



The Tanzania Drugs Quality Assurance/TLC Initiative

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Tanzania drugs quality assurance (QA) program goes back to April/May 2001 when the Ministry of Health through the Tanzania Food and Drugs Authority (TFDA) (then the Pharmacy Board), in collaboration with Management Sciences for Health/Center for Pharmaceutical Management (MSH/CPM) based in Boston, USA, conducted an assessment on the pharmaceutical sector in Tanzania. This assessment revealed that about 46% of drugs circulating in the market were not registered by the TFDA; hence, the public could not be assured of the quality of drugs in the market. The same year, analysis results from the drug quality control laboratory revealed a drug quality failure rate of 13%.

Based on these results, the QA program was established with two major components: a well-structured drug inspection system and a drug screening system using the GPHF Minilab kits. The objective of the QA program was to establish an appropriate comprehensive National Drug Quality Assurance system to ensure availability of good-quality medicines to consumers. In achieving this objective, the World Health Organization (WHO) donated ten Minilab Kits and funds for training. MSH, through the Strategies for Enhancing Access to Medicine (SEAM) Program, offered technical support and funds.

Implementation of the drugs QA program was based on four major components:

1. Establishment of a Level I drug inspection program that includes standard operating procedures (SOPs), forms, checklists, training materials, an inspection handbook for inspectors, and training of trainers and inspectors.
2. Establishment of a tier one Minilab-based screening program that includes SOPs for sampling and screening of drugs and training of inspectors on GPHF Minilab techniques, supplemented by sensitization of stakeholders on objectives and implementation of the program before launching of the program.
3. Implementation of the drug inspection program at ports of entry (POEs) and postmarketing surveillance (PMS), for which ten screening centers have been established. Screening is conducted for targeted antimalarials, antibiotics, and antiretroviral drugs. Two proficiency tests were performed to assess the screening results obtained. A total of 359 drug inspectors and analysts have been trained, including 17 trainers of inspectors; 1,257 drug samples have been screened, with a failure rate of 3.7% including 5 counterfeit drugs. An increase in the number of inspections and a decrease in the number of unregistered drugs in the market have been noted.
4. Establishment of a personal digital assistant (PDA) inspection data logging system. Nine drug inspectors are using PDAs in conducting inspections.



Conclusions

The evaluation of the program has shown that the program was sustainable and can be adopted by other countries, although a few limitations were noted. The thin-layer chromatography (TLC) experience in Tanzania has shown Minilab technology to be rugged and robust. In addition, the testing is low cost with respect to materials used and personnel costs. The large number of facilities inspected and samples screened since the launch of this program shows that the Minilab is a cost-effective tool for drug quality assurance. When coupled with structured POE and PMS inspections, this program can greatly contribute toward improving the quality of drugs in the market.