# **SIAPS Guinea End of Project Report**

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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.

#### **Recommended Citation**

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#### BACKGROUND

Guinea is a coastal West African country with a population of approximately 10.63 million, all of whom are at risk of malaria. The disease remains a major public health issue, with an incidence of 101/1,000 population as of 2010.<sup>1</sup> More than 90% of infections are caused by *Plasmodium falciparum*, and according to national health statistics, the morbidity rate for malaria is 148/1,000. Among children under the age of five, malaria accounts for 31% of consultations, 25% of hospitalizations, and 14% of hospital deaths.<sup>2</sup>

The organization and operation of Guinea's pharmaceutical sector do not allow the government to meet its mission of providing its citizens with quality health products at affordable prices. Working with the private and informal sectors, the Central Pharmacy of Guinea (PCG) remains the main instrument for procurement and supply of health commodities in the public sector. The PCG struggles to fulfill its responsibilities of ensuring the availability of quality and affordable health products to the Guinean population because of financial problems and governance issues.

When the US Agency for International Development (USAID)-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program started in Guinea in 2012, public health facilities faced prolonged stock-outs of antimalarial medicines and other health commodities. This was due to a shortage of products in the country and insufficient reporting of essential commodity logistics data (e.g., stock on hand, consumption), both of which impacted the country's ability to accurately forecast malaria commodity requirements. The supply chain was functioning in silos that were vertically funded and managed by different health programs. As a result, stakeholders had little common understanding of the supply chain and no formal procedures for its operation, which led to fragmented supply chain efforts across the system. The Ebola outbreak that devastated the country in late 2014 had significant negative effects on the supply chain system. Efforts shifted to controlling the Ebola epidemic and disrupted other services, including the supply chain.

Over the past six years, Guinea's health indicators have demonstrated progress, particularly in decreasing the malaria prevalence rate and the under-five mortality rate. Unfortunately, the Ebola crisis wiped out the health gains up to that point due to a breakdown in many aspects of the public health system. The impact of Ebola on the health system decreased the utilization of health services, disrupted the pharmaceutical supply system, and weakened the health workforce. With support from funding and technical partners, the Government of Guinea developed a post-Ebola socioeconomic recovery plan in 2015 that articulated investment programs and accompanying measures relevant to the recovery of the socioeconomic sector, particularly in health. Consideration was given to recovering and rebuilding the health system to increase its capacity and resilience in the face of the existing needs and challenges related to pandemics such as Ebola.

The goals of SIAPS in Guinea were to strengthen governance in the pharmaceutical sector, enhance capacity for pharmaceutical management and services, make pharmaceutical management information systems available at all levels, improve pharmaceutical services to

<sup>&</sup>lt;sup>1</sup> Guinea National Health Statistics

<sup>&</sup>lt;sup>2</sup> ibid.

achieve desired health outcomes, and ultimately save lives and protect the public's health by improving access to and use of medicines of assured quality.

While activities primarily focused on malaria, SIAPS broadened its scope of work to aid in managing the Ebola outbreak in Guinea and expand the logistics management information system (LMIS) to other key disease programs.

SIAPS' technical assistance to the Ministry of Health (MOH) aimed to achieve coordinated and sustainable improvements in the critical components of the pharmaceutical system, make it more responsive and resilient, and enhance its performance to achieve better health outcomes.

## **KEY INTERVENTIONS AND ACHIEVEMENTS**

Over the project's six years of implementation, SIAPS deployed key interventions that contributed to the shared goal of the Government of Guinea, the President's Malaria Initiative (PMI), and USAID/Guinea to reduce malaria-related morbidity and mortality and end preventable maternal and child health. To accomplish this, SIAPS took an evidence-based, systems strengthening approach that is rooted in collaborative relationships with all partners and clients at the local, regional, national, and global levels, including the MOH, the *Direction Nationale de la Pharmacie et du Médicament* (DNPM), the PCG, the *Programme National de Lutte contre le Paludisme* (PNLP), the *Agence Nationale de Sécurité Sanitaire*, the *Unité de Gestion Logistique*, the *Directions Régionales de Santé* (DRS), the *Directions Préfectorales de Santé* (DPS), and health facilities.

#### **Governance in Pharmaceutical Management**

#### Providing a National Assessment of the Pharmaceutical Sector

To provide the country with a comprehensive picture of the level of transparency and potential weaknesses of pharmaceutical-sector functions, SIAPS supported the MOH to undertake a national assessment of the pharmaceutical sector, the results of which provided a baseline for the country to revise and adjust its laws and policies, administrative structures, and processes and later served to guide the development of a strategy for promoting good governance in medicines regulation, procurement, and supply.

#### Revising the National Pharmaceutical Policy

The Government of Guinea adopted the first National Pharmaceutical Policy (NPP) in 1994 and updated it in 2007. The policy was adopted at a time when the country's health sector and particularly the pharmaceutical sector were facing many challenges, including the lack of regulatory policies. While the 2007 policy document provided an essential orientation for the development of various aspects of the Guinean pharmaceutical sector, most were not implemented. The socioeconomic context at that time also made the implementation of the NPP difficult. Therefore, it was judged appropriate to update the NPP (validated in June 2014) and publish a new policy document that aligns with the state of the pharmaceutical sector, both in Guinea and at the international level.

SIAPS support to the DNPM resulted in a revised NPP in 2012 that provided policy orientations that were likely to provide solutions to persistent problems in the Guinean pharmaceutical sector. The policy was accompanied by an implementation plan—the Pharmaceutical Master Plan—that sets out objectives, strategies, activities, and expected results after all identified and prioritized policy components are implemented. Over the last six years, SIAPS regularly supported the DNPM in promoting the implementation of the NPP to improve the quality of pharmaceutical services in Guinea.

# Updating the Pharmaceutical Law

Guinea's first medicine-related law was issued in 1994, without subsequent revision. However, the pace of regulatory development has been rapid at both the regional and global levels. Guinea's regulatory systems did not keep pace with the market expansion or the increasing number of new and sophisticated categories of health products. As a result, Guinean regulatory authorities were continually faced with new and complex challenges. SIAPS provided technical assistance to the national committee established by the Minister of Health to draft new pharmaceutical legislation that meets Guinea's needs. To date, the draft law, which has received input from national and international legal and health experts, has been technically validated with assistance from SIAPS and submitted to the Minister of Health for endorsement. When enacted by the National Assembly, the revised law will help to ensure that the manufacture, trade, and use of medicines in Guinea are regulated appropriately and that the public has access to accurate information on medicines and other health products.

## Improving Standards and Revising the National Essential Medicines List

To enable the MOH to take advantage of the latest World Health Organization (WHO) guidelines on the most efficacious, safe, and cost-effective medicines for priority health problems and further promote rational medicine use, SIAPS supported the DNPM's review and update of the National Essential Medicines List (NEML) in 2013 and 2016. SIAPS facilitated a series of technical sessions with health experts from the national, regional, prefectural, and facility levels that led to the most recent NEML, which was later endorsed by the Minister of Health, printed, and disseminated.

SIAPS also helped revise the therapeutic flow charts to promote rational medicine use. These flow charts were last reviewed in 1993 and were no longer applicable to current realities. The new versions of these documents are helping to upgrade health care workers' knowledge in priority disease case management, contributing to improved health outcomes. The therapeutic flow charts cover case management at the health center level.

SIAPS also collaborated in updating 13 standard operating procedures (SOPs) to align with WHO guidelines and supported the PCG's prequalification of products and suppliers and first competitive tender for procurement of essential medicines. Following this success, the PCG launched its first international tender in October 2014. In December 2014, SIAPS helped review the bids with the National Commission for Public Procurement of Guinea and supported the commission during the prequalification process.

## Assessing the National Supply Chain

SIAPS assisted the DNPM to undertake a comprehensive assessment of the pharmaceutical supply system. This assessment analyzed all components of the pharmaceutical system, including governance, product selection, quantification, procurement, warehousing and inventory management, transportation, pharmaceutical waste management, appropriate medicine use, regulatory systems, and the LMIS. The assessment provided a strategic view of the operational, technical, financial, political, legal, and human resource factors facilitating or constraining the

pharmaceutical management system. Findings from the assessment helped show the level of maturity of the country's public-sector medicine management system and its operational performance. The assessment results also served as a baseline for future pharmaceutical system strengthening efforts and helped to identify practical options to inform decision making about interventions that may ultimately contribute to improved health commodity security in Guinea.

## Pharmaceutical Management Capacity Building

SIAPS' capacity building technical assistance aimed to assist the MOH in addressing shortages of skilled and qualified supply chain staff at all levels of the public system, with the ultimate goal of improving health outcomes through better management of Guinea's supply chains. In building the capacity of supply chain cadres, SIAPS utilized standardized, competency-based training materials (e.g., the *Medicines for All* training) and built on adult learning principles that were approved by the MOH. To date, SIAPS has built the capacity of nearly 1,100 health workers and has supported the following achievements:

- Job descriptions for regional pharmacists (DNPM) were developed.
  - The Medicines Registration Department at the *Direction Nationale de la Pharmacie et du Laboratoire* has been reorganized, making it more efficient and effective.
- Quality assurance teams at the PCG have been restructured and trained on the new SOPs and are now implementing self-inspections; weather and moisture monitoring forms for PCG warehouses were revised to meet WHO good practices of medicine distribution recommendations.
- The PNLP's procurement and supply management technical working group was trained on techniques and tools and equipped with adequate knowledge and skills to develop accurate national forecasts and supply plans of antimalarial commodities using Quantimed and Pipeline. Building on the training outcomes, SIAPS supported the PNLP to carry out a multiyear forecast of antimalarial commodities using both consumption and morbidity/service statistics data. Results were used to develop subsequent supply plans and help the program identify the financial resources required to support the malaria program's prevention, diagnostic, and treatment objectives through 2022.
- Nearly 1,100 health personnel were trained in pharmaceutical management based on the *Medicines for All* module. The training module, which was introduced in 2014, has helped to ensure rational management of pharmaceutical commodities in health facilities through improved inventory management.



(target: 750; achieved: 1,074)

• Six pharmacists from the regional depots of the PCG were trained in inventory management; warehousing best practices; and distribution of health commodities, specifically antimalarial medicines, which is in line with future decentralization plans to the regions in a bid to improve routine medicine and other commodity distribution.

The capacity building activities administered with the introduction of standardized trainings and tools have helped increase the capacity of supply chain staff by providing them with improved competencies and resources to effectively manage health supply chains in support of desired health outcomes.

#### **Pharmaceutical Information**

To address challenges related to the availability of information for decision making, SIAPS' approach consisted of strengthening the system for collecting, aggregating, analyzing, validating, and displaying logistics data to be used for informed decision making about supplying health commodities to end users. SIAPS worked with the PNLP, the health management information system, and other MOH partners to redesign the reporting system for malaria epidemiological and logistics data. This included reviewing the reporting processes and tools to identify programspecific and commodity data availability gaps. Through the PNLP, SIAPS provided districts with Internet access and introduced new reporting tools and a performance-based reward to motivate districts to improve reporting rates, the timeliness of reports, and the quality of data. SIAPS also provided capacity building for health workers through training, supportive supervision, and mentorships, which helped with the successful nationwide implementation of the redesigned malaria LMIS. As a result, facility reporting rates improved significantly in PMI zones in 2014 (from an estimated baseline of 30% in 2012), reaching 99% in the first three months of 2015 and consistently maintaining this level of performance through July 2017.



Figure 2. Monthly LMIS reporting rates at the central level

SIAPS provided monthly coaching to the PNLP through the established procurement and supply management (PSM) and monitoring and evaluation (M&E) technical working groups to review, analyze, and increase data visibility and information sharing through an Excel-based dashboard for informed supply chain decisions. Such decisions have been helping to guide future planning of malaria commodity procurements and calculation of facilities' order resupply.

Using the disease-specific and logistics data reported by health facilities, SIAPS aided the PNLP in organizing regional quarterly meetings to review the performance of the malaria program. By bringing together health professionals from the PNLP, DRS, DPS, health facilities, and other partners, these meetings served to review and analyze the performance of supply chain and other program indicators. They have served as experience-sharing platforms in which health professionals share common challenges and practical interventions that have been proven to address them.

SIAPS' interventions in strengthening the Guinea pharmaceutical management information system have resulted in improved inventory management, increased medicine availability, and better patient care.

# Supply Chain Management to Improve Availability

SIAPS carried out two supervised emergency distributions in 2012, following long periods of artemisinin-based combination therapy (ACT) stock-outs countrywide, and it was the only partner helping both the PNLP and PCG distribute malaria commodities in Guinea at that time. More than 400 health facilities (hospitals, health centers, and military clinics) received stocks of malaria rapid diagnostic tests and ACTs. This distribution also served to introduce new reporting tools in an attempt to improve the availability of malaria logistics data to guide the PNLP in calculating resupply quantities to fill health facility orders.

SIAPS contributed to the startup of the new ACCESS project and the withdrawal of the ACT, artesunate-amodiaquine, and its replacement with artemether-lumefantrine in the six districts of Guinea where the project is implemented.

To streamline the storage and distribution functions and further improve malaria commodity availability at the health facility level, SIAPS established a service level agreement with the PCG to guide the storage and distribution of PMI-funded malaria commodities. This agreement reflected the need to decrease stock-outs at the last mile by implementing a quarterly distribution plan to health facilities that was established in collaboration with the PNLP. Further support from SIAPS allowed the PCG to decentralize the storage and distribution of malaria commodities at the regional depot level in mid-2015. This development happened concurrently with the shift from a push to a pull system, which saw facilities receiving commodities based on their individual orders rather than the allocation of quantities by the PNLP. Other support from SIAPS included introducing additional infrastructure improvements for optimal storage through procurement and delivery of adjustable pallet racking, material handling equipment, shelves, and pallets for both the PCG and health facilities in PMI-supported regions. Through its technical support, SIAPS provided capacity building activities to staff from the PCG central warehouse, regional depots, and health facilities to promote best storage practices and embed inventory management principles.

All of these efforts led to constant availability and flow of essential quality health commodities in appropriate quantities and in a timely and cost-efficient manner throughout the supply chain system. More specifically, health facilities with stock-outs of a preselected group of malaria commodities for three days or more in the previous three months<sup>3</sup> decreased from 76% (2013) to 28% (2017). For more details, see figure 3.



Figure 3. Stock-out data from health facilities, 2013–2017

<sup>&</sup>lt;sup>3</sup> EUV Survey

# EBOLA SUPPLEMENTAL FUNDING ACTIVITIES

Building on PMI investments through SIAPS, the Ebola Supplemental Funds contributed to USAID efforts toward implementing the Guinea post-Ebola recovery plan, with a particular focus on improving coordination and transparency of the supply chain system; building the capacity of individuals and organization in information and communication technology-based pharmaceutical management tools; implementing robust and integrated logistics management information systems at the national, regional, and district levels; optimizing the storage and distribution of Ebola infection prevention and control materials; and promoting rational medicine use.

Working with the MOH and other partners, SIAPS provided technical support on a national scale (central, regional, district, and peripheral levels) to re-establish the conditions for a quick return to a more resilient and sustainable pharmaceutical supply system.

## Strengthening Pharmaceutical Sector Governance

Like many countries, Guinea recognized the need for a Logistics Management Unit (LMU) and gave establishing one high priority. The LMU is a management structure that is responsible for organizing, monitoring, and supporting supply chain activities within a logistics system. It is a vehicle for institutionalizing good supply chain management practices that link upstream and downstream logistics activities across Guinea's supply chain system.

Through its technical support, SIAPS assisted the MOH in facilitating consultative meetings with all supply chain stakeholders and in developing the LMU governance documents, including Terms of Reference (ToRs) for the unit, an organogram with job descriptions for staffing needs, and a ministerial order creating the LMU. Further support from SIAPS included equipping the LMU with office furniture, equipment, and supplies; supporting LMU operating costs from January to September 22, 2017; and assisting with the recruitment of temporary staff to support key functions while waiting for the appointment of full-time staff by the MOH. SIAPS also facilitated the process that led to the Minister of Health's endorsement of the ToRs that established the LMU and the appointment of the LMU coordinator through a ministerial order.

#### **Enhancing Capacity for Pharmaceutical Management and Services**

SIAPS' organizational capacity building interventions focused on addressing gaps related to weak information systems at the PCG. To strengthen the PCG's warehouse management system, SIAPS adopted a holistic approach that included conducting a rapid assessment of PCG business and operational needs; identifying gaps that need to be addressed; streamlining processes; selecting the most suitable enterprise resource planning (ERP) solution; and finally rolling out the ERP through training of users and implementation and post-implementation support. Through technical support to the PCG, SIAPS successfully implemented the SAGE L100 i7 Enterprise Resource Planning system, which integrates procurement, finance, human resources, warehouse, and client functions. The PCG has shifted from manual to automated operations—a

historic shift that has resulted in increased efficiency of PCG operations. Easy access to highquality information; improved cash flow; and tight links among procurement, storage, distribution, and financial information are other benefits arising from the implementation of the Warehouse Management System (i.e., SAGE L100 i7).

## Strengthening Capacity to Use Information for Decision Making

In 2012, Guinea's supply chain lacked strong information systems that could help ensure that adequate quantities of high-quality essential medicines and supplies are always available to meet patient demand. SIAPS' interventions to help the MOH address the information system gaps involved redesigning the health commodities logistics system and implementing streamlined distribution/re-supply processes, harmonized and standardized LMIS tools, SOPs, and a single inventory control system across all vertical health programs. In addition, the roll out of the revised LMIS to the eight regions of Guinea involved building the capacity of 511 health professionals in supply chain essentials with more emphasis on SOPs and competencies needed to effectively operate the integrated supply chain system.

In mid-2014, SIAPS helped the PCG quantify Ebola commodity needs and develop distribution plans. In November 2014, SIAPS conducted a joint mission with the essential medicines program of WHO/Geneva and the UNICEF regional office in Dakar to assess the impact of Ebola on the operations of the PCG and determine urgent actions to support the PCG, with a particular emphasis on the PCG's role in coordinating logistics for Ebola at the national level.

In addition, SIAPS trained 90 pharmacists and Ebola logisticians on Ebola commodity logistics. SIAPS also assisted the PNLP in drafting a malaria case management plan in the context of the Ebola outbreak and ToRs for a survey measuring the impact of Ebola on malaria treatment.

Finally, in August 2015, SIAPS, in collaboration with WHO, supported the establishment of an ad hoc committee for the integration of Ebola-related commodities into the current quality control system at the PCG. Going forward, all commodities, including those specific to emergency response, are now quality assured, and other procedures have been implemented at the PCG to streamline and enhance central supply management processes.

All of these efforts contributed to overcoming the Ebola outbreak in the country.

## CONTRIBUTION TO US GOVERNMENT GOALS

SIAPS' strategies have been closely aligned with PMI's to use efficient, sustainable approaches to reduce malaria-related morbidity and mortality. Improving the availability of essential medicines has contributed to the goal of universal health coverage in the country. SIAPS' interventions have also been aligned with the US Government's vision of ending preventable child and maternal deaths, as malaria is the principle cause of death in children under the age of five in Guinea. Toward this end, SIAPS has contributed to reinforcing governance and transparency in the pharmaceutical sector, ensuring the constant availability of pharmaceutical commodities, promoting rational medicine use, and using quality data for decision making.

# LESSONS LEARNED

- The alignment of the project's work plans with the MOH's policies and strategic vision was paramount in ensuring a high-level political commitment from all MOH institutions and their full participation in achieving results.
- The creation of solid partnerships among the MOH, donors, and implementing partners was instrumental in raising the level of ownership of most interventions by government counterparts.
- Pharmaceutical sector strengthening is influenced by multiple factors, some of which fall beyond the health sector. Consequently, the involvement of non-health sector actors, such as the Ministries of Finance, Economy, Justice, and Labor, can have a significant impact on the performance of the pharmaceutical sector through targeted interventions.
- Pharmaceutical data quality remains poor, and onsite supervision findings show that malaria commodity mismanagement is common within health facilities nationwide.
- Inadequate management and coordination between the vertical disease programs and the PCG at the central level limits the implementation of a reliable and integrated logistics management system.
- Weak technical and human resource capacity remain obstacles and limit the availability and use of quality information to inform decision makers at all levels of the pharmaceutical system. This results in stock-outs or overstocks of pharmaceutical products for different disease programs.
- A lack of congruence persists between the different information tools and the needs of their users.

## CONSTRAINTS

The Ebola outbreak was the main unanticipated constraint faced by SIAPS. The outbreak required the attention of all health system stakeholders, especially the MOH, and prevented the implementation of SIAPS activities as previously planned. Consequently, the outbreak reduced the attendance rate of patients in health facilities across the country and impeded the appropriate use of malaria commodities. Finally, countrywide election activities were disruptive to transportation and planned activities, further slowing implementation.

#### SUSTAINABILITY

One of the major challenges identified has been the need for Government of Guinea partners to take more ownership of the malaria end user verification survey, particularly the data analysis and follow-up on recommendations. SIAPS was working to gradually transfer competencies to the PNLP. Although SIAPS exceeded targets for conducting training, there is a continuing need for support to reinforce skills learned and to train additional personnel due to staff turnover.

SIAPS worked with the MOH to ensure the sustainability of compliance with good practices in pharmaceutical governance and effective commodity management by supporting the redaction and adoption of the pharmaceutical sector reference document and quality assurance procedures. Other activities included updating pharmaceutical laws and SOPs, adopting good practices for the PCG regarding international tender for procurement of essential medicines, and finalizing a pre-qualification of products and suppliers.