



Quality Assurance: Improving Regulatory Reach and Capacity: Developing a National Regulatory Projection Scheme

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One of the major problems of drug regulatory authorities in developing countries is a lack of trained personnel to establish a comprehensive, viable national infrastructure. The problems frequently are compounded by geographical size and poor communication and transportation infrastructure. To better fulfill its mission, a regulatory authority could seek to leverage with appropriate time allocations through other governmental personnel resources by providing training on basic product examination techniques and reporting structures. If programs such as these can be properly implemented, the regulatory reach of the authority can be extended throughout the drug supply chain to reach even geographically remote areas of the country.

Management Sciences for Health (MSH)/Strategies for Enhancing Access to Medicines (SEAM) Program provided technical assistance to the Pharmacy Board/Tanzania Food and Drugs Authority (TFDA) to aid in defining, documenting, and developing program elements and inspection tools to establish ordered pharmaceutical Level I inspection and German Pharma Health Fund (GPHF) Minilab[®] screening procedures. Initially, 12 TFDA inspectors were trained to perform inspections of premises and ports of entry and to screen selected products using Minilabs.

To expand its regulatory reach and capability, the TFDA has developed a six-zone administrative structure to coordinate and focus the activities in the 21 governmental regions into a more manageable configuration. The TFDA has organized zonal training of health workers who are employees of regional/district/local governmental authorities to serve as an auxiliary cadre to perform food and pharmaceutical product examinations and to report the findings to the TFDA. The training was based on the model and training materials that had been previously developed by the TFDA and MSH/SEAM. For the pharmaceuticals training segment, the training was focused on raising awareness of product quality, performing structured physical examinations of products, and inspecting both public and private drug dispensing outlet facilities. Stakeholder sensitization meetings also were held at the zones during the training sessions to alert stakeholders of the improved regulatory presence and thereby to enhance voluntary compliance with legal standards.

In addition to Level I inspection training, a select group of health workers was trained in Minilab drug quality screening procedures to manage testing sites in the various zones. On this basis and with the support of the World Health Organization (WHO), which provided additional Minilabs, it has been possible for the TFDA to expand Minilab screening centers from 6 to 10 sites and increase the number of screened samples. The zonal centers provide a possibility for TFDA regulatory extension through the incorporation of other governmental health workers to perform on behalf of TFDA compliance assessments. Out-of-compliance findings are referred to the TFDA for compliance action through a designated TFDA desk officer, who also serves as liaison with zonal centers to help ensure good communication.



The success of this extension effort demonstrates the transferability of these product quality elements provided that a committed, stable host organization is willing to allocate resources to attain this end. This poster presents the scope and current status of this initiative.