

# Strengthening Regulatory Systems in Democratic Republic of the Congo to Improve Access to Safe, Effective, and Quality Medicines

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## OVERVIEW

Chronic underfunding of the health sector coupled with long-term civil unrest in the Democratic Republic of the Congo (DRC) has contributed to insufficient regulatory capacity to effectively manage the registration and approval of new medicines in the country. In partnership with the US Agency for International Development-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, implemented by Management Sciences for Health, the country's Ministry of Health (MOH) supported a number of broad interventions to strengthen DRC's pharmaceutical regulatory system. SIAPS provides technical assistance to the three national control programs—malaria, HIV/AIDS, and tuberculosis—to improving access to quality medicines and other commodities and increase the potential for achieving desired health outcomes.

## A SYSTEMWIDE APPROACH

Strong regulatory systems—including registration and surveillance—help ensure that knowledgeable staff are dispensing safe, quality medicines at licensed pharmacies and private medicine outlets. SIAPS takes a systemwide approach to boosting countries' capacity to take over program ownership and sustain progress. Goals in the DRC included:

- Strengthening the governance of the pharmaceutical sector
- Strengthening individual, organizational, and institutional capacities to better manage pharmaceutical supply and provide health services
- Solving information issues for critical decision making in the pharmaceutical sector

## INTERVENTIONS

### MEDICINES REGISTRATION

Since 2012, SIAPS has provided institutional capacity-building support to the DRC's Drug Regulation Authority, the Direction de la Pharmacie et du Médicament (DPM), to help it streamline and better coordinate its registration process. Created in 1982, the DPM had been functioning with neither written procedural standards nor a national registration committee. As a result, a large number of unregistered, substandard, and falsified medicines were circulating in the DRC.

In 2010, SIAPS' predecessor project, Strengthening Pharmaceutical Systems, supported the DPM in developing guidelines and standard operating procedures for product registration and trained

staff to implement them. It has also supported the DPM in training regional and district pharmacist inspectors and other initiatives. With SIAPS technical support, the DPM has continued to improve its new standard operating procedures to align them with international guidelines and good governance recommendations.

The DPM also established and began to increase the capacity of the country’s first National Medicines Registration Committee, which is now fully functional. The committee produces an annual medicines registration plan and a distribution map of the Directory of Approved Medicines to help ensure adequate dissemination throughout the country.

SIAPS also helped the DPM install and configure new registration software, the Integrated System of Computerized Management of Regulatory Process in a Drug Regulatory Authority. The program also helped to migrate legacy data for previously registered products and brought in two experts to train 25 staff on the new software.

**PHARMACEUTICAL GOVERNANCE DOCUMENTS**

In 2012, SIAPS helped the DPM develop the first Directory of Approved Medicines, with the goal of helping regulatory authorities track unregistered and unauthorized medicines. Customs officers use the directory to identify unregistered medicines at border posts, and provincial pharmacists use it to track and confiscate unregistered products during inspections of pharmaceutical storage and health facilities.

SIAPS also supported the MOH in revising the National Essential Medicines List (NEML) and disseminating it throughout the country. Finally, SIAPS coordinated with the MOH to produce Standards and Guidelines for the Use of 13 Life-saving Medicines for Mothers and Children.

**STAFF CAPACITY**

SIAPS assisted the DPM in convening its quarterly product registration sessions. The program helped the MOH establish 12 medicine provision working groups to help ensure that central regulatory support is received and implemented. These working groups play a critical role in coordinating medicine provision, distribution, and use among all MOH partners to help ensure access and appropriate use that will promote patient safety and healthier outcomes.



Two customs officers and a pharmaceuticals inspector receive a Registered Medicines Directory in Matadi, Kongo-Central.



Regional Health Division and Drug Regulatory Authority members plan for the dissemination of the Registered Medicines Directory and the NEML in South Kivu province.

## RESULTS: INCREASED ACCESS AND EFFICIENCY

- In the fifth year of SIAPS, the National Medicines Registration Committee received 1,002 dossiers and approved 404 pharmaceutical products. This brings the total number of medicines that have been registered in DRC to 4,606, up from 400 in 2011 when SIAPS began supporting quarterly application evaluations.
- In addition, 1,392 products were deregistered during the year because their marketing authorizations expired. Unregistered medicines can no longer be imported into DRC.
- Of the medicine categories currently included in the NEML, 72% have at least one product registered, an increase from 44% in 2011.
- The number of days to process a new application decreased from a peak of 82 in 2013 to 58 by September 2016.

Indicator	Baseline	Current (2016)
Medicines registered with the DPM	400 (2011)	4,600
Days to process registration	84 (2013)	58
Percentage of NEML items that have registered products	44 (2011)	64

**Figure 1. Stronger regulatory systems increase medicine registration efficiency and effectiveness**

## THE WAY FORWARD

SIAPS has been transitioning management of these new committees and procedures to full country ownership. The National Medicines Registration Committee now meets quarterly without SIAPS support, and other partners are now providing support to the committee to ensure that it continues to function after SIAPS ends. The Registered Medicines Directory is now owned and used by national pharmacist inspectors and customs officers. The DPM has asked the World Health Organization to evaluate the country's new registration process to ensure that it complies with international regulatory standards.

**ABOUT SIAPS** | The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program works to assure access to quality pharmaceutical products and effective pharmaceutical services through systems-strengthening approaches to achieve positive and lasting health outcomes. SIAPS is funded by the US Agency for International Development (USAID) and is implemented by Management Sciences for Health.

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