



Ethiopia's Food, Medicine and Health Care Administration and Control Authority: Protecting the Public Health

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The absence of regulatory systems to monitor the quality, safety, and efficacy of medicines can compromise the overall effectiveness of health care services and endanger the public health. A strong regulatory system is considered an essential component of a health system. In Ethiopia, the Food, Medicine and Health Care Administration and Authority (FMHACA), formerly known as the Drug Administration and Control Authority, regulates the country's pharmaceutical sector in an environment vulnerable to drug smuggling and the circulation of substandard medicines. Although it is difficult to collect accurate data, it is widely reported that more than half of medicines sold in sub-Saharan Africa are counterfeit.

The United States Agency for International Development (USAID)-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program uses a systems-strengthening approach to improve pharmaceutical sector governance and strengthen regulatory systems to ensure timely access to medicines and other health supplies. USAID/SIAPS and its predecessor program Strengthening Pharmaceutical Systems (SPS) have provided critical support to Ethiopia's FMHACA to strengthen its regulatory and enforcement capacity to deter deadly counterfeit drugs from crossing the border.

Ethiopia's Vast Frontier: Port of Entry for Counterfeit and Substandard Medicines

Ethiopia has a boundary length of 5,328 kilometers or 3,311 miles. Surrounded by a number of countries with weak regulatory systems, Ethiopia's long border is susceptible to the smuggling of a variety of contraband, including illegal drugs and substandard medicines. Prior to 2008, FMHACA was unable to effectively regulate the importation, storage, distribution, and use of medicines outside the capital city of Addis Ababa. There were no branch offices in the regions, and the absence of human and financial resources severely limited the authority's reach beyond the capital. It was well known that private clinics, pharmacies, and rural drug vendors received and distributed the substandard medicines that flowed across Ethiopia's porous borders. Although there are no official reports documenting the economic and health consequences of illicit and substandard medicines, the impact is believed to be substantial.

Controlling What Comes In: FMHACA Branches Out to the Regions

SPS, the predecessor program to SIAPS, had been working closely with FMHACA since early 2007. In 2008, FMHACA reached out to SPS to request financial, human, and technical support to build and staff branch offices in strategic locations around the country—Mekele, Bahirdar, Hawassa, Jimma, and Diredawa.

"The all-round support we received from our partner USAID/SPS was crucial to the establishment of the five branches of FMHACA, which are now fully owned and operated with our own resources. This is a great example of institutional capacity building and we are thankful to USAID/SPS."

Mr. Yehulu Denekew
FMHACA Director General



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March 2014

SPS and FMHACA developed a joint plan of action to extend the authority's reach out to the regions to the newly established branch offices. The partners signed a memorandum of agreement that detailed the activities and timeline for the transfer of ownership to FMHACA, once the branches were viable.

SPS provided a broad range of support to FMHACA to establish the five regional branches. SPS rented the buildings to house the branch offices in each of the towns, and purchased the office furniture, computers, and office equipment. SPS seconded three pharmacists to each of the branch offices. An important aspect of the staffing plan was to recruit professional and support staff in the regions using a salary scale recommended by FMHACA. This enabled a smooth staffing transition to FMHACA, once SPS phased out its support.

SPS rented vehicles for each of the five branches to inspect health facilities and monitor transactions of medicines at the border. Within a year of start-up, SPS purchased five four-wheel drive Toyota Land Cruisers and donated them to FMHACA, thereby strengthening the monitoring capacity and reducing the cost of inspections.

FMHACA collaborated with SPS to train and mentor staff in the newly established branch offices. FMHACA regularly organized performance reviews in each of the field offices as well as the head office in Addis Ababa. SPS supported FMHACA for two years while it constructed branch offices in each of the towns using its own resources.

A Regional Success Story

At the end of the two years, all staff working in the branch offices was transferred to FMHACA. Operations were gradually transferred to FMHACA, and today there are five fully functioning FMHACA branch offices in the regions. The result of this partnership is FMHACA's greater access to health facilities in remote locations and more systematic and frequent inspections at ports of entry for illicit medicines. Recent reports in East Africa show that the circulation of counterfeit and substandard medicines in Ethiopia is the lowest compared to other countries in the region.

USAID/SIAPS continues to work with FMHACA by providing support in developing the necessary regulatory tools and standards to ensure quality health services delivery nationwide. In 2011, SIAPS collaborated with FMHACA to develop the "Medicines Waste Management and Disposal Directive." In 2012, USAID/SIAPS provided technical support to develop health facility standards to serve as a cornerstone for improving the quality of health services nationwide. The efforts of USAID/SIAPS to build the capacity of the National Adverse Drug Reaction/Pharmacovigilance Center in the past few years has enabled FMHACA to closely monitor the safety of medicines and take regulatory actions on products that are identified to be harmful to the Ethiopian people.

USAID/SIAPS, in partnership with the regulatory agency of Ethiopia's Ministry of Health, is working to establish a strong pharmaceutical system to promote improved access to quality medicines, improved services, and better health outcomes for the Ethiopian people.