



Zambia's Traceability Vision and Progress

February 2024



National Context

Zambia National Health Sector Overview

- ❑ Zambia is a Landlocked country with a population 20 million
- ❑ GRZ has declared the health care improvement to be among the priority sectors linked to the human rights
- ❑ Emerging infectious diseases as well non-communicable diseases have increased demand for high quality, safe and efficacious medicines.
- ❑ Health facilities has increased from less than 1,762 in the year 2012 to 3,378 in the year 2023 - operating with limited or no dedicated supply chain logistics
- ❑ Local pharmaceutical production has decreased to only 3 firms - increasing dependency on importation of medicines, with over 90% of medicines imported
- ❑ Demand for essential medicines far exceeds supply; demand is significantly affected by seasonality, with malaria and other common illnesses becoming more prevalent in the rainy season and, supply is challenging, with remote health posts hard to reach – meaning patients cannot access required medicines leading to abundance of falsified and sub-standard drugs on the market





National Traceability Strategy Implementation

Zambia National Traceability Strategy and Milestones



National
Pharmaceutical
Traceability Strategy

STRATEGY



National Product
Catalog Established

MASTER DATA



GDSN Integrations

GDSN



Automatic Identification
and Data Capture
discovery and planning

AIDC



National Guidelines for
Traceability

REGULATION



National Traceability
Model Architecture
& Roadmap *(draft)*

MODEL DESIGN

2019

2021

2022

2023

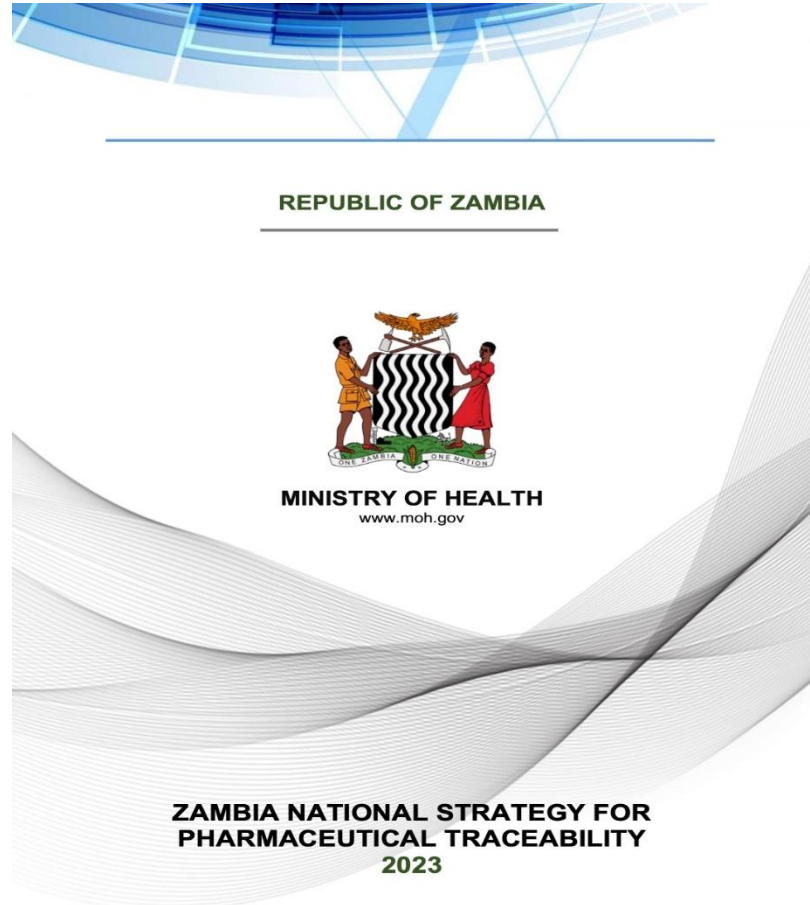
2023

2023

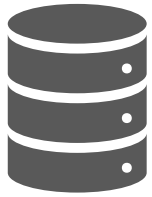


In July 2019, the Ministry of Health (MOH) hosted a collaborative workshop to launch the pharmaceutical traceability initiative through collective action of government, private sector, and development partner stakeholders

ZAMBIA NATIONAL PHARMACEUTICAL TRACEABILITY STRATEGY



Traceability Vision: “Implement a system of global standards to increase patient safety through enhanced quality of supply chain data, enabling efficiencies, supporting systems interoperability and to create visibility in the supply chain to address risk of pilferage and prevent falsified medicines from reaching patients..”



In September 2021, the country's National Product Catalog initiative was launched with the an open-source Product Catalog Management Tool (PMCT) application selected to host the country's source of truth for product master data.

ZAMBIA NATIONAL PRODUCT CATALOG

- ❑ A component of Zambia's vision for an integrate HIE Framework through Smart Zambia
- ❑ PCMT configured to support relational data models and flexible enough to integrate with other national systems
- ❑ More than 7414 products (pharmaceuticals) harmonized
- ❑ 551 GTINs available in PCMT
- ❑ Integrated with Zambia's National WMS Expert
- ❑ Onboarded and trained Catalog Managers

PRODUCTS /
7414 results

Search on label or identifier

1 2 3 ... 297

ID	MSL SKU	Image	Label	Family	Status	Complete	Created at	Updated at	Va
P10000	ARV0002		Abacavir Suphate 300mg Tablet(60)	PRODUCT	ENABLED	100%	02/22/2023	03/06/2023	N/A
P10001	ARV0003		Didanosine 100mg tab (60)	PRODUCT	ENABLED	100%	02/22/2023	03/06/2023	N/A
P10002	ARV0004		Efavirenz 200mg tab (30)	PRODUCT	ENABLED	100%	02/22/2023	03/06/2023	N/A
P10003	ARV0005		Efavirenz (Scored) 200mg Tablet(90)	PRODUCT	ENABLED	100%	02/22/2023	03/06/2023	N/A
P10004	ARV0006		Efavirenz 50mg tab (30)	PRODUCT	ENABLED	100%	02/22/2023	03/06/2023	N/A
P10005	ARV0007		Efavirenz 600mg Tablet(30)	PRODUCT	ENABLED	100%	02/22/2023	03/06/2023	N/A
P10006	ARV0008		Efavirenz 600mg tab (60)	PRODUCT	ENABLED	100%	02/22/2023	03/06/2023	N/A



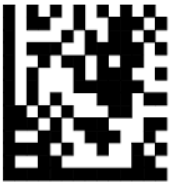
In September 2022, the MOH partnered with GS1 South Africa to integrate its Product Catalog Management Tool with the Global Data Synchronization Network (GDSN) to source master data directly from suppliers.

GLOBAL DATA SYNCHRONIZATION NETWORK SYNCHRONIZATION

The screenshot displays the 'PRODUCT-DETAIL Overview' page for a specific product. The main navigation on the left includes Dashboard, Product Browser, Company Management, User Profile, Reports, and Utilities & tools. The product details section shows three hierarchies: a Pallet (48 units), a Case (48 units), and an Each (1 unit). The product is published to the Government of Republic of Zambia Ministry of Health on 8th Feb 2023. A 'Completeness' bar indicates 40% completion. The 'Basic Data' section lists various identifiers and names for the product, including GTIN, PUBLISHED GTIN, PROVIDER GLN, INFORMATION PROVIDER NAME, SKU, BRAND NAME, NAME, FUNCTIONAL NAME, INVOICE NAME, DESCRIPTION, SUBBRAND, CATEGORY, GPC CATEGORY CODE, GPC CATEGORY NAME, and TARGET MARKET NAME.

GTIN	08903726229088
PUBLISHED GTIN	
PROVIDER GLN	890372600004
INFORMATION PROVIDER NAME	Hetero Labs Ltd
SKU	4022908
BRAND NAME	Hetero Labs Limited
NAME	Tenofovir Disoproxil Fumarate 300mg + Lamivudine 300mg + Dolutegravir 50mg, 30 Tab
FUNCTIONAL NAME	TDF 300mg / 3TC 300mg / DTG 50mg
INVOICE NAME	
DESCRIPTION	Tenofovir Disoproxil Fumarate 300mg + Lamivudine 300mg + Dolutegravir 50mg
SUBBRAND	
CATEGORY	51000000
GPC CATEGORY CODE	
GPC CATEGORY NAME	
TARGET MARKET NAME	Development Assistance

- ❑ Global Location Number obtained to facilitate publication of data to Zambia
- ❑ Piloted data synchronization with 13 suppliers from ARV and ACT commodities ~ 62% response rate from suppliers engaged
- ❑ 76 products and 200 GTINs successfully synchronized to PCMT
- ❑ GDSN data simplifies PCMT data enrich allowing for information such as volumetrics to drive optimization at ZAMMSA



In March 2023, ZAMMSA leverage integration with PCMT to utilize supplier provided barcodes for implementing GS1 enabled barcoding in internal processes i.e., standard identification at receiving (inventory management) and authentication (genuine product and product check/ verification prior to dispatch)

AUTOMATIC IDENTIFICATION AND DATA CAPTURE AT ZAMMSA



- ❑ WMS Expert data configured to receive GTIN data from PCMT (one-to-many-relationship)
- ❑ Automated capture of Batch/Lot and Expiry
- ❑ Eliminate internal barcodes for products with GS1 labels for data processing from receipt through inventory management
- ❑ Increase data granularity from generic identification to trade item identification – foundational for serialization and traceability
- ❑ Automated volumetric data capture for warehouse optimization efforts



In 2023, ZAMRA exercised its authority under section 20 (j) of Statutory Instrument No. 79 of 2019 promulgated of the Medicines and Allied Substances Act No. 3 of 2013, to enforce a ‘suitable coding’ system for all medicines and allied substances meant for the Zambian market as part of “Product Labelling and Packaging Requirements.”

NATIONAL TRACEABILITY GUIDELINES

Packaging Type	Requirement	Deadline
Primary Pack Trade Item	Required for cartonless packaging, preferred for other product: GSI DataMatrix encoded with GTIN, Expiration Date, Batch/Lot, and Serial Number	GTIN, Expiration Date, and Batch/Lot: July 2025 for imported product, July 2026 for domestically-manufactured product Serial Number: July 2028
Secondary pack trade item	GSI DataMatrix encoded with GTIN, Expiration Date, Batch/Lot, and Serial Number	GTIN, Expiration Date, and Batch/Lot: July 2025 for imported product, July 2026 for domestically-manufactured product Serial Number: July 2028
Tertiary pack trade item	GSI-I28 or GSI DataMatrix encoded with GTIN, Expiration Date, Batch/Lot, and Serial Number	GTIN, Expiration Date, and Batch/Lot: July 2025 for imported product, July 2026 for domestically-manufactured product Serial Number: July 2028
Logistic Unit	GSI-I28 encoded with SSCC	July 2028

Requirement	Details	Deadline
Master data linked to GTINs and GLNs	65 attributes, including 13 mandatory attributes, to be shared with ZAMRA via Excel-based form during registration process	Under Review



In August 2023, the MOH hosted a collaborative workshop to design Zambia's traceability approach and model through collective action of government, private sector, and development partner stakeholders

TRACEABILITY MODEL DESIGN

- ❑ Stakeholder mapping on traceability data reporting (manufacturers, distributors & SDP)
- ❑ Centralized traceability system using ZAMMSA WMS Expert as the traceability platform (initially)
- ❑ Three use cases identified
- ❑ Phased approach to implementation to align with national guidelines

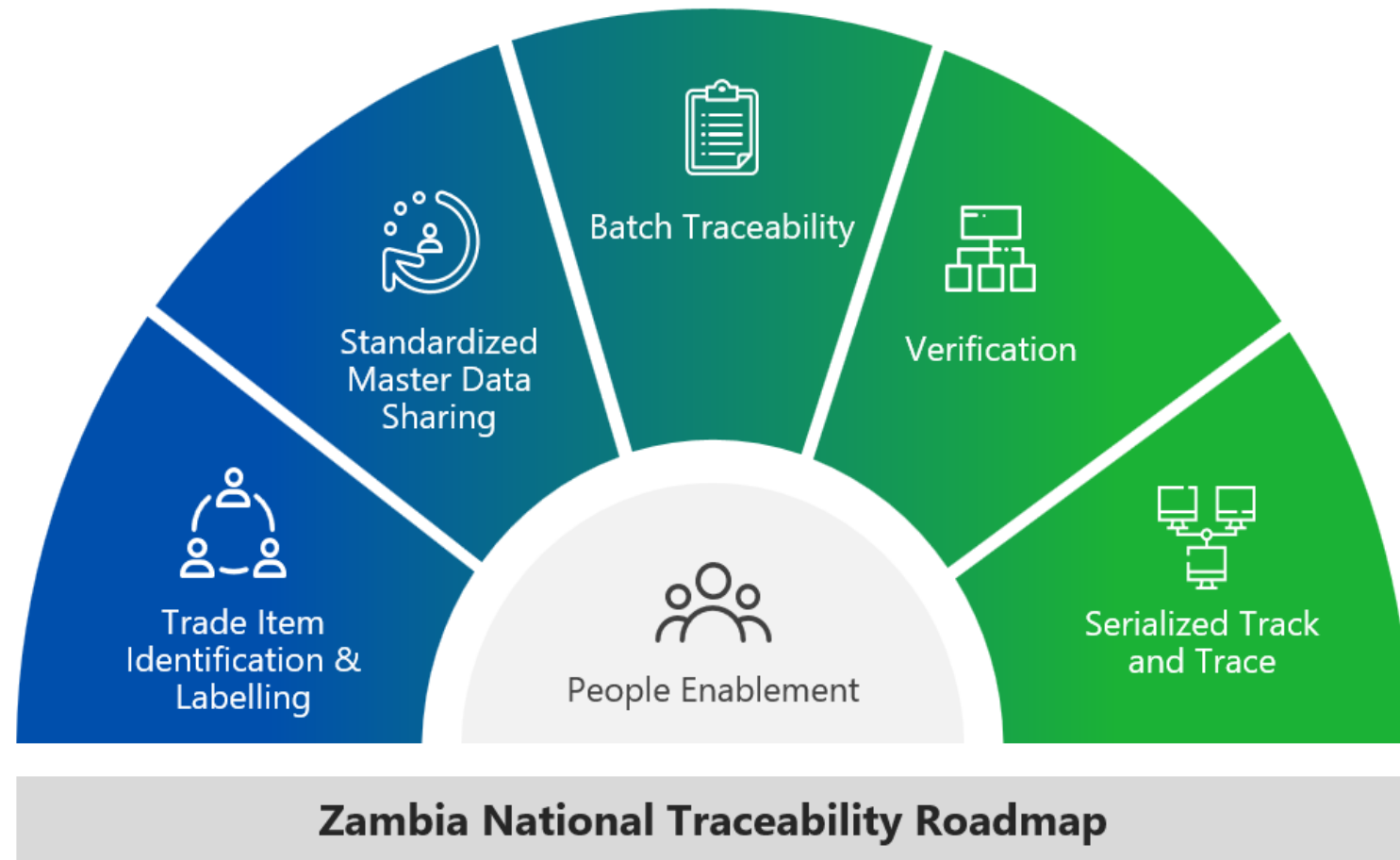




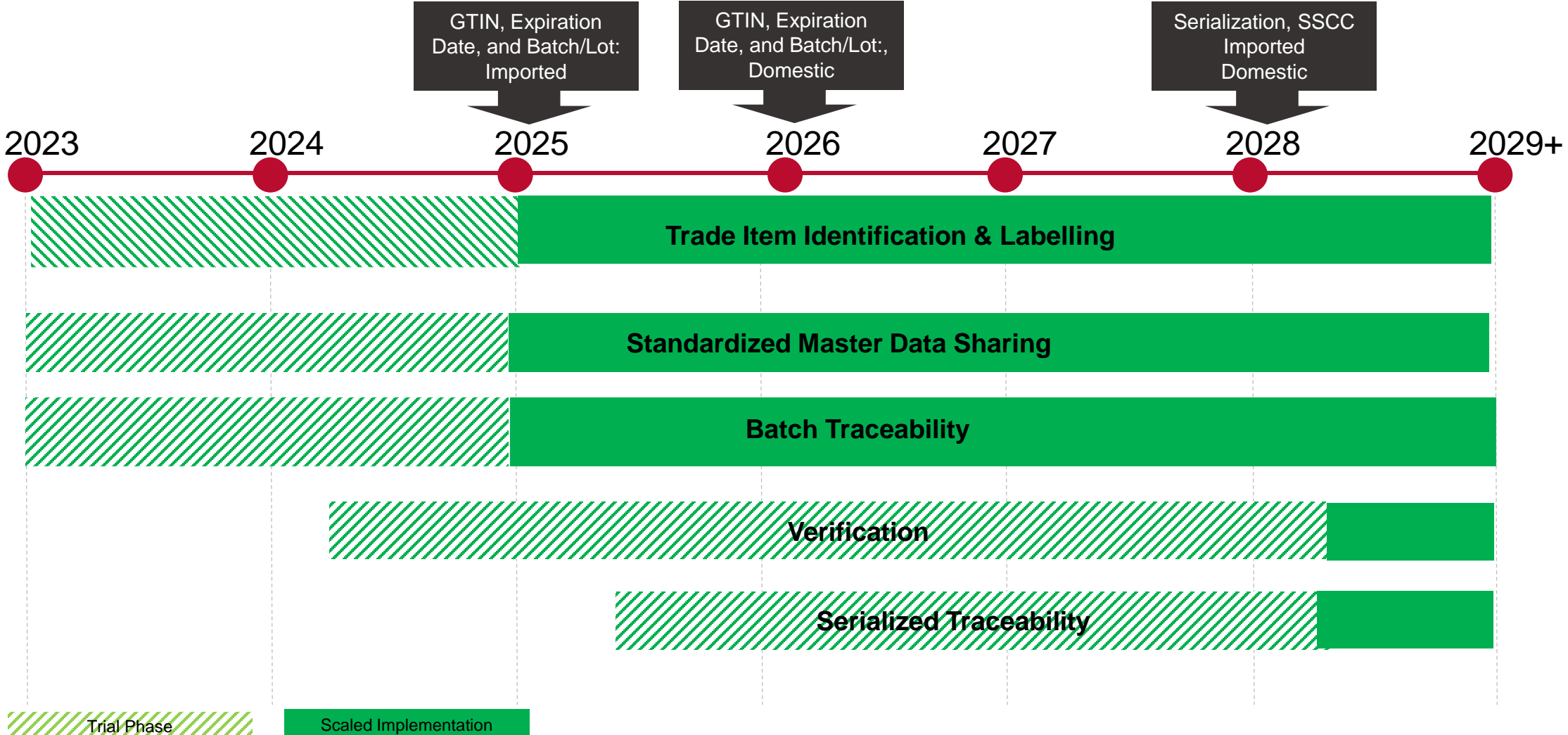
National Considerations for Serialization

Zambia Traceability Vision Roadmap

- ✓ All pharmaceutical products must be labelled with a GTIN, Batch/Lot, Expiration date and Serial number at secondary packaging encoded in a GS1 DataMatrix or GS1 128 Barcode
- ✓ Manufacturers are required to share trade item master data (including GTIN + specified attribute information) with the relevant Authority.
- ✓ Manufacturers, distributors, and SDPs are required to maintain batch traceability information, including GTIN, batch/lot, and expiration date, within their own electronic information systems.
- ✓ Manufacturers are required to share serialized traceability data with the Zambia National Traceability system prior to distributing goods on the national market.

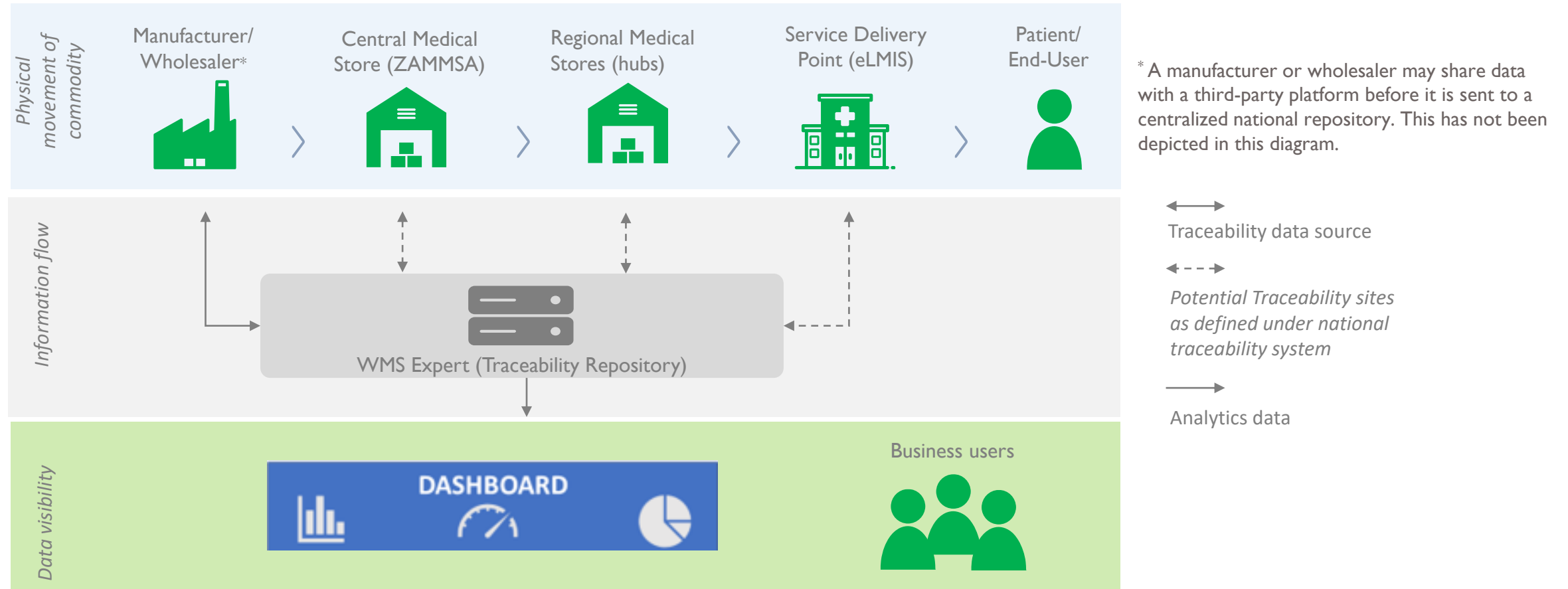


Phased Traceability Implementation Approach



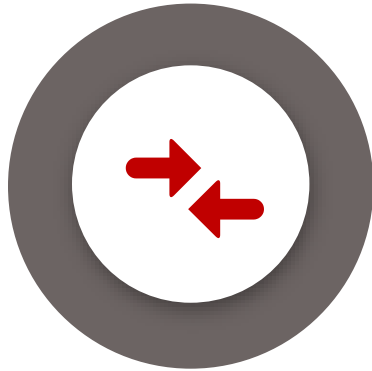
Zambia Traceability Architecture

Description of system: A manufacturer or wholesaler will share data with ZAMMSA (WMS Expert Platform). WMS Expert will be used as a centralized repository where master, batch/lot, expiry date, and Critical Tracking Events are stored. GTIN and batch/lot data will be used to track commodities from ZAMMSA to Regional Medical Stores (hubs).



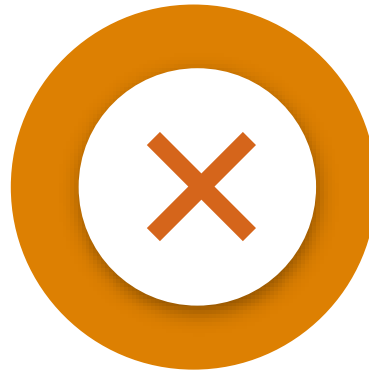
Trial Period Traceability Use Cases

Leverage Zambia WMS Expert as the centralized system where master, serialized data and Critical Tracking Events are stored to pilot traceability with a three-product scope: **ARVs, ACT, MNCH**



Product Diversion

GTIN + Batch/Lot information used to track inventory from ZAMMSA to RMS (**Batch Traceability**)



Counterfeit Products

Validate SGTIN and update its status (e.g., decommissioned) before being dispensed to patients (**Serialized Verification**)



Inventory Management

SSCC and aggregation in AIDC format to optimize inventory management processes at the central warehouse and expedite receiving at the Hub (**Serialized Traceability**)

How GSI South Africa can support Zambia

- Prepare to respond to national Coding Guidelines: identification for donor commodities (2025); Serialization (2028)
- Visibility of local and regional suppliers to comply with the ZAMRA Coding Guidelines:
Sharing of product master data for all commodities donated to Zambia via **PCMT/GDSN through GSI South Africa**
Implement electronic Advance Shipment Notices for goods coming to Zambia
- Share lessons from reference implementations for selecting / configuring systems to enable event data capture and exchange ensuring where possible system interoperability (eLMIS to WMS)
- Capacity building efforts and list of accredited solution providers to enable local manufactures to respond to the Coding Guidelines

Q&A

Annex A: Barcode Requirements

GS1-128 and DataMatrix data carrier

GS1-128 LINEAR BARCODE



(01)10222222333334(17)091231(10)A1345B(21)1234

GTIN-14

Expiry Date

Batch Number

Serial Number

GS1 DATAMATRIX



(01) 20887511007346

(17) 150331

(10) A1B2C3D4E5

(21) 123456789