Ethiopia's Integrated Electronic Regulatory Systems:

Building the Foundation for End-to-End Medicine Traceability

In partnership with Ethiopia's Food Medicine and Healthcare Administration and Control Authority (FMHACA) and the Pharmaceuticals Fund and Supply Agency (PFSA), JSI is developing and implementing a new, fully integrated open-source electronic regulatory information system (ERIS) that will enable end-to-end pharmaceutical supply chain visibility in Ethiopia.

The new technology will give FMHACA tools to trace medications along the supply chain and ensure that they are registered, safe, and of high-quality. JSI is also providing technical policy support for the implementation of GS-1 global track-and-trace standards to strengthen the medicine regulatory system.

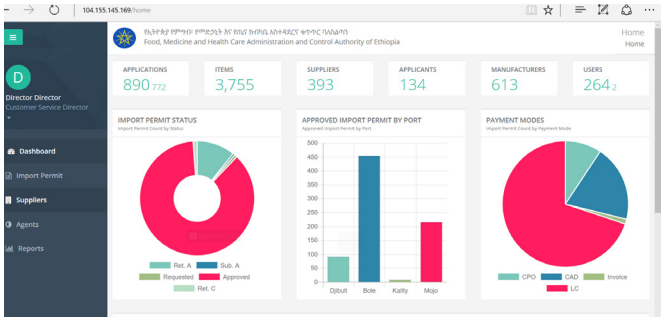
These activities are supported with funding from USAID's Strengthening High Impact Interventions for an AIDS-free Generation (AIDSFree) project and the Bill & Melinda Gates Foundation. The activities build on earlier JSI-led pilots that were launched under USAID | DELIVER PROJECT.

Implementing a Modernized, Integrated Electronic Regulatory Information System

Interoperable systems that automatically share data offer significant benefits and advantages, including enhanced visibility, data quality, and ultimately medicine quality and availability. Over the past year, JSI's work on the ERIS has expanded to technical support for the development and implementation of an integrated management information system (MIS) for FMHACA that is fully interoperable with the supply chain management system. Two integrated systems will allow greater transparency and information exchange between the FMHACA, which oversees medicine and medical device selection, registration, import approval, pharmacovigilance, and product quality, and the PFSA, which is responsible for forecasting, procurement, storage, and distribution.

JSI and FMHACA launched the first module of i-Import—the new open-source online approval system for pharmaceutical imports—in July 2017. i-Import allows FMHACA to see submitted applications for permits and their status in real time. All of the modules on the ERIS platform will use the same master database of medication product information as PFSA, which will improve data quality and consistency nationwide. i-Import is interoperable with PFSA's enterprise-level information system, the Health Commodity Management Information System (HCMIS), allowing data to flow automatically between PFSA and FMHACA, so that every purchase order placed by PFSA is synced to i-Import and immediately visible. In the past, approvals required hard-copy purchase orders to be sent between the agencies, often resulting in lost paperwork and weeks-long delays in the approval process.

i-Import was custom-built by JSI's local technical team using an iterative, agile development framework. The team relied on frequent feedback and user-testing from FMHACA staff to ensure that the final platform was user-friendly and met the FMHACA's critical needs. The platform is open-source, which allows Ethiopia to maintain control and ownership of the system, instead of tying the country to a specific contractor or proprietary platform.



Building the Foundation for GS1 Global Track and Trace Standards

Ethiopia is one of the first countries in sub-Saharan Africa to prioritize GS1 standards—the leading international standard for pharmaceutical and medical device naming—for pharmaceutical supply chain management and regulation. JSI is conducting a comprehensive feasibility assessment at FMHACA, including stakeholder and landscape assessments and development of an implementation roadmap, on the introduction of GS1 standards. JSI is also working closely with FMHACA to establish the policy framework necessary to implement GS1 global standards for medication track and trace.

Implementing GS1 standards allows FMHACA and PFSA to identify products uniquely and track and trace shipments within and across borders from the manufacturer to the importer or distributor, the health care facility, and even the patient level. Once implemented, the agencies will be able to use GS1 barcodes to capture and share supply chain data in real-time, greatly reducing staff workloads and increasing data quality. Product traceability also improves patient safety by identifying counterfeit medications and facilitating product recalls and reports of adverse drug reactions.

Scale up

In May 2017, JSI joined with UNFPA, USAID, FMHACA, and PFSA to coordinate an awareness-raising workshop on track and traceability for medical products. This work builds on an earlier pilot conducted by the USAID | DELIVER PROJECT to test the feasibility of using GS1 barcodes on PFSA-distributed products. The manufacturer in the pilot printed barcodes and QR codes on a shipment of emergency contraceptive pills, including Global Trade Item Number serialization. Products were shipped and scanned at each of the following points: PFSA's central warehouse in Addis Ababa, the Addis Ababa Distribution hub, and two pilot health care facilities. Use of a barcode reader during the pilot allowed staff to capture batch information and expiration dates 2.5 times faster than the existing manual process.

Other learnings from the pilot include:

- The mobile application was able to read standard 1D barcodes better than 2D QR codes.
- Secondary-level packages were more challenging to track at the warehouse.
- Using dedicated hardware scanners instead of mobile applications on smartphones may expedite the scanning and tracking process.

In the past, JSI worked with PFSA to implement Global Document Type Identifiers (GDTI), another element of GS1 global standards. Using GDTI serial numbers and QR codes allows PFSA to validate, authenticate, and archive key documents, including purchase orders, invoices, and stock transfer vouchers. Recipients are able to scan their document's barcode and log into a secure PFSA web portal to verify the document's authenticity. This technology helps reduce the incidence of fraudulent documentation.

JSI continues to work closely with FMHACA and PFSA to design, develop, and implement new modules and services to ensure a streamlined, effective medication regulatory and supply chain system in Ethiopia. We are implementing a system that will allow consumers to verify the identity of ACTs for malaria treatment using a smartphone. The system is expected to be ready for deployment before the end of 2017.