

TANZANIA: Product Quality Assurance Program

Problem: Substandard medicines circulating in the market are a problem in many countries. In its 2001 assessment, SEAM found that of 110 samples of 10 different drugs, 6.5 percent of the samples from public facilities and 8.7 percent from private pharmacies were substandard. A further measure of the quality of drugs in the marketplace is the percentage registered with the TFDA. The quality of unregistered drugs cannot be assured, since they have not passed through the registration process. SEAM observed that only 26 percent of the drugs surveyed in 39 *duka la dawa baridi* were registered, while a further 24 percent were in the registration queue.

Strategy for Change: Initially, the SEAM quality assurance strategy included thin-layer chromatography (TLC) Minilab[®]-based product screening at selected ports of entry, but it became evident that the wider TFDA inspection process needed to be addressed to ensure the overall success of the program. Over the course of the program, the TFDA, with SEAM support, broadened the initial strategy toward a comprehensive national quality assurance program that could help assure that both imported and locally manufactured drug products met approved quality standards throughout the supply chain. Although the focus of the SEAM intervention continued to be product examination and testing at ports of entry, efforts expanded to include surveillance and testing of products in circulation. Market surveillance requires routine facility inspections and product sampling in the marketplace, including distributors and retail outlets. This strategy required building the inspection and pharmaceutical testing capacity within the TFDA through a number of tools and activities, including—

- Developing flowcharts and standard operating procedures for structured inspection activities at ports of entry and facilities
- Establishing a Minilab-based drug product screening program using thin-layer chromatography (initially targeted antimalarial drugs, then selected antibiotic and antiretroviral drugs)
- Developing quality assurance protocols and training materials based on a combination of physical examination and Minilab-based testing
- Supporting TFDA inspectors with improved instrumentation, training, and monitoring and evaluation

Results: Since the program started in October 2002, TFDA dramatically increased the number of drug products screened and the number of premises inspected—

- Port of entry inspections in 2001 included 942 consignments. From the time the quality assurance program began through the first quarter of 2005, TFDA inspected 4,299 consignments, or about 1,700 consignments per year, containing almost 15,500 batches of pharmaceutical products.
- Premises inspections rose from 201 in 2001 to 735 in 2003—and followed the same trend in subsequent years.
- As of April 2005, TFDA had screened 1,257 batches of targeted drugs at the quality laboratory with a failure rate of 3.7 percent, including five counterfeit drugs.
- Using the Minilab to screen products in the field is cost-effective—needing an average of 1.5 hours per sample; 1,200 samples over a 2.5-year period required only about one person-year of activity in Tanzania.
- Despite high volumes and pressure at ports of entry in Tanzania, introducing Minilab-based product screening has not caused unnecessary delays in clearing legitimate products for entry into the market.

Lessons Learned:

- Successfully implementing a tiered approach to quality assurance in resource-limited countries by using low-cost, low-maintenance technologies, is clearly possible. The improved standards and inspection processes have resulted in many product confiscations, importation refusals, and premises closures. The challenge is to position the technologies as sound and reliable and not simply as a second-rate approach for countries that cannot afford the high-cost, high-maintenance technologies used in developed countries.
- Obtaining political support, working closely with stakeholders, and sensitizing them to quality requirements helped establish the quality assurance program.
- Developing protocols and integrating these protocols into TFDA's regular work process were essential to success and required the involvement of both TFDA management and inspectors. Adequate training, along with monitoring and follow-up, were critical.
- Improving efficiencies in inspections and screening allow relatively few inspectors to conduct a large number of inspections.

- The quality assurance activities were conducted with relatively modest resources, but have markedly increased the visibility and presence of the TFDA in the marketplace, providing a significant deterrent to marketing substandard and counterfeit products.

Activity Update (February 2007): The quality assurance initiative that developed with support from the SEAM Program has been fully absorbed into the TFDA's regular work processes. The model has also been picked up by other countries. Management Sciences for Health's Rational Pharmaceutical Management (RPM) Plus Program started supporting this project in 2005, and is now providing technical assistance to TFDA, as needed, for their level-one inspection program and to set up thin-layer chromatography testing centers. To increase its capacity in quality assurance testing, the TFDA purchased a densitometer that uses spectrometry to measure the density of the images or "spots" that a drug substance makes on a TLC plate. These spectrometric measures are not dependent on visual judgments and eliminate the subjective quantitative measures that require a person's visual acuity. The densitometer also allows more accurate measures through the use of high-performance TLC plates. In addition, RPM Plus has worked closely with TFDA to provide technical training for its staff on the use of densitometry as an analytical method; for example, a high-performance TLC expert from India provided a five-day technical training session. Training materials on Minilab screening procedures, specifically for antimicrobials, and on data management and reporting using personal digital assistants have also been developed. Finally, monitoring and evaluation procedures for TFDA to accurately review program implementation have been established and implemented.

Next steps:

- Develop a series of publications for submission to topic-appropriate, peer-reviewed journals to document the scientific base for using low-maintenance, low-cost technologies as part of a tiered approach to quality assurance in developing countries.
- Package and disseminate the procedures and materials developed for the Tanzania initiative in a way that they can be adapted and used in other limited-resource countries.
- Through the RPM Plus Program, continue to provide technical support to collaboration established between the TFDA and the Faculty of Pharmacy—Muhimbili University College of Health Sciences Tanzania to develop and validate inexpensive, high-throughput methods to analyze finished pharmaceutical dosage forms, while minimizing the amount of organic solvents used during analysis.