

SEAM Tanzania

Quality Assurance: The Drug Inspection and Testing Program

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Background

Poor-quality drugs, including counterfeits, are widely available in Tanzania. It is estimated that half the drugs on the market are not registered with the Tanzania Food and Drugs Authority (TFDA). In addition, during the SEAM Tanzania assessment, 11 percent of samples collected from public facilities and 13 percent from private pharmacies failed quality testing. Resource constraints presently prohibit the TFDA from providing regular inspection of all outlets for pharmaceuticals in Tanzania. To help address quality concerns, SEAM Tanzania has provided assistance to the Tanzania Ministry of Health (MOH) and the TFDA to develop a quality-testing program. In October 2002, the Drug Inspection and Testing Quality Assurance Program was launched.



Improving Inspection and Compliance

- The MOH, the TFDA, and SEAM Tanzania developed a ranked inventory of requirements and policies, and drawing from this inventory, created a compliance decision tree, or flow chart, to direct the inspection process. The flow chart outlines the procedures that drug inspectors at ports-of-entry (POEs) must follow in inspecting and testing drugs entering the country.
- Drug inspectors were trained on the use of the flow chart, and a workshop was held with wholesalers and importers to make them aware of changes in regulatory expectations.
- If consignments fail to conform to any of the requirements outlined, the inspector will stop the inspection, complete a rejection/detention form, and inform the Tanzania Revenue Authority, Customs and Excise (TRA/C&E). In the event that detention issues are resolved and the TFDA gives written permission to proceed, the inspection process will continue.

documentation → label examination → physical examination → sampled → screened

Legal and Regulatory Framework

The Tanzania Food and Drugs Authority

- The TFDA is legally empowered to regulate all pharmaceutical transactions by ensuring that only drugs that are effective, safe, and of good quality reach the public.
- Poor inspection and compliance procedures have made it difficult for the TFDA to deal effectively with irregularities in the importation of drugs.

TFDA Act of 2003

- Provides for control of importation of pharmaceuticals or any substance used for their manufacture
- Requires that any person dealing with the importation of pharmaceuticals be registered and that the products imported be registered according to regulations and importation guidelines

Pro forma Invoices

Each importer must complete a Pro forma Invoice (PI) containing the following information for each drug—

- Name and strength
- Quantity
- Name of supplier and manufacturer
- Country of origin
- Product registration number
- PI number and POE name

Components of Inspection

The drug inspector will verify the following **documentation**—

- The consignee has an approved PI.
- The Clean Report of Finding (CRF) date is before the PI expiration date.
- All consignment information matches the information on the approved PI.
- Each batch of products has an approved Certificate of Analysis (COA).
- At the time of arrival, products with shelf lives of more than 24 months have 60% of their shelf life remaining, and those with less than 24 months have 80% of their shelf life remaining.

The inspector will perform a **label examination** for all products.

- Labels must bear the name and address of the manufacturer.
- There is no evidence of tampering; tamper-proof seals are intact.
- Labels and package inserts must be written in Swahili and/or English.
- Batch numbers and expiration dates on the samples must match the numbers on the COA unit samples.

The inspector will perform a **physical examination**.

Solid form: Odor, uniformity of size, shape, color, coating, and markings. Breakage, cracking, foreign particle contamination, splitting, pinholes, broken or open capsules, and stickiness.

Liquid or semi-solid form: Evidence of cracking, breakage, tearing, leakage, particulate matter, clarity, fluidity, uniformity, and re-dispensability.

The following antimalarials will be **sampled**—

- Quinine tablets
- Injectable artesunate
- Sulfadoxine-pyrimethamine (SP) tablets

The following antibiotics will be **sampled**—

- Amoxicillin
- Ampicillin
- Co-trimoxazole
- Erythromycin
- Metronidazole

The samples will be **screened** with the following tests—

- Color reaction
- Disintegration
- Thin-layer chromatography (TLC)
- Dissolution test (for each SP sample)