Democratic Republic of the Congo
End of Project Report

March 2017

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SIAPS
Systems for Improved Access to Pharmaceuticals and Services

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About SIAPS

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to ensure 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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Key Words

Democratic Republic of the Congo, pharmaceutical systems strengthening, health systems, pharmaceutical services, pharmaceutical management, access to medicines

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CONTENTS

ABBREVIATIONS AND ACRONYMS

ACPE	Accreditation Council for Pharmacy Education
AIDS	acquired immune deficiency syndrome
ART	antiretroviral therapy
ARV	antiretroviral
ASRAMES	Regional Procurement Association for Essential Medicines
CDR	central regional medical store
CNM	National Medicine Committee
CNPV	PV center
CPM	Provincial Medicine Committee
DISMED	an electronic tool
DPS	provincial health division
DRA	Drug Regulatory Authority
DRC	Democratic Republic of the Congo
DTC	Drug and Therapeutics Committee
EDT	Electronic Dispensing Tool
EUV	end user verification
FOPS	Faculty of Pharmaceutical Sciences
FP	family planning
HIV	human immunodeficiency virus
LMIS	Logistics Management Information System
MDR-TB	multidrug-resistant TB
MNCH	maternal, neonatal, and child health
MOH	Ministry of Health
MSH	Management Sciences for Health
NEML	national essential medicines list
NMCP	National Malaria Control Program
PNAM	National Medicine Supply Program
PV	pharmacovigilance
SCMS	Supply Chain Management System [Project]
SIAPS	Systems for Improved Access to Pharmaceuticals and Services [Project]
SIGIP-ARP	Integrated System for Computerized Management of Regulatory Processes within DRA
SOP	standard operating procedure
TB	tuberculosis
WHO	World Health Organization

BACKGROUND

Pharmaceutical services play a critical role in any health system. The Democratic Republic of the Congo's (DRC) National Health Strategic Plan 2011–2015 describes medicines as an essential link in the development of the health system. The 2009 World Health Organization (WHO) Essential Medicines report asserts that all health strategies from governments and development partners depend on essential medicines. Unfortunately, the DRC health system lacked a fully functional pharmaceutical regulatory system and a comprehensive national pharmaceutical policy framework to guide regulation of the pharmaceutical system and coordination of pharmaceutical sector activities to achieve system objectives based on priority health problems. This resulted in:

- The mushrooming of illegal and uncontrolled pharmaceutical businesses
- Non-adherence to good distribution practices and good manufacturing practices by suppliers, wholesalers, and local manufacturers
- Loopholes that facilitated the circulation of counterfeit and substandard medicines in the country, which directly led to the high number of available unregistered and unauthorized medicines

Furthermore, the lack of infrastructure, unreliable information systems, the shortage of trained and qualified pharmaceutical personnel, the overreliance on international partners' funding, and the poor coordination among those partners resulted in bottlenecks that hampered the delivery of pharmaceutical services in the country.

The USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program focuses on achieving positive health outcomes by ensuring the availability of quality pharmaceutical products and effective pharmaceutical services. The main objective of the SIAPS Program in DRC is to help strengthen the pharmaceutical system by:

- Improving governance
- Building institutional and individual capacity
- Strengthening information systems for informed decision making
- Strengthening financing mechanisms
- Improving service delivery

During the five years of the program, SIAPS provided comprehensive technical assistance to the Ministry of Health (MOH) through the Drug Regulatory Authority (DRA), National Medicine Supply Program (PNAM), national disease programs (i.e., malaria, tuberculosis [TB], HIV/AIDS, family planning [FP], maternal, newborn, and child health [MNCH], etc.), and provincial health divisions (DPS). SIAPS' technical assistance has also been to central regional medical stores (CDRs) and health facilities to improve the availability of medicines and patient outcomes.

KEY INTERVENTIONS

Supporting the DRA to Improve Governance and Leadership

From 2012 to 2016, SIAPS supported the DRA in developing successive annual operational plans to improve governance, support the implementation of a fully functional pharmaceutical regulatory system, and develop a comprehensive national pharmaceutical policy framework. SIAPS assisted the DRA in establishing a Medicine Registration Committee that meets regularly on a quarterly basis to coordinate and streamline registration processes. To ensure efficiency, accountability, and control, members of the registration committee were trained on standard operating procedures (SOPs); a registered medicines directory was developed and updated each quarter and disseminated for use by pharmacist inspectors and customs officers at border posts, the main entry points for medicines, to track unregistered and unauthorized medicines. In addition, SIAPS assisted the DRA in updating the National Essential Medicine List (NEML) and including 13 lifesaving commodities endorsed by the UN Commission on Life-Saving Commodities for Women's and Children's Health.

SIAPS supported the DRA and DPS to better coordinate the supply mechanism of essential medicines and to steward equitable distribution, redistribution, and reallocation of pharmaceutical resources throughout the country. SIAPS also assisted the DRA in training pharmacist inspectors to promote good distribution and dispensing practices.

To ensure traceability and quality of medicines circulating in the DRC, SIAPS supported the DRA in acquiring the Integrated System for Computerized Management of Regulatory Processes within Drug Regulatory Authority (SIGIP-ARP) software. The software will help the DRA achieve end-to-end management of the medicines registration process and enable transparency and traceability of the medicines registration process.

Supporting Improvements to Storage Conditions in Warehouses and CDRs

Over the five-year project lifetime, SIAPS supported supply chain management activities, including improvement of storage conditions (i.e., procurement of thermos-hygrometer, dehumidifier, cold chain equipment, extinguishers, and solar power kits). SIAP provided technical assistance to the CDRs in USAID-supported provinces to address the gaps identified by the MOH and implementation partners (e.g. Supply Chain Management System [SCMS]) and through surveys, such as the end user verification (EUV) surveys. SIAPS also supported the CDRs in updating their SOPs to ensure good distribution practices where HIV, malaria, TB, and FP/MNCH commodities are managed.

Furthermore, SIAPS assisted the Regional Procurement Association for Essential Medicines (ASRAMES), the largest warehouse in the eastern part of DRC, to meet the USAID/European Union pre-qualification standards. ASRAMES is now a USAID C-category supplier, meaning only commodities from US Food and Drug Administration-approved suppliers can be procured. ASRAMES is therefore used as a local supplier, thus, addressing the long lead time faced when importing pharmaceutical products from international suppliers.

Supporting the Quantification of Pharmaceutical Commodities

To ensure appropriate quantification of medicines and commodities, SIAPS began by supporting the MOH in updating the NEML as a tool for medicine selection at the health-facility level. With other USAID implementing partners, SIAPS supported assessment of the Logistics Management Information System (LMIS) and developed the LMIS roadmap, including data collection tools to ensure that relevant supply chain data and information are available and submitted in time to inform the quantification process.

SIAPS assisted the MOH in implementing quantification tools, such as QuanTB and Quantimed, and conducted training of health workers on the quantification of critical pharmaceutical commodities, such as malaria drugs, antiretroviral drugs (ARVs), TB drugs, and the 13 lifesaving MNCH products. In addition, SIAPS assisted the MOH in establishing quantification committees at both the national and provincial levels to ensure that stakeholders from all levels are involved in the quantification process.

Assisting Warehouses and Health Zones to Improve Medicines Management and Distribution

Through this intervention, SIAPS helped improve pharmaceutical management and distribution of pharmaceuticals from CDRs to health zones and health facilities in USAID-supported provinces. The intervention design consisted of the following:

1) Training health care workers on SOPS for good distribution practices and pharmaceutical management

2) In-service training of CDR and health zone store staff on stock management and quarterly distribution plans

3) Supporting the MOH in coordinating medicine distribution at both national and provincial levels through technical assistance to the National Medicine Committee (CNM) and Provincial Medicine Committees (CPMs)

4) Implementing the use of an electronic tool (DISMED) to better monitor medicines distributed in USAID-supported health zones

5) Updating SOPS for managers at the warehouse and health facility levels

6) Developing a roadmap for implementing activities related to LMIS

SIAPS supported the improvement of medicines availability in USAID-supported provinces both at CDR and facility levels. Because medicines management and distribution fees were paid to CDRs, they were able to enhance their operational capacities.

Building Capacity through Pre-Service Training

One of the key interventions carried out by SIAPS during its five-year lifespan was the revision of the training curriculum for the Faculty of Pharmaceutical Sciences (FOPS) of the University of Kinshasa. SIAPS has been the only USAID-funded program to provide the MOH with pre-service training support and to ensure that graduated health care providers are equipped with adequate and appropriate knowledge and skills relevant to the health needs of the country. The previous curriculum was outdated as it was inherited from the colonial period and did not reflect current public health needs. The revision process was coordinated with the Accreditation Council for Pharmacy Education (ACPE) based in Chicago.

To complete the curriculum revision process, a team of three members from FOPS and two SIAPS staff members participated in a highly technical consultation meeting held in Chicago in April 2016. Three FOPS documents prepared by the DRC team were presented: the five-year strategic plan, the operational plan, and the competency framework for pharmacists. The documents were improved by the US team, which consisted of ACPE members, academics, and curriculum experts from five Chicago-based universities, namely, Chicago State University School of Pharmacy, University of Illinois at Chicago College of Pharmacy, Rosalind Franklin University of Medicine and Science, Dewitt Baldwin Institute for Interprofessional Education, and Midwestern University of Chicago. During these consultation meetings, the three documents were thoroughly analyzed and updated. The DRC team was given directives and guidance on the way the curricular mapping should be developed and the revision process performed. Additionally, the DRC team took this opportunity to visit three of the above-mentioned Chicago universities to investigate and discuss a long-term partnership with them.

Enhancing Pharmaceutical Services

Other major SIAPS interventions consisted of supporting the National Malaria Control Program (NMCP) in training health care workers on malaria medicines and case management according to the 2012 guidelines of the NMCP and conducting biannual EUV surveys to evaluate access and availability of malaria commodities at the point of care.

SIAPS has also supported the MOH in implementing a multidrug-resistant tuberculosis (MDR-TB) and TB/HIV co-infection active pharmacovigilance (PV) system and training health care workers on the PV system, including appointing TB focal persons for PV activities.

To ensure better coordination and implementation of PV activities, SIAPS provided institutional capacity building to the PV center (CNPV). A collaborative system between key stakeholders, namely CNPV, DRA, and Drug and Therapeutic Committees (DTCs), was established following recommendations from the minister of health. PV training was conducted for health care workers, especially members of the newly established DTCs, to ensure smooth implementation of PV activities at provincial and health-facility levels. As a result, key stakeholders participate in regular meetings for effective planning and good coordination of PV activities.

KEY ACHIEVEMENTS

Supporting the DRA to Improve Governance and Leadership

With SIAPS assistance, the DRA established a Medicine Registration Committee that met on a quarterly basis to better coordinate and streamline registration processes; the members of the committee were trained to strengthen their competencies and promote best practices. Attendance of the SIAPS team at the meetings is no longer necessary to drive the registration process, unless purposely requested.

The DRA, with SIAPS assistance, managed to improve the SOPs to better align them with international guidance and good governance recommendations. In addition, SIAPS helped the committee establish a schedule for quarterly meetings and set up systems for biannual publishing and posting of the list of registered medicines to make it publicly available. The list continues to be used by customs officers and inspectors to control importation and conduct inspections nationwide.

SIAPS technical support helped strengthen the capacity of the national registration committee and streamline medicines registration. As a result, the number of registered medicines has increased from 455 in 2011 to 4,486 in September 2016; 72% of the medicines included on DRC's NEML currently have at least one product registered, up from 44% in 2011. The time taken to process a new application was reduced from a peak of 82 days in 2013 to 58 days in September 2016.

The MOH now has the capacity to systematically evaluate and approve medicines for registration in a timely manner by using processes that are more transparent and less vulnerable to corruption. Customs officers and inspectors are also better equipped to identify and confiscate unregistered medicines circulating within the market and at border posts. A stronger product registration system helps the government ensure that medicines in the country are safe, effective, and of acceptable quality.

The number of registered medicines circulating in the country has increased, from 455 at the baseline in 2011 to 4,486 as of September 2016. In addition, a medicine registration database has been developed to ensure record keeping for reference; 11 documents related to pharmaceutical management including norms, lists, and guidelines were produced; the number of pharmaceutical management guidelines, lists, and SOPs developed (or updated) and submitted for adoption has increased from zero (December 2011) to 13 in September 2016.

Assisting Warehouses and Health Zones to Improve Medicines Management and Distribution

Health workers were trained in good distribution practices and pharmaceutical management, which resulted in better management of medicines and related supplies, i.e., the EUV surveys conducted every six months reveals that the supply chain stock indicator shows that the proportion of health facilities managing and stocking medicines according to plan (between

minimum and maximum stock) improved from only 30% before the intervention to 80% after the intervention.

The percentage of health facilities using a standardized checklist to monitor storage conditions has increased from 0% in December 2011 to 75% in September 2016.

Supporting Quantification of Pharmaceuticals

With SIAPS support in collaboration of other partenr, the DRC MoH quantified the need for TB drugs, antiretroviral drugs, malaria drugs, other essential medicines and pharmcutical commodities using quantification tools such as Quantimed, QuanTB, tools adopted by the MoH as national quantification tools.

The Essential Medicine List has been updated and disseminated; the 13 life-saving medicines for mother and child health have been quantified and introduced in the counrty.

With SIAPS technical assistance, ASRAMES now met the USAID/European Union pre-qualification standards and is used as a local supplier, thus, addressing the long lead time faced when importing pharmaceutical products from international suppliers.

- The percentage of health facilities with stock-outs of a pre-selected group of medicines (tracer medicines) for three days or more in the last three months has decreased from 100% in December 2011 to 36% in September 2016.

- The percentage of warehouses with stock-outs on a pre-selected group of medicines for three days or more in the last three months has decreased from 100% in December 2011 to 13% in September 2016.

Building Capacity through Pre-Service Training

With SIAPS support, the University of Kinshasa FOPS developed a strategic plan to better coordinate, monitor, and evaluate faculty operations and a competency framework that defines the required cognitive, procedural, and compartmental/behavioral competencies that a student should have at the time of graduation. The competency framework was the basis for overhauling the old training curriculum which, according to the ACPE evaluation conducted in July 2014, did not respond to the public health concerns of the country and did not address the supply chain issues faced by the pharmaceutical sector. As a result, FOPS became the first training institution in DRC to have a strategic plan and, during the official presentation ceremony of the strategic plan in June 2015 before country stakeholders, the minister of high education recommended that all other DRC training institutions adopt this model and use the FOPS strategic plan as a reference. FOPS is thus far the only training institution in DRC that meets the World Bank requirement of submitting a strategic plan as a prerequisite for any future funding.

Enhancing Pharmaceutical Services

In 2012, SIAPS and CNPV initiated a collaborative mechanism between key stakeholders, namely CNPV, DRA, and DTCs, to strengthen the PV system, following recommendations from the minister of health. Further, trainings for relevant staff on PV were conducted, including members of the 30 established DTCs, to ensure smooth implementation of PV activities at provincial and health-facility levels. STGs were developed to promote the rational use of medicines and the FOPS training curriculum was revised to include PV issues. In addition:

- The number of persons trained with SIAPS support in pharmaceutical management has increased from none in December 2011 to 1,217 in September 2016.
- On average, CNPV receives 1,500 individual case safety reports per year with a completeness score (> 75%) well beyond the average score for other countries (50%).
- Causality assessment is done under the supervision of the university's clinical team.
- CNPV staff support the management of adverse events at the point of care.

SIAPS supported the EUV survey conducted at the health-facility level, which aimed to measure the availability and the rational use of malaria commodities. The findings from the EUV were shared and discussed with decision makers at national and regional levels, and corrective measures were put in place to address the weaknesses. For example, SIAPS assisted the health zones and CDRs in developing their DISMED.

This resulted in a significant improvement of the availability of malaria commodities. The first EUV survey conducted in March 2013 showed the availability of ACTs was only 39% at health facilities whereas the last EUV in 2016 showed a significant improvement of over 90%. A subsequent increase in the number of under-5 cases of malaria treated was achieved.

SIAPS supported the implementation of DTCs and conducted a study that revealed that prescribing behavior indicators (number of medicines per prescription, use of antibiotics and injections, use of the NEML, and use of generic names) were better in hospitals with DTCs than in those without DTCs. The study further found that patients in hospitals with DTCs had an overall better knowledge of their medication (route of administration, frequency, duration of the treatment) than those in hospitals without DTCs. Finally, the study revealed that prescriber adherence to national treatment guidelines (STGs) was better in hospitals with DTCs than in those without. For example, 60% of malaria cases were managed according to the STGs in hospitals with DTCs versus only 40% in hospitals without DTCs.

SIAPS has also supported the MOH to implement MDR-TB and TB/HIV co-infection active PV system and the training of health care workers on the PV system, including the appointment of TB focal persons for PV activities. This helped improve the management of MDR-TB and TB/HIV co-infection patients, which eventually reduced significantly the occurrence of irreversible medicine-induced deafness cases (from 44 cases in 2014 to none in 2015 and 2016).

LESSONS LEARNED

- To ensure supply continuity, medicines should be procured from both local and international suppliers, as the long lead time of procuring from international suppliers compromises the timely availability of medicines.

- Partners' coordination is central to avoid mismanagement and wastage of resources due to overlapping interventions.

- Performance and incentives are linked in the sense that monetary and/or other non-monetary motivations often bring government officials to better deliver.

- Shortage and high turnover of health care workers at health facilities challenge good implementation. However, SIAPS managed to provide capacity building to at least two staff members in each health facility and knowledge/skills sharing was conducted by SIAPS trained staff in each facility. Implementation was thus made sustainable.

SUSTAINABILITY AND COUNTRY OWNERSHIP

SIAPS has continuously advocated for and provided support to the DRA by emphasizing the key role it plays in strengthening health systems. Following SIAPS' support, not only has the DRA gained full ownership of the medicines registration process, but also and most importantly, many MOH partners, such as World Health Organization, European Union, and Belgian Technical Cooperation, are now providing significant support to the DRA with and without SIAPS' collaboration.

The following SIAPS interventions have been sustainably transitioned to the MOH:

- All the norms, lists, guidelines, and SOPs developed with SIAPS assistance are now owned by the MOH.
- The medicine registration sessions are now routinely held by the DRA.
- National and provincial medicine committee meetings are now regularly conducted without SIAPS support.
- The NMCP has adopted EUV as one of its monitoring and evaluation mechanisms and major findings of the EUV are part of the NMCP annual report.
- PV activities are routinely conducted by DTCs and CNPV.

THE FUTURE OF PHARMACEUTICAL SYSTEMS STRENGTHENING

To ensure continued strengthening of the pharmaceutical systems in the DRC, it will be critical to:

- Provide technical assistance to the National AIDS Program (PNLS) to implement adherence counselling and monitoring methods so as to survey patients' adherence to antiretroviral therapy (ART) at ARV-dispensing pharmacies. In so doing, patient adherence will be improved, thereby preventing drug resistance and treatment failure

- Monitor early warning indicators for ART in USAID-supported sites to detect and address ARV drug resistance at the early stage

- Implement the Electronic Dispensing Tool (EDT) to improve dispensing of medicines at the health-facility level and facilitate data gathering and reporting of medicine use. This will facilitate the capture and reporting of stock and patient management data for informed decision making on quantification, adherence to treatment, and patient management

- To improve governance in pharmaceutical systems, the Leadership Development Program should be provided to high-level MOH officials at the central and provincial levels

- Support the finalization and implementation of the National System for Medicines Supply strategic plan

- Integrate aspects of the supply chain into the training curriculum for the FOPS

- Support the effective functionality of the National Quantification Commission

- Continue supporting the CDRs in the management of medicines funded by USAID-supported projects

- Support partner CDRs for improving medicine storage conditions

- Support the functioning of the LMIS

- Support the strengthening of supply coordination mechanisms put in place by the MOH through the CNMs and CPMs

- Continue supporting training for health workers on medicine management

ANNEX. IMPLEMENTING AND STAKEHOLDER PARTNERS

Implementing Partners	Intervention(s)	Year(s)
ACPE	• Revision of the FOPS training curriculum	2014, 2015 and 2016
CNPV	• Development of STGs for general referral hospitals • Capacity building of health workers on disease case management and rational use of medicines • Submission of adverse drug event reports to Uppsala Monitoring Center	2012 to 2016

Stakeholders Partners	Intervention(s)	Year(s)
Integrated Health Project–Plus	• Capacity building in supply chain management • Review of MNCH standards and guidelines • Procurement, planning, and monitoring report for contraceptives (PPMRc)	2012-2016
Ecumenical Pharmaceutical Network	• Quantification of MNCH commodities	2012-2016
SCMS	• Strengthening the supply chain	2014-2016
Deliver Project	• Capacity building in supply chain management • Procurement, planning and monitoring report for malaria commodities (PPMRm)	2012-2016
Santé Rurale Program	• Capacity building in supply chain management	2012-2016
NMCP	• PPMRm • EUV survey; • Capacity building for malaria case management	2012-2016
PNLS	• Capacity building in ARVs management • EDT piloted at treatment sites for persons living with HIV/AIDS • Distribution of ARVs to treatment sites	2012-2016
National Tuberculosis Control Program	• Quantification of TB medicines • Transfer of TB medicines from TB coordination offices to CDRs • Capacity building in TB medicines management and supervision visits to TB treatment sites • Update of the TB Management Guidelines (PATIMED)	2012-2016
PNAM	• Capacity building in pharmaceutical management • Update of the PNAM strategic plan • Update of PNAM's medicine management technical sheets • EUV survey	2012-2016
National Reproductive Health Program	• PPMRc	2012-2016
13 Provincial health divisions	• Supply chain coordination mechanism at provincial level (CPM meetings) • Implementation of national-level strategies at provincial level	2012-2016