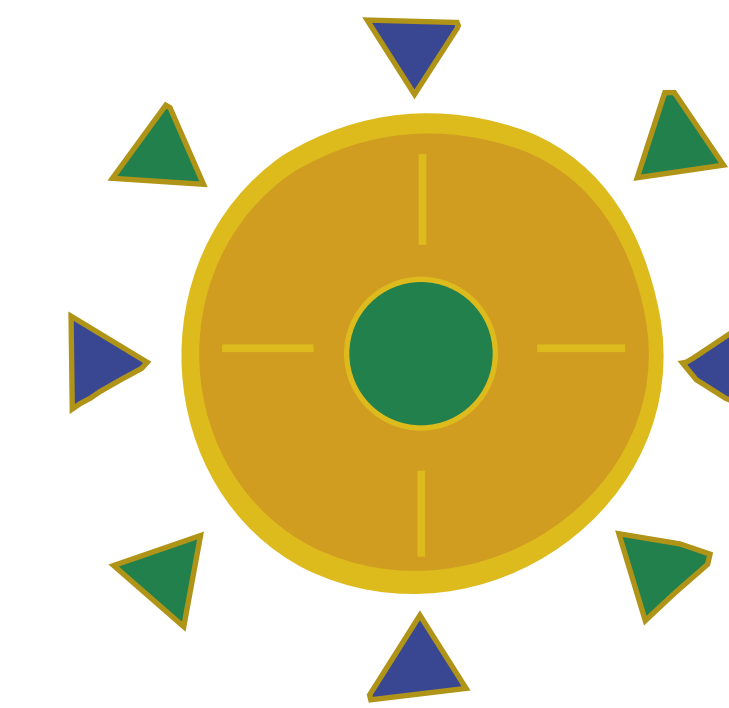


SEAM Tanzania



Quality Assurance: Inspection Training

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Background

The Tanzania Food and Drugs Authority (TFDA) was established by the passage of the Tanzania Food, Drugs, and Cosmetics Act of 2003 (the pharmaceutical sector was formerly regulated under the Pharmacy Board). Previously, rules and requirements governing pharmaceutical imports had been established through laws and regulations issued by the Pharmacy Board and the Tanzania Revenue Authority. The TFDA legislation assigns the responsibility of assuring the quality, safety, and efficacy of all human and veterinary drugs in the Tanzanian marketplace. To fulfill this responsibility, the TFDA must inspect the processes of research, development, manufacture, control, distribution, and dispensing of medicines. To properly discharge these duties effectively, the TFDA must have a cadre of well-qualified and well-trained drug inspectors.

To establish ordered processes to guide the inspection staff, it was necessary to develop an ordered hierarchy for the examination of pharmaceutical products and to prepare flow charts/decision trees to guide the clearance of products for marketing and also for postmarketing surveillance. After consensus was achieved on the ordering of the laws and regulations into these flow charts, the processes guiding inspectors through the clearance procedures were documented through the preparation of a series of standard operating procedures (SOPs). These SOPs and flow charts then were incorporated into a Drug Inspector's Handbook to guide and direct the conduct of inspections and examinations.

The TFDA and SEAM then developed training courses for drug inspection and the German Pharma Health Fund Minilab-based screening programs for selected antimalarial, antibiotic, and antiretroviral (ARV) drugs. The one-week inspection training program covers inspection of importation documents, compliance with labeling requirements, physical examination of pharmaceutical products, and other procedures. In addition, the inspectors complete a one-week, Minilab-based, screening-test training program that enables them to field-test and assess the quality of products.

In phase one of the training, nine candidates successfully completed training in inspection techniques and Minilab screening of antimalarial drugs. In phase two, 15 inspectors, one each from the seven administrative zones and eight from the TFDA, were trained to serve as trainers. Twelve inspectors also were trained in Minilab screening of antibiotics. In phase three, 10 inspectors were trained in testing selected ARV drugs and also received refresher training in antimalarial and antibiotic drug testing.

Course Objectives

- ❖ Teach inspectors how to implement the SOPs for inspecting and testing drugs
- ❖ Advise inspectors on the appropriate use of SOP forms, including—
 - ❖ Rejection/Detention
 - ❖ Sample Receipt
 - ❖ Surveillance Program 02-00 Suspicious Products
 - ❖ Surveillance Program 02-01 Antimalarial Drugs
 - ❖ Surveillance Program 03-01 Antibiotic Drugs
 - ❖ Surveillance Program 05-01 Antiretroviral Drugs

Course Methodology

- ❖ Lectures
- ❖ Demonstrations
- ❖ Group discussions
- ❖ Practical exercises
- ❖ Theoretical and practical examinations

Course Curriculum

- ❖ Preparatory module, including glossary
- ❖ Inspecting, screening, and testing drugs at ports-of-entry (POEs)
- ❖ Physical examination procedures
- ❖ Antimalarial Surveillance Program
- ❖ Antibiotic Drugs Surveillance Program
- ❖ Antiretroviral Drugs Surveillance Program
- ❖ Chain-of-custody, packing, and shipping
- ❖ Postmarketing Surveillance Program (dispensing outlet inspection)
- ❖ Screening of antimalarial, antibiotic, and ARV drugs and suspicious samples
- ❖ Introduction to thin-layer chromatography (TLC) methodology
- ❖ Using the Minilab, including—
 - ❖ Verification of drug identity and content
 - ❖ Screening for quality of antimalarial, antibiotic, and ARV drugs
- ❖ Visual inspection
- ❖ Color reactions
- ❖ Disintegration testing

Retraining

Periodic retraining of the inspectors on specific tasks has been done. Retraining has been particularly required when introducing a new surveillance program, to ensure that the inspectors have acquired the knowledge and practical experience required to adequately perform the new tasks. In addition, a performance qualification exercise on discerning concentration differences in TLC procedures was instituted to improve the competency of inspectors on Minilab procedures.

Output from the Trained Drug Inspectors

- ❖ The inspectors have performed inspection, drug quality screening, and testing at POEs and dispensing outlets.
- ❖ They have performed comprehensive physical examinations of pharmaceutical products both at POEs and dispensing outlets.
- ❖ They have managed the Antimalarial and Antibiotic Surveillance Programs.
- ❖ They have successfully established and maintained chain-of-custody in packing and shipping drug samples from the field to the National Quality Control Laboratory.
- ❖ They stay informed of current record-keeping methods.

Conclusion

The Drug Inspector's Handbook and the training programs have served to build uniform and ordered inspection processes. The inspectors not only gain knowledge in how to perform the inspections and be guided to decision points but also gain confidence in their work. Making the Handbook widely available to the stakeholders also has aided in improving voluntary compliance throughout the pharmaceutical sector.



Minister of Health issuing certificates to drug inspector trainees