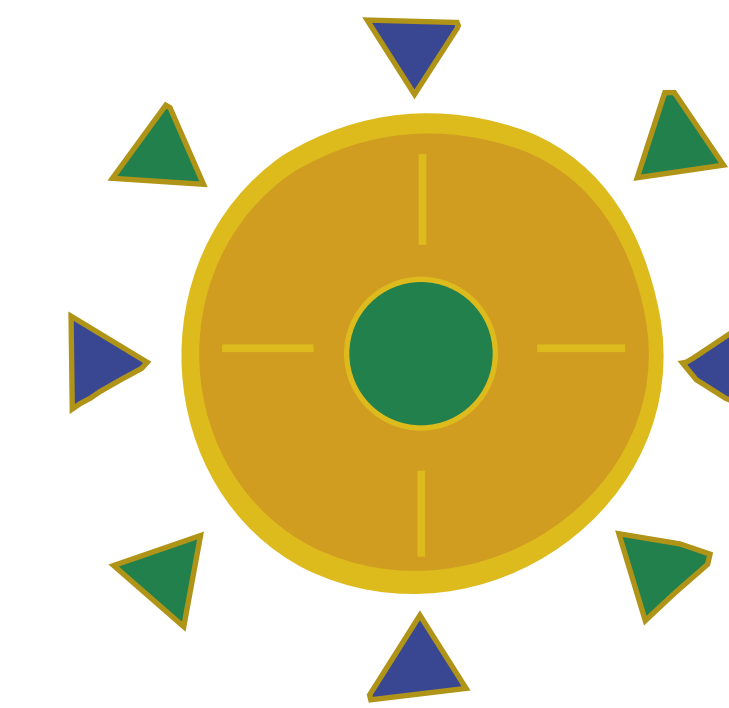


# SEAM Tanzania



## Quality Assurance: Results from the Use of PDAs in Regulatory Efforts

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### Introduction

In March 2003, the Tanzania Food and Drugs Authority (TFDA), working closely with Management Sciences for Health, implemented a data collection system using personal digital assistants (PDAs) for the recently strengthened activities in the ports of entry (POEs) and postmarketing surveillance (PMS) inspection programs. Field inspectors, who required ready access to TFDA's drug marketing authorization database and needed a method for efficiently collecting and submitting inspection data, were trained on the use of the devices and related recording forms, and given PDAs to use in their everyday efforts. The units were deployed to inspectors responsible for monitoring the POE and PMS programs in the northern and central regions of Tanzania. After some initial piloting with an alpha version, a beta version was developed that the inspectors have used regularly since October 2004. Follow-up surveys with the inspectors after six months of continuous use revealed a number of points about the program.

### Program Pros

#### For Inspectors

- ❖ Provides a listing of legal products, manufacturers, and premises, along with other data, which allow the inspector to make faster and more confident decisions
- ❖ Significantly reduces the amount of paper forms that must be carried around
- ❖ Increases the prestige/authority factor
- ❖ Forms are easily searchable and questionable records can be quickly retrieved
- ❖ Eliminates the need for inspectors to compile weekly summary reports, saving four to five person hours per week for each inspector

#### For Management

- ❖ Quickly produces reports based on multiple analyses of data elements captured on the forms
- ❖ Helps ensure that a disciplined quality inspection process is followed by all inspectors
- ❖ Increases accuracy of data entered by eliminating handwritten responses that could be misinterpreted
- ❖ Individual inspector's data entries can easily be brought up electronically and audited for quality purposes
- ❖ Saves the TFDA USD 1,300 in photocopy charges annually
- ❖ Removes the need to correctly file and store 30,000 pages of completed forms, translating into labor savings
- ❖ Inspectors' immediate supervisors are relieved of the need to spend four to five days collating and validating data for up to four inspectors into a monthly summary report. This can now be done easily with an electronic report

### Program Cons

#### For Inspectors

- ❖ Programmed forms are too structured to be able to deal with "exception" situations that are not accounted for in the software
- ❖ Delays occur in obtaining monthly listing updates for the registered manufacturers, products, and stores

#### For Management

- ❖ Because of program inertia and lack of familiarity with the technology, inspectors required more frequent and comprehensive training than expected

### Considerations

- ❖ Be Prepared: Before planning and implementing a PDA program, good practices must already be in place.
- ❖ Be Practical: Start with a small test group and work with it consistently for a period of time to find and correct errors before rolling out to a larger group.
- ❖ Be Encouraging: Expect minor resistance to change if the PDAs are replacing an older method. Explain at length how PDAs will make inspectors' jobs easier.
- ❖ Be Patient: Conversion, even with an existing system, takes time. The TFDA began work with SATELLIFE and MSH in June 2003, and only within the last 6 months has the program been fully implemented.
- ❖ Be Flexible: When converting paper forms to PDA versions, the forms will require changes to better fit the new medium.
- ❖ Be Serious: A dedicated and knowledgeable IT staff must be available to help in transitioning to and maintaining the new system, database, and PDAs.
- ❖ Be Thoughtful: Know beforehand exactly what reporting outputs you expect from the system. These outputs factor heavily into the design of the forms and database.

### Conclusions

Two years after what was to be a six-month project, the PDA inspection program is now running smoothly and the TFDA can finally begin to harvest the original expected results. Although it took more time (and thus more money and labor) to reach this baseline point than was initially imagined, both the inspectors and TFDA management have found the PDAs to be an enhancement to the quality assurance program. At this point, however, it is not possible to declare the PDA program either a success or failure.

FACILITY INSPECTION REPORTS – NUMBER OF PRODUCTS CONFISCATED	
Pharmacy – Non-sterilized Products Confiscated:	
Pharmacy – Sterilized Products Confiscated:	5
Part B (BSE) – Non-sterilized Products Confiscated:	244
Pharmacy – Sterilized Products Confiscated:	
Pharmacy – Non-sterilized Products Confiscated:	5
Part B (BSE) – Sterilized Products Confiscated:	82

All pharmaceutical products entering the country must be registered with the TFDA and distributed in accordance with the applicable regulations. Unregistered and unauthorized products are illegal and may be confiscated.

PORT OF ENTRY INSPECTIONS	
Total number of consignments inspected:	648
Total Value of Consignments Inspected:	
EU France	Total Goods Here
Kenya Shillings	Total Goods Here
S.A. Rand	Total Goods Here
Swiss Francs	Total Goods Here
Tanzania Shillings	Total Goods Here
UK Pound	Total Goods Here
US Dollars	Total Goods Here
ZMK	Total Goods Here
Total number of pharmaceutical consignments inspected:	38
Total number of pharmaceutical products received:	542
Total number of pharmaceutical batches received:	2429
Total number of batches of surveillance products received:	258
Total number of consignments detained:	28

The ports of entry at Namanga (on the border with Kenya), Dar es Salaam International Airport, and Dar es Salaam Harbor are the primary entries for consignments of medicinal products. A consignment is a group of products that is shipped under one order. Inspectors conduct independent physical examinations on all batches of a given pharmaceutical product. If any of these batches fail, they are detained and samples sent to the National Quality Control Laboratory for further testing. Additionally, certain pharmaceutical products are routinely sampled and screened using Minilab testing protocols ("surveillance samples"). The number of consignments and their included products per month is daunting, and the TFDA expends significant amounts of resources to control these entry points.

POE INSPECTIONS – CONSIGNMENTS DETAINED			
Total number of consignments detained:	28		
Consignment	Country of Source	Inspector	Reason Detained
03630	SA	Mamuna Haji	Batch no. Manufacturing date and expiring date not shw
04196	Kenya	Ella Nyirwa	no proforma invoice
05056	China	Mamuna Haji	Fail labelling requirements, no manufacturing date, no exp
07450153552	Belgium	Mamuna Haji	Sample of Anivale 100mg collected for screening
07470482984	Belgium	Mamuna Haji	Contains Anivale sample collected for screening test
0745484213	United Kingdom	Ella Nyirwa	no import certificate for psychotropic substance
07674	Switzerland	Mamuna Haji	Wait for screening test results
07683	Switzerland	Mamuna Haji	Wait for analysis result
0829	Kenya	Ella Nyirwa	-waiting for screening results of SP
10091	Kenya	Ella Nyirwa	-results for SP screening
10170	India	Mamuna Haji	Waiting for screening test results
10312	India	Mamuna Haji	Waiting for screening test results
10347	India	Mamuna Haji	Sample collected for screening test
1251051013	Greece	Mamuna Haji	Sample collected for screening
13019	India	Mamuna Haji	Sample collected for screening test

Products that do not comply with all of the required documentation are detained at the port of entry until the TFDA resolves the issues. After resolution, the products may be released for distribution, denied entry and be exported, or destroyed.

PORT OF ENTRY – PHYSICAL EXAMINATIONS		
Consignment	Country	Name of Inspector
3471	India	Mamuna Haji
02073	Kenya	Ella Nyirwa
2764	Kenya	Donesta Simoni
0745480143	Canada	Mamuna Haji
19423	Italy	Mamuna Haji
13117	India	Donesta Simoni
24946	Kenya	Ella Nyirwa
1757408234	Belgium	Mamuna Haji
0747048964	Belgium	Mamuna Haji
0745052052	Belgium	Mamuna Haji
13454	China	Mamuna Haji
5726	Germany	Donesta Simoni
03855	China	Mamuna Haji
18773	China	Mamuna Haji
17977	China	Mamuna Haji
04804	Switzerland	Mamuna Haji
09450	United Kingdom	Mamuna Haji

All imported pharmaceutical products that have all documentation in proper order are submitted for physical examination to obtain an estimate of product quality. Products that fail the physical examination are denied entry or confiscated and destroyed. Products that pass the physical examination and are not subject to surveillance programs are released for distribution. Products that pass the physical examination and are subject to surveillance programs are submitted for screening using the German Pharma Health Fund Minilab testing protocols. Products that fail any aspect of the Minilab screening are then sent to the National Quality Control Laboratory for confirmatory analysis.