

## TANZANIA: Using Personal Digital Assistants to Improve Inspections

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**Problem:** To perform their jobs effectively, field inspectors must have ready access to the country's drug marketing authorization database and must be able to efficiently collect and submit inspectional data to authorities. In addition to this database of approved products and manufacturers, inspectors need to have a portable listing of pharmacists, pharmacies, drug shops (*duka la dawa baridi* and *duka la dawa muhimu*), and importers to enforce registration requirements. Although the TFDA updates this information frequently, distance, cost, and maintenance factors have prevented it from being readily available to inspectors in the field. Also, the sheer number of handwritten forms returned by the inspectors made analyzing inspection data tedious and time consuming (inspectors used a combination of ten different inspection forms to perform their job). Because of a shortage of staff, the pace of data compilation was greatly limited, and the data collected was not easily available for use in making public health regulatory decisions. The frequency of typographical and naming errors also limited the data's usefulness to management.

**Strategy for Change:** To address the problems in the flow of drug inspection data and preparation of reports, the TFDA, working with the SEAM Program and SATELLIFE, a nonprofit health information and communications firm, incorporated personal digital assistants (PDAs) into the inspection process. The alpha version of the PDA-based inspection system used menu-driven forms that listed approved products, consignees, and manufacturers. Inspectors responsible for monitoring the ports of entry and postmarketing surveillance programs in the northern and central regions of Tanzania were given the PDAs to pilot. The inspectors used the PDAs in conducting their normal day-to-day business, stopping once a month to receive new memory cards from the TFDA and mailing back the old ones with the data for that month to TFDA headquarters, where it was then consolidated and used for various reporting needs. Based on their experience, a much-improved beta version was developed that inspectors have used since October 2004.

**Results:** Both the inspectors and TFDA management have found that PDAs enhance the drug product quality assurance program. While a comprehensive program evaluation will need to be based on a longer period of use, follow-up surveys with the inspectors after six months of continuous use showed that the PDA program—

- Provides a ready and updated listing of legal products, manufacturers, premises, and other data that allow the inspector to make faster and more confident decisions
- Significantly reduces the amount of paper forms inspectors must carry
- Gives the inspectors flexibility and convenience in their work by making current forms easily accessible
- Increases the inspector's prestige and authority
- Allows inspectors to easily search and retrieve historical forms
- Eliminates the need to compile weekly summary reports, saving each inspector four to five work hours per week
- Allows quick production of reports using multiple analyses of collected data
- Helps ensure that all inspectors follow a disciplined quality inspection process
- Increases the accuracy of data entry by eliminating many handwritten responses that could be misread or misinterpreted, thereby preserving the integrity of the central database
- Facilitates quality control audits, since individual inspector's data can be easily reviewed electronically

**Lessons Learned:** Some initial lessons learned include—

- A dedicated and knowledgeable information technology staff must be available to help in transitioning to and maintaining the new system, database, and PDAs.
- Good inspection practices must already be in place before initiating a program.
- Starting with a small test group to find and correct errors before rolling out to a larger group is essential.
- Expect some resistance to change if the PDAs are replacing an older method. Demonstrate how PDAs will make inspectors' jobs easier, and involve inspectors in conceptualizing, developing, and testing the new approach.
- Implementing a new methodology, even when converting from an existing system, takes time. When moving from paper to PDA format, the various inspection forms and related procedures required numerous changes in inspection practices and processes to operate effectively.

- Inspectors required more frequent and extensive training than expected, due to the gap in time between the use of the alpha and beta versions and their lack of familiarity with the technology.

**Activity Update (February 2007):** Managerial commitment and support have been keys to the continued use of PDAs. Inspectors still use the PDAs to collect inspection data from ports of entry, including Dar es Salaam International Airport, the Dar Harbor, and Namanga. However, the use of PDAs in postmarketing surveillance inspections is still limited to a few inspectors, which is puzzling. A closer look would be needed to determine if this limitation is related to personnel, the instrument/program, or a combination. To assure transferability to other countries, the technology will need to be flexible enough to be able to modify static fields to accommodate changes in the drug regulatory authority's procedures and forms (for example, the TFDA's current forms are about three years old).

**Next steps:**

- Survey TFDA inspectors and management to identify needed adaptations to the current electronic forms
- Identify areas where IT personnel and end users require training and provide the requisite follow-on training to ensure self-sufficiency (e.g., in use and development of the electronic forms)