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Pharmaceutical Regulatory Information Systems: The forgotten link for end to end visibility

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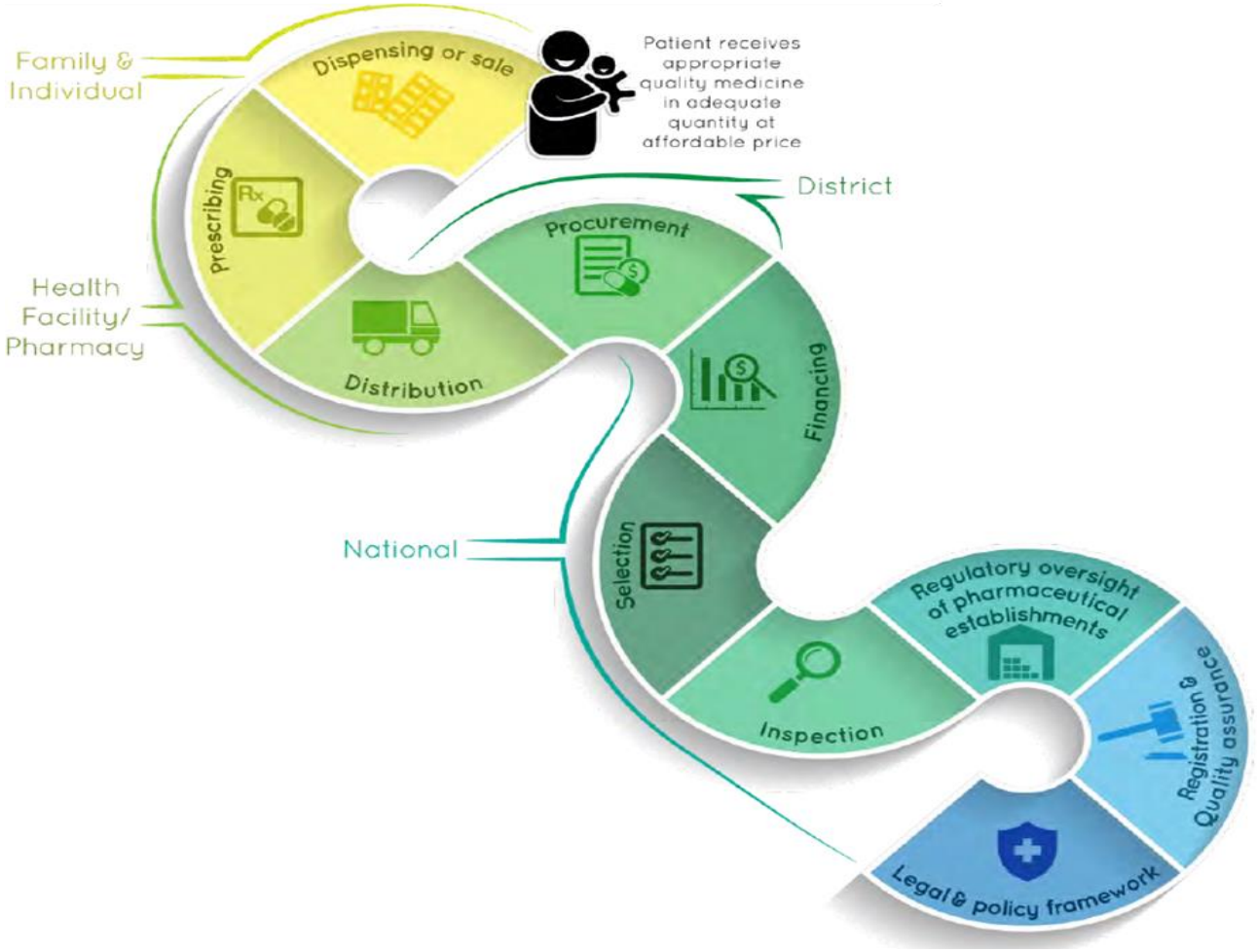
End to End Visibility



Argument

- End to End Visibility – usually refers to the supply chain. What functions should be covered to achieve End to End Visibility?
  - Significant investment in LMIS over past 15-20 years
- Can we say End to End visibility is achieved, if we exclude several functions? e.g., Regulatory System
- Comparatively little investment in MIS for regulatory systems; and any systems developed are rarely interoperable with LMIS

Agenda

- Background
- Automation MIS at PSA
- Rationale
- i-Register and i-Import (Demo)
- Interoperability with supply chain MIS
- Future planned work
- Conclusions

Background: Ethiopia Regulatory System

- FMHACA
- Autonomous federal agency under the Federal Ministry of Health
  - Regulatory Standards Setting
  - Inspection and Licensing (facilities, providers, manufacturers
  - Product Quality: Assessment & Registration/Approvals (food, medicines, devices, cosmetics, traditional medicines)
  - Regulatory Information Delivery

Background: Healthcare Supply Chain

- Pharmaceuticals Supply agency (PSA)
- Autonomous federal agency, under the FMOH
  - Responsible for end to end supply chain (forecasting, procurement, storage, delivery, and availability of quality health commodities at public sector health facilities.
  - Also supplies private sector

Supply Chain MIS

Year Initiated	Name	Level	Functions	Deployment
2010	Dagu	Health facility	Inventory management & LMIS	850 hospitals & health centers
2011	Vitas	Center & hubs (regional)	WMS, procurement, Integrated to financial management	Center + 19 hubs
2012	PDS	Center, hubs	Master Data App	Center & 19 hubs
2013	Fanos	Any	SC dashboard	
2016	mBrana	District	Mobile vaccine management, e-ordering	350 districts

Rationale

- In 2016, FMHACA requested through USAID, JSI MIS support for the regulatory system
- At the time, automation was minimal:
  - a pharmaceutical registration system had just been implemented but was not open source and so restricted in terms of upgrading & interoperability
  - There was also a database for pharmacovigilance (PV)
- FMHACA had a vision for an “integrated” platform- Ethiopian Regulatory Information Systems, eRIS - linking various systems (importation, registration, PV, licensing etc.)
- Stakeholders also recognized benefits from interoperability with supply chain systems
  - Visibility
  - Data quality

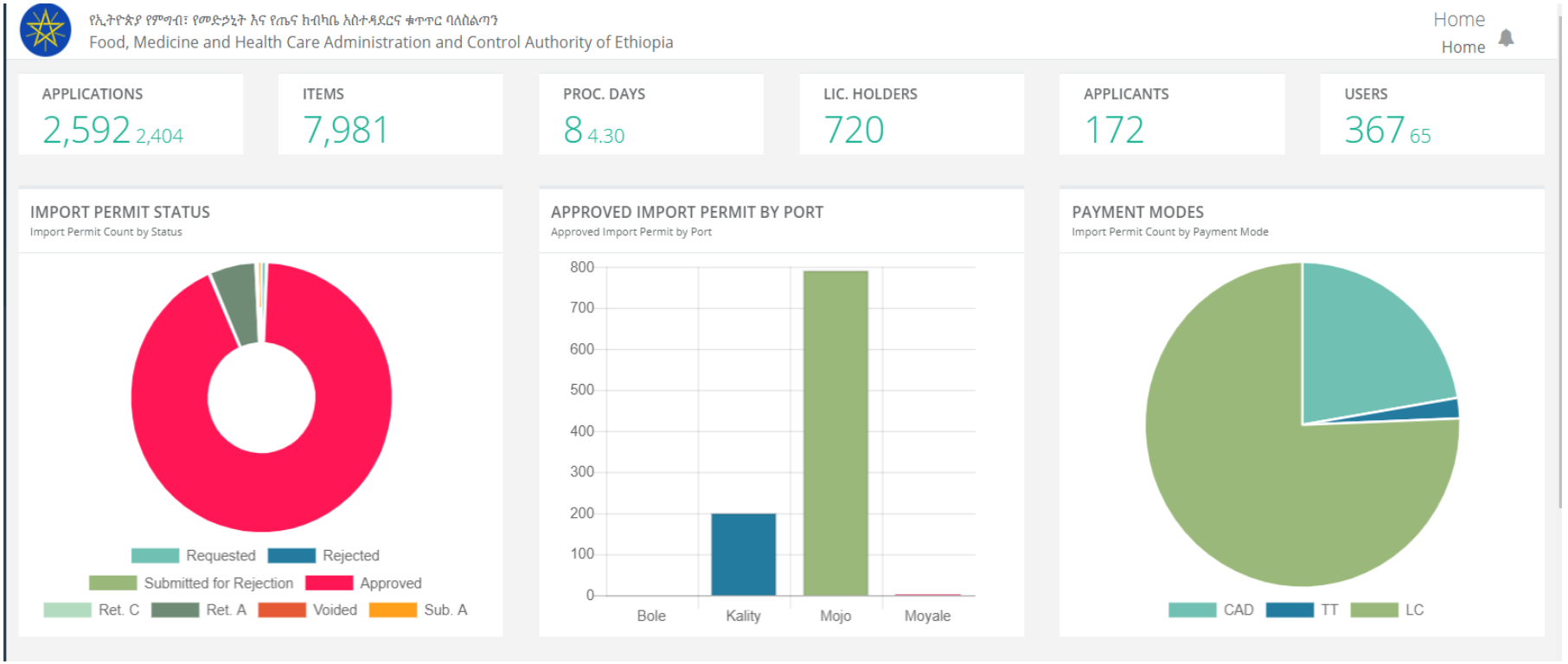
Approach

- Agile software development – build and deploy quickly, solicit feedback, adapt system and add new features
- Step by step (incremental) approach to systems deployment
  - Allows “quick wins”,
  - Developers and users become more familiar with the benefits technology can bring, and how to both develop and implement them successfully
  - Reduces risks
  - Flexible
  - Software driven by what users need now; not everything they might need in the future

i-Import

- First system for FMHACA developed, launched in 2017
- Online, open-source import approval system
- Due to restrictions on hard currency, health commodity importers - including PSA - must first receive approval from FMHACA
- Improved efficiency & transparency
- Interoperable with PSAs MIS (Vitas)
- Uses same Master Data as PSA enhancing visibility and data quality
- Since deployment, >1,400 import permit requests & >1,300 approvals

Screenshot of i-Import

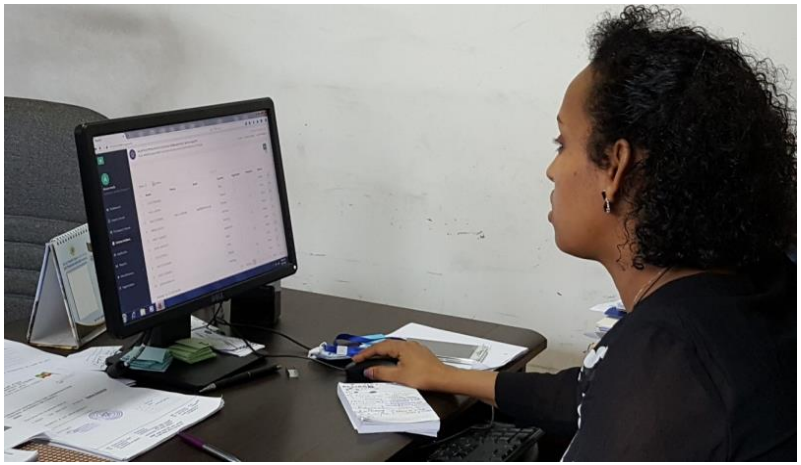


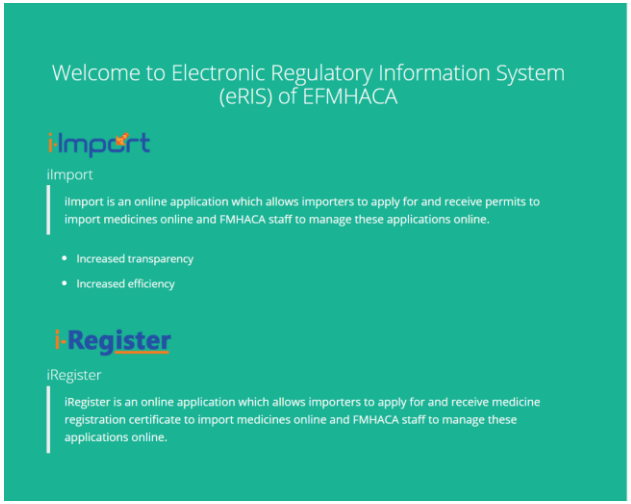
i-Register

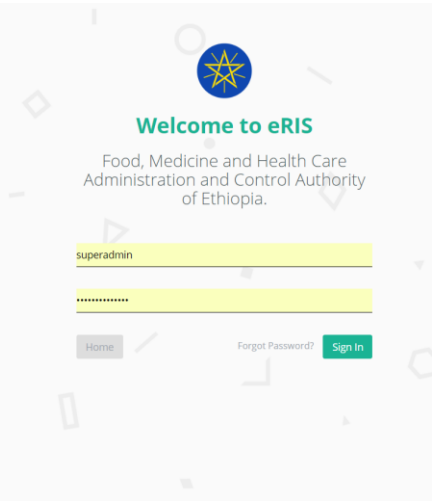
- Open source, web-based management information system that automates medical product registration, application submission, screening, review, and market authorization
- Implemented in 2018
- Improves
  - Efficiency
  - Transparency: all can track status
  - Workforce management – FMHACA managers can manage caseloads and track performance
  - Improved data quality
  - Interoperable with i-Import and PSA MIS
- Being used by FMHACA and > 100 importers
- Since deployment > 500 market authorization requests, >200 approvals

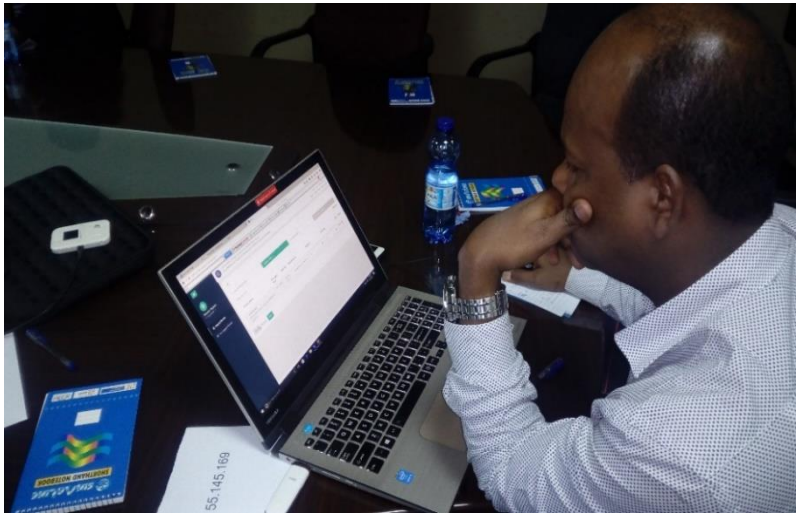
Photos

FMHACA's Customer Service Director using eRIS to approve application and applicant to submit application









2018 Global Health Supply Chain Summit
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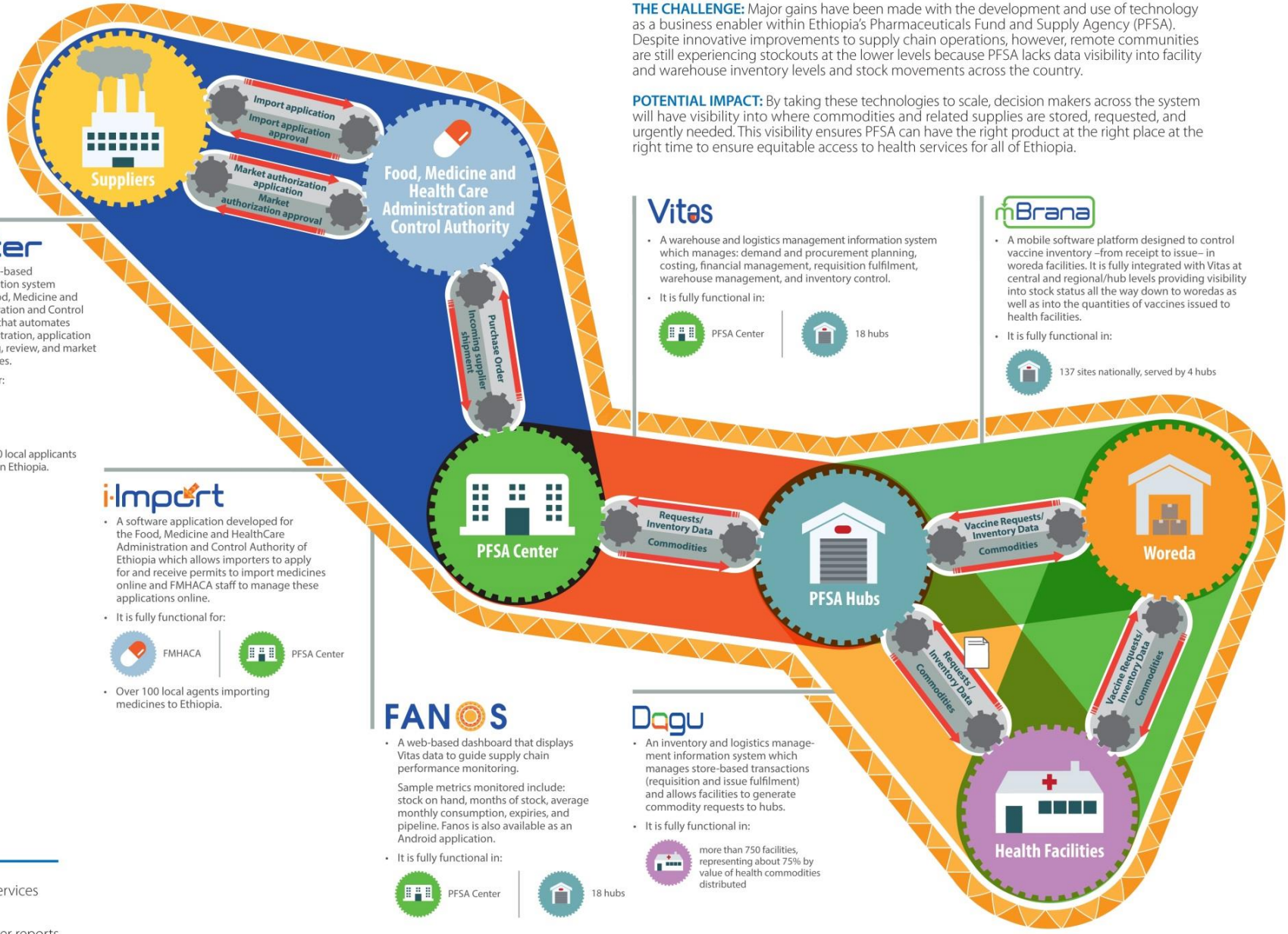
Technology in Ethiopia for Healthcare Supply Chain Management

Improving decision making by making quality data accessible in real time

THE CHALLENGE: Major gains have been made with the development and use of technology as a business enabler within Ethiopia's Pharmaceuticals Fund and Supply Agency (PFSA). Despite innovative improvements to supply chain operations, however, remote communities are still experiencing stockouts at the lower levels because PFSA lacks data visibility into facility and warehouse inventory levels and stock movements across the country.

POTENTIAL IMPACT: By taking these technologies to scale, decision makers across the system will have visibility into where commodities and related supplies are stored, requested, and urgently needed. This visibility ensures PFSA can have the right product at the right place at the right time to ensure equitable access to health services for all of Ethiopia.



i-Register

- A public domain, web-based management information system developed for the Food, Medicine and Health Care Administration and Control Authority of Ethiopia that automates medical product registration, application submission, screening, review, and market authorization processes.
- It is fully functional for:
  - FMHACA
- Used by more than 100 local applicants registering medicines in Ethiopia.

i-Import

- A software application developed for the Food, Medicine and HealthCare Administration and Control Authority of Ethiopia which allows importers to apply for and receive permits to import medicines online and FMHACA staff to manage these applications online.
- It is fully functional for:
  - FMHACA
  - PFSA Center
- Over 100 local agents importing medicines to Ethiopia.

Vitas

- A warehouse and logistics management information system which manages: demand and procurement planning, costing, financial management, requisition fulfilment, warehouse management, and inventory control.
- It is fully functional in:
  - PFSA Center
  - 18 hubs

mBrana

- A mobile software platform designed to control vaccine inventory –from receipt to issue– in woreda facilities. It is fully integrated with Vitas at central and regional/hub levels providing visibility into stock status all the way down to woredas as well as into the quantities of vaccines issued to health facilities.
- It is fully functional in:
  - 137 sites nationally, served by 4 hubs

FANOS

- A web-based dashboard that displays Vitas data to guide supply chain performance monitoring.

  Sample metrics monitored include: stock on hand, months of stock, average monthly consumption, expiries, and pipeline. Fanos is also available as an Android application.
- It is fully functional in:
  - PFSA Center
  - 18 hubs

Dagu

- An inventory and logistics management information system which manages store-based transactions (requisition and issue fulfilment) and allows facilities to generate commodity requests to hubs.
- It is fully functional in:
  - more than 750 facilities, representing about 75% by value of health commodities distributed

LEGEND

- Directory Services
- Printed paper reports are keyed into Vitas

Next Planned work

- Strengthen use of existing systems
- Extend registration to Medical Devices & Food
- Move onto new modules of eRIS (e.g. Port Release, pharmacovigilance, quality control)

Conclusions

- Significant benefits in MIS for regulatory systems: Efficiency, transparency, quality
- Additive benefits if systems are made interoperable with supply chain MIS
  - Same master data = improved data quality
  - Enhanced visibility (capturing more “functions”
- Moving beyond the physical supply chain to a “value chain” Regulatory processes may not involve physical custody of commodities but they are critical to ensuring quality medicines are available

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