



Quality Assurance: Inspection Training

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The Tanzania Food and Drugs Authority (TFDA) pharmaceutical sector, formerly under the Pharmacy Board (PB), was established by the passage of the Tanzania Food, Drugs and Cosmetics Act of 2003. Prior to the passage of this legislation, there had been established through law and regulations issued by the PB and the Tanzania Revenue Authority rules and requirements governing pharmaceutical imports both from commerce and quality perspectives. To provide an ordered hierarchy process for the examination of pharmaceutical products, it was necessary to prepare a flowchart decision tree to guide the clearance of products for marketing. After consensus on the ordering of the laws and regulations into the flowchart had been achieved, the processes guiding inspectors through the clearance procedures were documented through the preparation of standard operating procedures (SOPs). The inspection process includes review of required import documents, compliance with labeling requirements, physical examination of products, etc., and outlines procedures for inspection at both ports of entry and dispensing outlets.

In addition to the SOPs, reporting forms were prepared to document decision points in the inspection process. The SOPs and forms were pilot tested by experienced inspectors for several months to improve the communication and smooth the order of the work. After the SOP and form reporting processes were refined through these field tests, the materials were compiled into the Inspector's Manual. A facilitation guide with daily study guides and examination materials was prepared to guide a one-week training program through the SOPs and forms. In addition to the product inspections, the inspectors were given a week of training on the proper use of the German Pharma Health Fund Minilab to perform product screening consisting of colorimetric identification, thin-layer chromatographic (TLC) estimate of amount and identification confirmation, and measurement of disintegration time. The current training program, along with the expanded inventory of test products, will be presented.