DRAFT Concept Note for the

Zambia Product Information Management Initiative

Background

A core component of the Zambia e-Health Strategy (2017-2021) is the adoption and institutionalization of international standards to improve access to timely, integrated and interoperable data for improved decision making at various levels of service delivery. In line with the e-Health Strategy, the Government of Zambia and its development partners are calling for increased application of standards to strengthen stewardship and technical leadership in supply chain management and commodity security including the application of standards in strengthening pharmaceutical commodity management systems and data management. The goal is ultimately to improve supply chain visibility, improve supply chain security, enable supply chain efficiencies, and ultimately ensure patient safety.

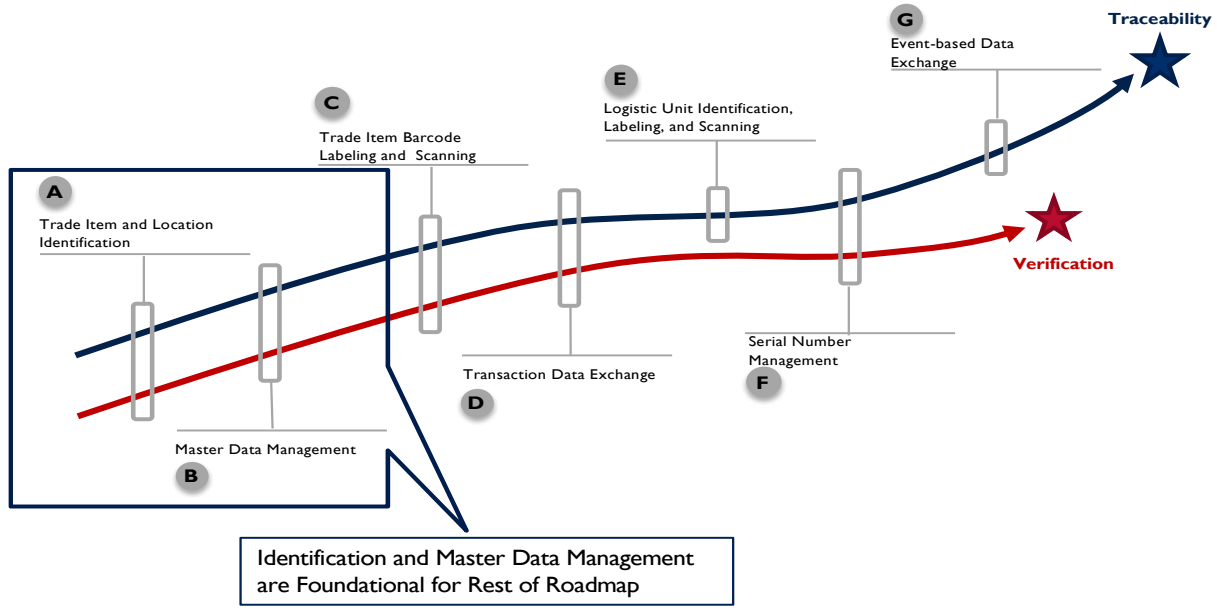
A number of initiatives were undertaken in FY19 to create the enabling environment for global standards and traceability in Zambia, including:

- **Global Standards and Traceability (GST) Subcommittee:** In October 2019, the Procurement and Supply Chain Management Technical Working Group agreed to establish the f Global Standards and Traceability (GST) Subcommittee which will provide advocacy and leadership in implementing global standards for trade item identification, data capture, and data exchange to advance commodity traceability and end-to-end data visibility. The GST sub-TWG is led by the MOH, Information Communications and Technology (ICT) with Zambia Medicines Regulatory Authority (ZAMRA) and Medical Stores Limited (MSL) as Co-Secretaries. Members include MOH, Clinical Care and Diagnostic Services – Pharmacy Unit, JSI AIDSFREE and GHSC-PSM.
- **Zambia National Pharmaceutical Traceability Workshop:** In June 2019, USAID GHSC-PSM Project supported the MoH in hosting a workshop to launch the pharmaceutical traceability initiative. The workshop was attended by key stakeholders including representation from ZAMRA, MSL, GHSC-PSM, SMART Zambia and JSI AIDSFree. A key objective of the workshop was to raise awareness among stakeholders of the benefits of traceability and the existing global standards used in the healthcare industry to enable traceability across the supply chain. The output of the workshop was the establishment of a vision for pharmaceutical traceability in Zambia, leveraging GS1 global standards through a process of assessing the current state and identifying gaps.
- **National Vision & Strategy for Pharmaceutical Traceability**: The Zambia National Vision & Strategy for Pharmaceutical Traceability Leveraging GS1 Global Standards has been drafted and is currently under review by the MOH. The strategy will assign and drive the work required to advance implementation of global standards to drive pharmaceutical traceability in the public and private sector supply chains – including implementation of a national drug registry.
- **Participation at the 2nd African GS1 Healthcare Conference:** ZAMRA and MSL representatives participated at the 2019 African GS1 Healthcare Conference in Lagos, Nigeria. The Zambian delegation, alongside 24 African Regulatory authorities and 6 health financing and donor organizations signed a Call to Action to pursue pharmaceutical traceability by adopting global supply chain standards.
- **Review of Existing Marketing Authorization Requirements:** ZAMRA is reviewing and drafting a requirement for submission of Global Trade Item Numbers (GTIN) and Global Location Numbers (GLNs) as part of the marketing authorization process.

In parallel to continuing to support Government of the Republic of Zambia in strategic efforts to advance pharmaceutical traceability (e.g. ZAMRA policy support, MSL AIDC implementation support), GHSC-PSM seeks to provide MOH/ICT with tactical support to advance the ability to use global standards across the health sector, including creating an enabling environment for GS1 barcode use in the supply chain. In FY20, this support is primarily focused around standardizing trade item (i.e. GTIN where applicable) identification and establishing scalable and sustainable product master data management (PMDM) processes supported by a product information management (PIM) application that will serve as a drug registry. The adoption of a standards-based common structure of product master data is a critical enabler for successfully controlling how commodities are identified and managed, as well as increase in efficiencies in downstream supply chain functions. Product master data includes trade item identifiers and all their fixed descriptive attributes such brand name, unit of measure, net content, shelf life as well as operational data such as batch and expiry information.

This approach is aligned with GHSC-PSM's HSS Global Standards and Traceability Implementation Roadmap as seen in Figure 1.

Figure 1. GHSC-PSM Illustrative Traceability Implementation Roadmap



This concept note outlines the current state of product information management in Zambia and the proposed approach in FY20-21 for implementing a standards-based system for managing product master data in Zambia.

Current State of Product Master Data Management

In order to implement a well-defined PMDM function supported by a PIM application in Zambia, a comprehensive people, process, and technology approach is required to maintain how production information is generated, maintained, stored (in a drug registry), accessed, and integrated with external systems such as e-LMIS and MSL WMS. The current state in Zambia is summarized from these three parameters:

	CURRENT STATE	OPPORTUNITY
PEOPLE	• Initial stakeholder buy-in for GS1 implementation in Zambia • MOH/ICT is currently the lead champion in development of a national drug registry	• Potential to centralize and formalize governance and management of product master data • Professionalize product data management with qualified technical resources to oversee the product data lifecycle • Assess potential to partner with GS1 South Africa to advance initiative, including supporting identification and GDSN data exchange with local manufacturers
PROCESS	• Multiple sources of product information across different systems • Health care commodities are identified in nonstandard ways, with proprietary identification numbers reassigned at various points in the supply chain and housed • Current product master data requires routine manual reconciliation. • Current product master does not adhere to common nomenclature and supported classification and hierarchies	• Introduce concept of trade item • Review and align nomenclature and classification structures, classification or taxonomy • Introduce concept of packaging hierarchies • Establish SOPs for key functions including product introduction, product audits, etc. • Collect existing metadata sources and product data. This may include old forms, commodity lists, administrative hierarchies (SKU), data dictionaries and other existing data element sources. • Develop data specification document describing the master product list data elements or the information to be managed in the drug registry. • Develop a data dictionary where the contents and format of data elements in the system are documented.
TECHNOLOGY	• SMART Zambia mandate is in place to support implementation of a broader e-health strategy, including drug registry implementation • A number of disparate information management systems (e.g. eLMIS, WMS, DHIS2) manage their own product master data repositories • No real time data exchange between public health supply chain systems.	• Landscaping of existing product information ecosystem • Support GS1 identify, capture, and share standards • Support adoption of standards for integration and interoperability • Implement a single source of truth for product master data; a product information management tool to serve as a national drug registry to be integrated with key information systems in the health sector • Establish APIs to facilitate the automated transmission of data and where feasible incorporate code into key public health supply chain systems such as WMS to consume the API. • Enable data exchange via the GS1 Global Data Synchronization Network (GDSN) to increase proportion of data being supplied directly from manufacturer

Approach

In support of the *Zambia National Pharmaceutical Traceability Strategy*, GHSC-PSM, with support from USAID, will support the Government of the Republic of Zambia in implementing a rigorous product master data management program enabled by a PIM application implemented by to serve as the national drug registry. This activity will seek to support implementation of the first road markers(i.e. Trade Item) Master Data Management) as a foundational step in adopting GS1 standards as foundation for improved supply chain data visibility and pharmaceutical traceability. The approach will focus on putting in place a governance framework for product master data management focused on enabling use of GS1 automatic identification and data capture (AIDC) standards; Product Master Data mapping and alignment through the adoption of a common nomenclature for product information; barcode scanning capture of product information; and, gathering requirements for a national drug registry and its integration with other systems such as Xpert WMS, eLMIS, SMARTCare and DHIS2.

Illustrative Timeline

Timeline subject to change based on workplan and funding approvals

Key Activity	Description	FY2020												FY2021				
		Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb
Product Master Requirements	Define trade item identification strategy, governance and PIM system requirements																	
MD Program Design and Development	Develop implementation plan																	
	Collect and harmonize product master data																	
	Develop governance framework, data management process flows, and SOPs																	
PIM System Design and Configuration	Validation of attributes against GS1 standards and data quality checks																	
	Develop overall PIM system architecture and technical design																	
	Data mapping and configurations/design for the PIM system																	
	Configure PIM																	
Alignment to in-country systems and GDSN	Develop roadmap for PIM system integration with in-country public health supply chain systems																	
	Develop roadmap for PIM system integration with GDSN other in-country systems as informed by the data mapping exercise																	
System deployment	Perform initial load of harmonized product master data																	
	Prepare training material and train PIM system users																	
	PIM Go-Live																	
PIM Integration with GDSN and in-Country System	Develop strategy and implementation plan for PIM system integration with in-country public health supply chain systems and with GDSN																	