment of the current infrastructure for e-TB manager (server, distribution of the PSc procured by the Global Fund project, etc.)
- Revamping of the technical working group
- Initiation of TB case management module in the regions where e-TB Manager already was piloted (Tashkent, Tashkent Oblast, Kara-Kalpakstan)
- Piloting of the drug management and laboratory management modules of e-TB Manager

### ***Deliverables***

For approval of e-TB Manager, at the request of Uzmedinfo, SIAPS pulled together, modified, and translated an extensive list of documents. These documents, along with an official letter were submitted by WHO/Europe on behalf of SIAPS to the MoH and Uzmedinfo.

### ***Partner contributions***

WHO/Europe, WHO Country Office staff, the DOTS Center, NTP, and MoH representatives continue to be important partners throughout this process.

### ***Constraints to progress***

SIAPS's efforts to move e-TB Manager forward have been hampered by lack of response. Requested documents were submitted to the MoH and Uzmedinfo in mid-May and SIAPS and its in-country counterparts are still awaiting feedback and approval.



***Objective 2: Strengthen the National TB Program of Turkmenistan through provision of technical assistance for improving the TB management information system***

For Turkmenistan, the SIAPS Team has been working with WHO and MoH TB counterparts to move forward the e-TB Manager pilot in the Ashgabat and Mary Region, which was agreed upon by all parties. During this quarter, WHO has increased its negotiations with the NTP and MoH on the timing for the pilot to begin, and to start in the Ashgabat Region. WHO is in the process of procuring of IT equipment, including a server, for e-TB Manager.

***Deliverables***

- Clarification of legislative and regulatory requirements for implementation and use of electronic health information systems
- Creation of the technical working group for adaptation of e-TB Manager for the need of Turkmenistan.
- Development of the requirements for customization of e-TB Manager for Turkmenistan.

***Partner contributions***

WHO/Europe and in-country WHO staff continue to move this work forward in Turkmenistan.

***Constraints to progress***

There are no real constraints to moving forward the pilot of e-TB Manager outside of normal bureaucratic delays and WHO's procurement of equipment.

## Ukraine

**Goal: Through a health systems strengthening approach, build local capacity and develop strategic partnerships to achieve the goal of improving access to, use of, and accountability for life-saving medicines and health commodities of assured quality to support priority health services to achieve desired health outcomes.**

**Objective 1: Strengthen pharmaceutical management information systems (PMIS) to support the HIV, AIDS, and TB programs**

During this reporting period, SIAPS focused on three key areas:

- 1) Establishing regular working meetings with the Ukrainian Center for Disease Control (UCDC) as a mechanism for engaging key stakeholders and coordinating e-TB Manager implementation, monitoring, and requests for enhancements
- 2) Expanding e-TB Manager implementation
- 3) Working toward a means of electronic, automatic submission of adverse drug reaction (ADR) reports through e-TB Manager

The process of implementing e-TB Manager and use of the resulting data for programmatic and clinical decision making received key support in this quarter. UCDC was proposed as the new principal recipient for the Global Fund Round 9 TB grant. The National Coordinating Council and the Deputy Minister of Health strongly endorsed implementation and formally appointed UCDC as the agency responsible for implementation.

SIAPS worked with UCDC to achieve the next critical step in the process—UCDC's order on the jointly developed e-TB Manager implementation plan for 2013. UCDC addressed the need for strong national support for implementation by requiring all oblasts to enter case management data for all TB and MDR-TB cases being treated in 2013 by July 1, 2013. This resulted in a sharp increase in oblast-user training requests. SIAPS worked with UCDC to focus training efforts on developing a cadre of trainers in each oblast who will be responsible for training their peers and becoming the first line of support for their questions. A schedule of trainings for the next quarter was developed to address those oblasts in greatest need of support. SIAPS conducted an orientation session for the new e-TB Manager national-level administrator of UCDC and, together with UCDC, conducted medicines-management module pilot-launch visits to Kyivs'ka and Odess'ka oblasts (a visit to Khersons'ka oblast is planned for the upcoming quarter). Staff also continued routine support to facilities utilizing the e-TB Manager, including two user support and implementation progress monitoring visits to Khmelnyts'ka and Zhitomirs'ka oblasts.

To assure continuity of case management information across all facilities treating TB patients, SIAPS obtained support from the deputy head of the Yanovskiy National Institute of Phthysiology and Pulmonology (TB Institute) to begin using the e-TB Manager system, and subsequently conducted e-TB Manager user training in June 2013 for 14 TB institute staff.

As of June 30, 2013, 24 of 27 oblasts routinely entered data in the e-TB Manager database; the total number of TB cases entered reached 67,000. To improve monitoring and transparency of e-TB Manager operation by oblasts, UCDC initiated regular publication of the number of TB and MDR-TB cases entered into the e-TB Manager on UCDC's website. Future information published may include standard e-TB Manager summary reports and other key information.

As the number of cases entered has increased, UCDC, with SIAPS support, focused on improving the quality of data entered. The SIAPS team drafted a data quality assurance protocol for standardizing the procedures for data quality monitoring. SIAPS began piloting data quality assurance procedures and automatic reports in Odess'ka, Kyivs'ka, and Khersons'ka oblasts. The first goal is consistency between routine manual reports prepared by each oblast and respective reports generated by e-TB Manager for Q1 of 2013 in those oblasts.

In coordination with the State Expert Center (SEC) of the MoH of Ukraine, SIAPS initiated development of a pharmacovigilance (PV) monitoring function in e-TB Manager to support routine, automated reporting of ADRs and lack of efficacy reporting for TB. SIAPS and SEC agreed on key technical assumptions to allow data exchange between the e-TB Manager and the SEC database.

### ***Deliverables***

- Data quality assurance protocol developed for piloting
- Updated e-TB Manager Medicines Management Module, reflecting changes in the new National Unified Guidelines on Treatment of TB
- Updated user instructions for entering MDR-TB case data

### ***Partner contributions***

- UCDC approved and issued an order on the e-TB Manager implementation plan for 2013 (UCDC's order #15 as of May 27, 2013)
- UCDC and the Fund for Development of Ukraine (FDU) collaborated with SIAPS to revise the Global Fund Round 9 TB PSM plan to include more specific information about the relative support of partners for e-TB Manager implementation and the use of data
- The current Global Fund principal recipient (FDU) completed procurement of computers and Internet connections for oblasts and raions worth approximately USD 300,000
- UCDC started regular publication of the number of TB and MDR-TB cases entered by oblast into the e-TB Manager on the UCDC's official website to increase transparency and improve monitoring of implementation in oblasts.

### ***Constraints to progress***

Although UCDC recently assumed responsibility for e-TB Manager, it lacked staff for its implementation. UCDC resolved the constraint by hiring additional staff with specific responsibilities for e-TB Manager. The deputy director of UCDC demonstrated clear support for the process and facilitated collaboration with oblasts.

**Objective 2: Improve supply chain management systems for HIV, AIDS, and TB commodities**

SIAPS provided support for identifying TB pharmaceutical management issues at the facility and national levels and for developing approaches to monitoring and strengthening those practices. A particular focus was on managing second-line TB medicines. The principal recipient for the Global Fund Round 9 TB grant (FDU) until June 30, 2013, began procurement of second-line medicines for treatment of MDR-TB patients through its sub-recipient, the HIV/AIDS Alliance in Ukraine. Twelve oblasts were selected for initial distribution and implementation of treatment for MDR-TB. It is anticipated that UCDC will be approved to take over as principal recipient (see objective 3) and will work to meet the Global Fund MDR-TB treatment targets in the 12 oblasts, as well as additional oblasts in the future.

Similar to the process for selection of the first set of oblasts, SIAPS in this quarter provided technical assistance for visits to identify four new oblasts for inclusion in 2013—Vynnyts'ka, Kirovohrads'ka, Sums'ka, and Poltavs'ka. The main criteria for selecting oblasts that will provide Global Fund procured second-line TB medicines were health facility level, availability of an MDR-TB department in the hospital, diagnostic capacity, pharmaceutical management capacity, and established M&E mechanisms. SIAPS participated in a pharmaceutical management monitoring visit to Poltavs'ka oblast and a raion medical store, and provided recommendations to improve TB medicine storage conditions, inventory management, and oblast and raion level reporting. In addition, the site visit included review of inventory storage in MDR-TB hospital departments. SIAPS also provided technical assistance in thinking through issues related to monitoring temperature control for pharmaceuticals procured under the Global Fund grant.

UCDC initiated development of the comprehensive facility form for TB institutions covering basic information on oblast TB facilities, as well as other institutions providing TB treatment. SIAPS supported development of the facility form for the section dealing with availability of anti-TB medicines and other commodities, as well as other supply chain information. Data included facility names, contact data, human resource capacity, oblast program status, financing, and status of national e-TB Manager data entry and monitoring. Other data collected included information on laboratories and their accreditation status, basic laboratory equipment, TB diagnostics, infection control measures, availability and conditions of storage space for pharmaceuticals, activities of the oblast TB/HIV coordination council, and collaboration with partners and academic institutions. The facility form is completed by oblast personnel and is intended to be updated annually.

SIAPS completed the analysis of data provided by oblasts on pharmaceutical management in TB and HIV facilities and began working on next steps. The rapid self-assessment indicated issues related to storage conditions, availability and training of personnel, and stock outs. Site visits by SIAPS and national personnel will allow further exploration of the problems and potential solutions. Findings will be used to inform the development of indicators and a shorter monitoring guide to be used by oblast and national personnel for performance improvement.

MoH used an interim methodology for quantifying TB medicines to be procured in 2013; however, in the development of the e-TB Manager implementation plan for 2013, the UCDC

emphasized the intention to use e-TB Manager for quantification in 2014, once the medicines management module is in place and the quality of the data are assured.

### ***Deliverables***

- Pharmaceutical management monitoring visit report (Poltava, Kremenchuk)
- Pharmaceutical management indicators and questions included in the facility form

### ***Partner contributions***

- UCDC worked with SIAPS and other partners to develop a comprehensive facility form
- UCDC facilitated a discussion with the deputy minister on implementation of the e-TB Manager and use of the resulting information for quantification and decision making
- UCDC committed to provide time for staff to work on pharmaceutical management with SIAPS on a regular basis

### ***Constraints to progress***

UCDC's limited human resource capacity and hiring of new staff has been addressed above.

### ***Objective 3: Enhance organizational and human resource capacity for pharmaceutical management***

SIAPS' focus of support was on preparing for a visit from the Global Fund prior to the final decision to sign a contract with UCDC as the new principal recipient for the Round 9 Global Fund TB grant (phase 2). SIAPS worked with UCDC to review pharmaceutical management issues raised by the Global Fund in the procurement and supply management (PSM) plan and to clarify their expectations for deliverables and conditions that would need to be met before signing an agreement with UCDC to assume the role of principal recipient. SIAPS provided input to refine the PSM plan relative to information systems and the use of e-TB Manager, supply chain management, rational medicine use (RMU), and PV.

SIAPS, together with USAID, met with UCDC to discuss the PSM gap analysis prepared in the previous quarter. The discussion was very productive and resulted in a series of working meetings with key stakeholders, agreement on priority problem areas, and key next steps. In April 2013, SIAPS, USAID, UCDC, and the State Service discussed and agreed on key activities for capacity development of UCDC, which was included in the overall technical assistance plan presented to the Global Fund and to MoH.

Since UCDC's designation as the MoH structure responsible for e-TB Manager implementation, SIAPS worked intensively with new UCDC staff to orient them to the e-TB Manager, achievements to date, and the use of resulting information for clinical and programmatic decision making. SIAPS is providing support to a working group established by UCDC to meet regularly to ensure agreement on activities; review progress, challenges, and opportunities; and provide a forum for feedback. UCDC also started taking advantage of VOIP technology as a cost-effective means of discussing important issues with oblast representatives.

### **Deliverables**

- Inputs for the PSM plan on the e-TB Manager, supply chain management, quantification, PV, and RMU
- Plan for technical assistance in support of UCDC capacity development in PSM

### **Partner contributions**

- UCDC's and FDU's roles in phase 2 of the Global Fund grant discussed above
- The Alliance provided support for development of documents on procurement of second-line TB medicines and also provided inputs to the PSM plan revision

### **Constraints to progress**

UCDC has limited human resource capacity discussed above; it is anticipated that, as of July, approximately 30 positions will be funded by the FDU, adding capacity to UCDC. Some of these personnel will have experience in PSM.

### **Objective 4: Improve pharmaceutical services for the TB and HIV and AIDS programs**

SIAPS continued providing technical assistance for strengthening PV in Ukraine. Since the December 2012 stakeholder meeting, organized by the SEC with SIAPS support, the concept of strengthening PV in Ukraine has been steadily gathering support from the leadership of MoH, the State Service, UCDC for public health programs, and other partners and consumer groups. SIAPS supported efforts to define the potential roles of stakeholders in PV. To formalize the process, SIAPS and the SEC signed a memorandum of understanding (MOU). Key areas of collaboration include the development of a protocol for active surveillance, an automated system for gathering ADR information for TB, procedures for conducting PV audits, and interventions for improving drug use.

In May, the SIAPS Ukraine senior technical advisor for PV and RMU took part in the 2013 MSH Fellowship Program in Washington, DC. The fellowship allowed the representative to interact with key technical experts to develop the first draft of an active PV protocol and a plan for its implementation.

Subsequently, SIAPS presented documents to the two institutions responsible for active PV (the SEC and State Service) and obtained their support. In June, SIAPS also provided support to UCDC to refine the Global Fund Round 9 PSM plan to include provisions for PV and mechanisms for monitoring RMU.

According to the active PV protocol, setting up two working groups is a necessary precondition for successful implementation in Ukraine. The first working group will adapt an active PV information system. The SIAPS/SEC team drafted a membership and action plan for the working group on adapting an existing tool for data collection, and the first meeting is scheduled for July.

The second working group will deal with protocol approval and further active PV implementation. SIAPS provided technical assistance to the SEC to draft a PV implementation plan for presentation to the State Service and MoH. SIAPS also proposed holding a joint working meeting of all stakeholders to launch the implementation plan. A meeting to obtain support from the deputy minister of health is tentatively scheduled for early July.

To begin work on establishing an automated system to support surveillance of ADRs due to registered medicines and/or their lack of efficacy was further developed. Key technical issues were agreed upon with the SEC to clarify design questions and facilitate development of the mechanism (see objective 1).

In June, the SIAPS/Ukraine team participated in the “Management of TB Medicines Supplies: Planning, Quantification, and Monitoring” training, co-sponsored by WHO and SIAPS (core TB team). Additionally, SIAPS TB and Ukraine team members worked together to identify possible means of supporting rational medicines in Ukraine, including implementing a TB drug use review program. The TB team provided relevant instruments to review and adapt with the aim of planning further activities in support of RMU.

### ***Deliverables***

- MOU between the SEC and SIAPS on strengthening PV and RMU
- Protocol for conducting active surveillance for TB and HIV medicines

### ***Partner contributions***

- The SEC signed an MOU with SIAPS for strengthening PV in Ukraine
- The SEC initiated a meeting with the deputy minister on PV to inform him and other decision makers on the need for active PV implementation
- The MSH Center for Pharmaceutical Management funded the 2013 Fellowship for the Senior Technical Advisor for RMU/PV

### ***Constraints to progress***

- MoH is demonstrating support for PV initiatives; however, implementation can be affected by unanticipated delays in responses or other bureaucratic processes.
- Although the growing support by state agencies for PV for TB and HIV and AIDS programs is welcome, additional work is needed to promote a common understanding of the processes and regulations and to establish realistic expectations and a timeline.

### ***Objective 5: Improve pharmaceutical management governance***

SIAPS supported several units of the Ukrainian MoH to develop and implement pharmaceutical, commodity management, and medicine safety policies. To support adaptation of the newly adopted European Medicines Agency (EMA) PV Guidelines, SIAPS supported translation of the EMA PV Guidelines into Ukrainian. With SIAPS support, the SEC is leading a working group to develop and seek approval for the PV guidelines. MoH issued an order to establish the working

group (MoH order # 2717/2.8-8, 06.26.2013), which started its activities in June 2013. Also in June, SIAPS collaborated with other working group members to adapt the first module.

MoH is developing a heightened interest in PV, e-TB Manager, and other pharmaceutical management issues expressed through orders, instructions to MoH units and partners, and increased frequency of meetings. At the end of May, the SEC and SIAPS met with the deputy health minister to discuss the need for setting up an advisory committee on medicines safety to ensure sufficient visibility and authority to obtain action, if needed. The proposal is under discussion between MoH and the SEC.

Currently, supply chain management in Ukraine is governed by a large number of policies and regulations, which may conflict with one another. To ensure standardized procedures for managing second-line TB medicines procured under the Global Fund, SIAPS, after consultation with USAID/Ukraine, agreed to provide technical assistance in this fiscal year to UCDC to start developing a series of SOPs, in collaboration with the FDU and the Alliance. SOPs to be developed include selection, quantification, procurement, distribution, and others.

SIAPS provided input to the State Service for revision of the National TB Program (2012-16), including those related to RMU, quantification, and PV.

### ***Deliverables***

- EMA PV Guidelines translated into Ukrainian
- List of proposed SOPs to be developed on supply chain management for TB

### ***Partner contributions***

- The SEC has taken the lead in establishing working groups on PV guidelines and active Surveillance and the PV Advisory Committee. The SEC interfaces with other agencies within MoH and the deputy minister to move these activities forward.
- UCDC has agreed to work closely with implementing partners to develop the guidance documents and SOPs needed to effectively manage TB medicines. UCDC has also taken up the role of facilitating interactions with the deputy minister to garner support for pharmaceutical management activities.

### ***Constraints to progress***

The Ukrainian system is highly structured, so it is important to identify and establish a mechanism that has the technical mandate and political support to be effective. Typically, this is time-consuming and affects both the M&E and PV working groups.