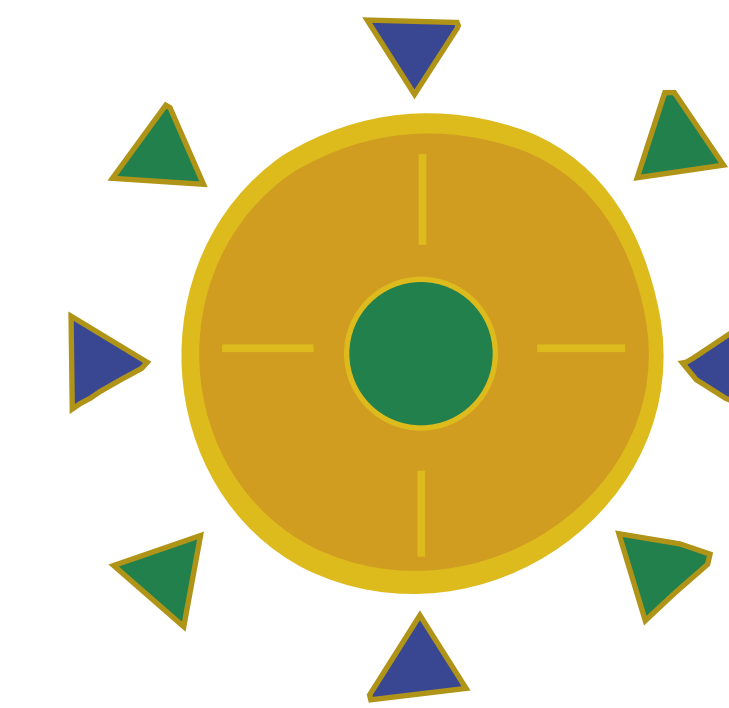


SEAM Tanzania



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

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Background

One of the major problems encountered by drug regulatory authorities in developing countries is an insufficient number of trained personnel to establish a comprehensive, viable national infrastructure. Frequently, this problem is compounded by geographical size as well as poor communication and transportation infrastructure. To better attain its objectives, a regulatory authority could leverage other governmental human resources, with appropriate time allocations, by providing training in performing basic product examination techniques and generating appropriate reports of examination findings. If programs such as these can be properly implemented, the regulatory reach of the authority can be extended further into the drug supply chain, even to geographically remote areas.

The 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 Minilab screening procedures. Initially, 12 TFDA inspectors were trained to perform premises and port-of-entry (POE) inspections and also to screen selected products using the Minilab. These training programs have subsequently been presented to new groups of TFDA inspectors.

Implementation

In order to expand its regulatory reach and capability, the TFDA has developed a six-zone administrative structure to coordinate and focus inspection activities in the 21 governmental regions into a more manageable configuration. The TFDA has organized zonal training programs for health workers employed by regional/district/local governmental authorities to serve as an auxiliary cadre performing, on a part-time basis, food and pharmaceutical product examinations and to report the findings to the TFDA. The training program was based on the model and training materials previously developed by the TFDA and SEAM for the Level I inspection system. For the pharmaceuticals segment, the training was focused on raising awareness of product quality, performing structured product physical examinations, and inspecting both public and private drug dispensing outlets. A total of 329 health workers have been trained by the TFDA during the zonal training programs (Table 1). In addition, the TFDA organized stakeholder sensitization meetings during the zonal session to alert them of the enhanced regulatory presence and encourage voluntary compliance with legal standards.

The TFDA also organized practical training sessions in Minilab drug-quality screening procedures for a select group of health workers from each zone. After successful completion of this training, these health workers began

managing testing sites in their respective zones. The training session model requires about four to six persons for three weeks: one week for set-up, one week of Level I inspection training, and one week on Minilab test procedures. Through this effort and with the support of the World Health Organization, which provided additional Minilabs, the TFDA was able to expand Minilab screening centers in Tanzania from six to ten sites (Fig. 1).

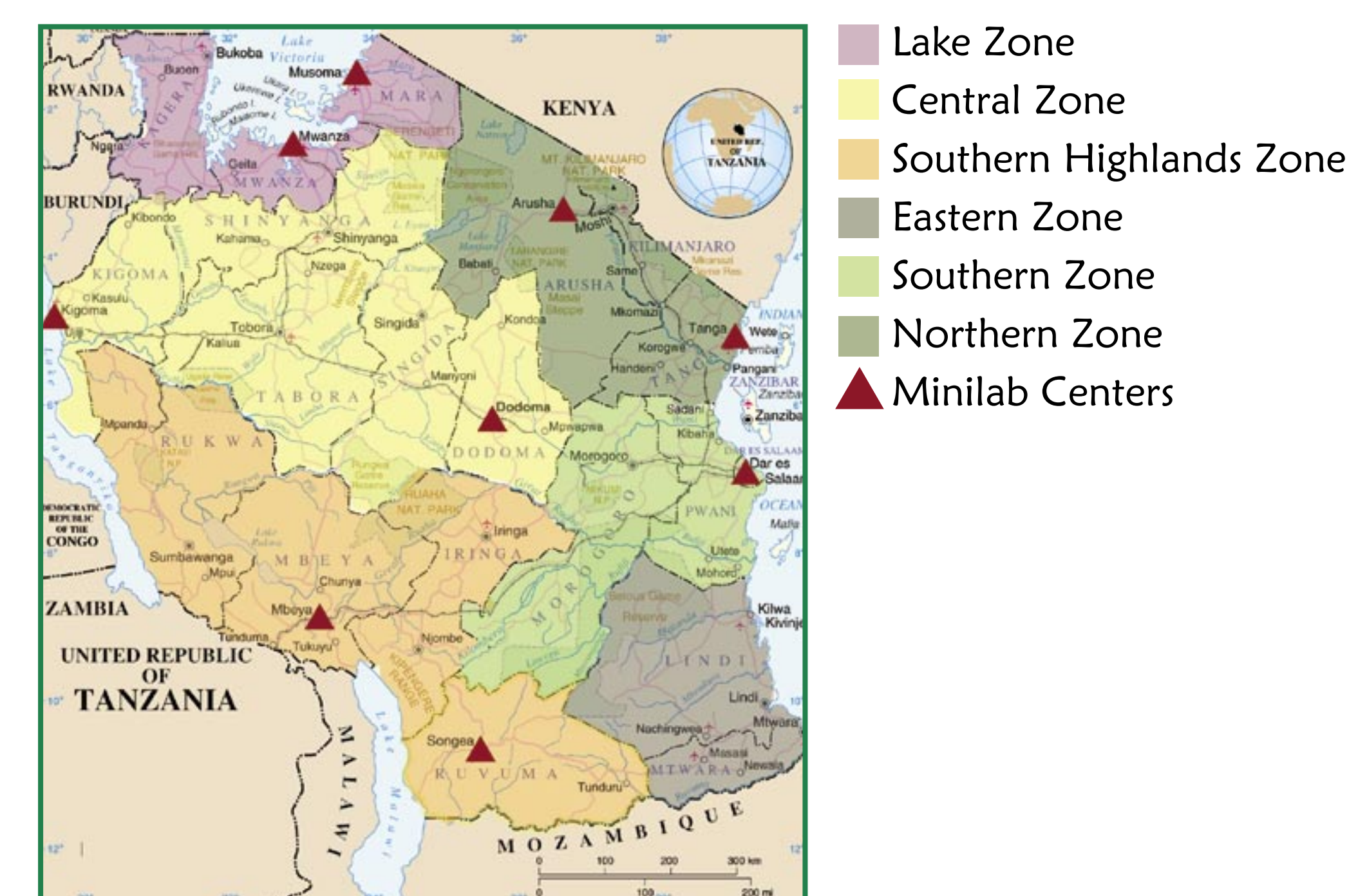


Figure 1. TFDA zonal structure and Minilab centers

The zonal centers created through the leverage of other government health workers have allowed the TFDA to extend its regulatory activities and presence. Out-of-compliance findings are referred to the TFDA for compliance action through a designated TFDA desk officer, who also serves as a liaison with zonal centers to help ensure good communication.

Required Resources

To ensure the success of the TFDA zonal outreach program and continuing competence and skills of the auxiliary inspection cadre, the host organization should be prepared to allocate a minimum of one-half day per week (10% of the total needed resources) or, preferably, one day per week in support of these programs. Similarly, the auxiliary Minilab testing cadre should allocate a minimum of one day per week to maintain skills. The quality assurance support and central liaison function will likely require approximately one day per month per zonal site.

Conclusion

The success of this extension effort demonstrates the transferability of the Level I inspection and product-quality screening elements provided that a committed, stable local host organization is willing to allocate resources to attain this end.

Zone	Number of trained health workers
Central	52
Eastern	43
Lake	78
Southern Highlands	66
Southern	32
Northern	58

Table 1. Number health workers trained to conduct structured drug dispensing outlet inspections and perform pharmaceutical product examinations in the various TFDA administrative zones