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## STRENGTHENING REGULATORY SYSTEMS TO IMPROVE ACCESS TO SAFE, EFFECTIVE, AND QUALITY MEDICINES



### CHALLENGE Inadequate regulatory processes allow medicines of uncertain safety and quality to enter the supply system

After decades of civil unrest and chronic underfunding of the health sector, the Democratic Republic of the Congo (DRC) lacked the regulatory capacity to effectively manage the complexity of registering and approving new medicines. There were also notable weaknesses in the governance of the registration process: authority to register medicines was assigned to just one person rather than a committee, no mechanism existed for tracking decision making, and there was no official register of approved medicines that could be used in the control of importation and sale

of medicines. These weaknesses in the product registration system contributed to the influx and distribution of unregistered and poor-quality medicines. A 2007 study reported that samples of antimalarials purchased in the informal market in Goma, DRC, did not meet quality standards in terms of packaging and, more disturbingly, bioavailability and bioequivalence standards, which affect therapeutic efficacy.<sup>1</sup> These are issues that can be better evaluated and regulated through a robust medicine registration process.

### SIAPS ACTIVITIES

#### Improving the transparency and efficiency of the medicines registration system

As a first step toward strengthening the regulatory system, the Strengthening Pharmaceutical Systems (SPS) Program assisted the Directorate of Pharmacy and Medicines (DPM) (part of the Ministry of Health [MOH]) to develop guidelines and standard operating procedures (SOPs) for product registration, and then to train the staff. These efforts led to the establishment of the first national medicine registration committee in 2010. SPS also helped the DPM create a registered medicines database, which contained information on the 200 products registered at that time.

Building on this work, SIAPS has provided further training for national registration committee

members to build their competencies and promote best practices. The DPM, with SIAPS assistance, has further improved the SOPs to better align them with international guidance and good governance recommendations. SIAPS also helped the committee establish a schedule for quarterly meetings and set up systems for biannual publishing and posting of the registered medicines list.

In August 2012, SIAPS supported the publication and dissemination of the first list of registered medicines in DRC. The list was quickly and widely used to improve the regulation of medicines—customs officers used it to check for unregistered

medicines at border posts and provincial pharmacists used it to track and confiscate unregistered products during inspections of pharmaceutical premises. When these improved regulatory actions triggered a rapid influx of applications for product registration that

created a backlog, SIAPS helped the registration committee adjust their procedures, particularly task distribution, to improve efficiency and reduce the backlog, which was successfully eliminated in 2013.

# RESULTS

## Streamlined, transparent, country-owned processes for registration of medicines

SIAPS technical support has helped strengthen the capacity of the national registration committee and streamline medicines registration. As a result, the number of registered medicines has increased from 200 in 2010 to over 3,000 in 2014; 72% of the medicines included on DRC's essential medicines list currently have at least one product registered, up from 44% in 2011. The backlog of applications has been completely eliminated and the time taken to process a new application has been reduced from a peak of 85 days in 2013 to 64 days at the end of 2014.

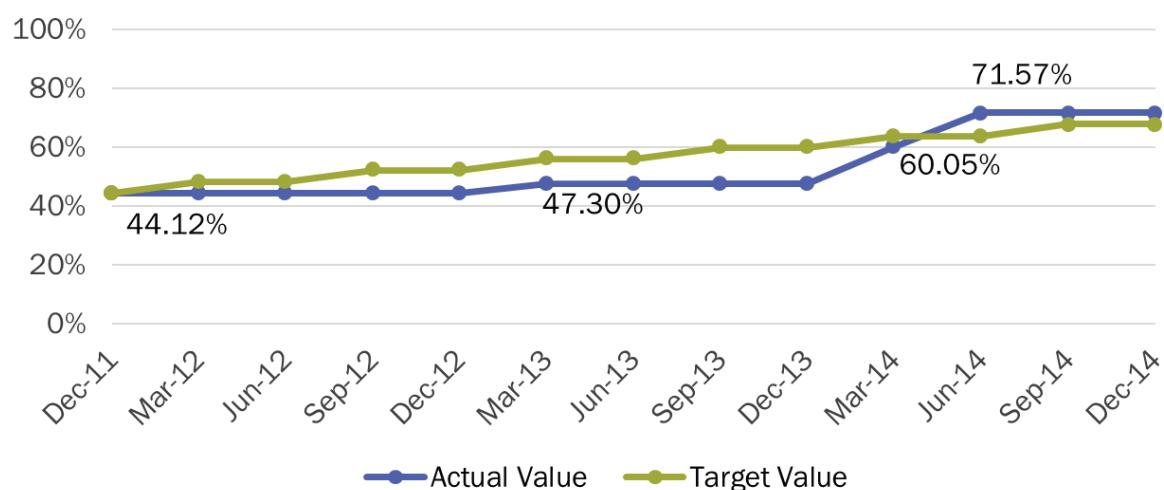
Now independently funded and managed by the MOH for over a year, the national registration committee has continued to meet regularly every quarter. Attendance of the SIAPS team at the meetings is no longer needed to drive the process and the team only participates on request. The lists of registered and newly approved medicines have been posted on MOH and provincial pharmacist

inspectors notice boards and made publically available biannually. The lists continue to be used by customs officers and inspectors to control importation and conduct inspections nationwide.

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The MOH now has the capacity to systematically evaluate and approve medicines for registration in a timely manner 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 at the border and in circulation in DRC. A stronger product registration system is helping the government ensure that medicines in the country are safe, effective, and of acceptable quality.

Figure 1. Percentage of EML Items that Have Registered Products in DRC



# NEXT STEPS

## Expanding committee membership and automating the medicines registration process

To further enhance the transparency and credibility of the national registration committee, the DPM recently accepted a SIAPS recommendation to extend committee membership to external stakeholders, including active health practitioners, experts working in academia, and members of professional associations. SIAPS will now focus its efforts on assisting the DPM recruit and train new members. Also, to increase efficiency and transparency, SIAPS is supporting the DPM to introduce software to help streamline and track medicines registration as well as publish the list of registered medicines on its website.

The World Health Organization (WHO) recently helped the DPM conduct an evaluation of the registration process. On the basis of the gaps identified, WHO developed a set of recommendations, many of which align with planned SIAPS technical assistance activities. Furthermore, SIAPS is planning to revise and enhance the existing SOPs which can be used to train new members of the committee and serve as an oversight tool for checking that decision making and tasks are executed appropriately.

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- 1 Gaudiano M, et al. Medicines informal market in Congo, Burundi and Angola: counterfeit and sub-standard antimalarials. *Malaria Journal*. 2007;6

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**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. For more information, visit [www.SIAPSPprogram.org](http://www.SIAPSPprogram.org).



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