

## In Botswana, Strengthening Drug Registration to Improve Access to HIV/AIDS Treatment

The Drug Regulatory Unit (DRU) of the Botswana Ministry of Health (MOH) is responsible for registering all drugs used in Botswana to ensure they meet required standards of quality, safety and efficacy. The Central Medical Stores can only procure DRU registered drugs for supply to national ARV treatment sites. At the end of 2007, there was a backlog of 400 applications limiting access to a narrow range of ARVs, preventing Botswana from access to alternatives available on the global market. The few DRU staff were overwhelmed with other regulatory activities and required registration training and systems strengthening support to efficiently overcome this backlog.

With weak processes and outdated information management software, DRU registration activities had reached a crisis. The MOH in Botswana requested SCMS (through CDC collaboration) to assist with DRU process improvements to address the registration backlog for better access to a wider range of ARVs.

SCMS and the DRU collaborated on a baseline gap analysis, followed by reengineering processes, developing and



implementing a “retreat plan” whereby staff went off-site to focus solely on working through the backlog and acquiring and installing of WHO-recommended software for drug registration. The method included SCMS capacity building support through training of DRU staff, review of guidelines and short term technical assistance that enabled mentoring

new staff while providing additional technical resource for evaluating applications.

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***The program eliminated a backlog of 400 drug registration applications that had prevented Botswana from accessing lower-cost generic ARVs.***

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A six month secondment of a technical consultant from Ghana strengthened DRU capacity enabling the review of 400 applications for Drug Advisory Board approval.

The retreat approach contributed to increasing individual evaluation output from one application in two days at the office to an average of 8 dossiers per day during the retreat period. The acquisition of a user friendly, WHO information management software was also essential to the success of these efforts by keeping track of product information and minimizing registration errors.

The increased pool of generics and generics suppliers available for procurement supported the increase in CMS procurement of ARV generics vs. branded ARVs from 65 percent (FY06/07) to 99 percent (FY07/08).

Developing countries with regulatory authorities still in their infancy can benefit from the following three approaches to address registration capacity challenges to improve patient access to ARVs and other new essential medicines:

1. Training, mentoring and on site support through technical assistance from established regional regulatory authorities
2. Use of a dossier review retreat system as necessary to enable efficient approval of qualifying products
3. Installation of appropriate software for tracking registration activities

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## ABOUT SCMS

The Supply Chain Management System (SCMS) was established to collaborate within country and global partners to ensure a reliable, cost-effective and secure supply of high quality medicines and health products for HIV/AIDS prevention, care and treatment. SCMS is funded as part of the President's Emergency Plan for AIDS Relief. Visit us at [www.scms.pfscm.org](http://www.scms.pfscm.org).

The author's views expressed in this publication do not necessarily reflect the views of the US Agency for International Development or the United States government.