REPUBLIC OF RWANDA

MINISTRY OF HEALTH

Rwanda National Vision & Strategy for Pharmaceutical Traceability Leveraging GS1 Global Standards

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ACRONYMS

AMR	Antimicrobial resistance
ASN	Advanced ship notice
BUFMAR	Bureau des Formations Médicales Agrées du Rwanda
CBV	Core Business Vocabulary
CDC	United States Center for Disease Control
CHAI	Clinton Health Access Initiative
DP	District Pharmacy
EAC	East African Community
EDI	Electronic Data Interchange
EPCIS	Electronic Product Code Information Services
GDSN	GS1 Global Data Synchronization Network™
GHSC	Global Health Supply Chain Program
GLN	Global Location Number
GOR	Government of Rwanda
GTIN	Global Trade Item Number
KPI	Key Performance Indicator
MOH	Ministry of Health
MPPD	Medical Procurement and Production Division
MSH	Management Sciences for Health
NPP	National Pharmacy Policy
NPSSP	National Pharmaceutical Sector Strategic Plan
PO	Purchase Order

PRIMS	Pharmaceutical Regulatory Information Management System
PSF	Private Sector Federation
PSM	Procurement and Supply Management
QA	Quality Assurance
RBC	Rwanda Biomedical Center
RFDA	Rwanda Food and Drug Authority
RFID	Radio frequency identification device
RH	Referral Hospital
RISA	Rwanda Information Society Authority
RNP	Rwanda National Police
RSSB	Rwanda Social Security Board
SF	Substandard or Falsified
SOP	Standard Operating Procedure
SSCC	Serial Shipping Container Code
TWG	Technical Working Group
UNFPA	United Nations Population Fund
USAID	United States Agency for International Development
WHO	World Health Organization

FOREWORD

The Government of Rwanda with the support and collaboration from the development partners is implementing strategies that ensure the availability of quality health commodities to support the implementation of various public health programs and to improve the health status of the population and the socio-economic development of the country.

However, the safety, quality and efficacy of health commodities is a global challenge that is also affecting our country. As a result, there is a tremendous surge in demand by healthcare providers to control and exchange information regarding medical products quality and traceability within the supply chain. In response, many institutions and healthcare facilities are developing different solutions without common basic principles and globally accepted standards that enables them to track and trace product delivery from the source to the patient and back through the supply chain.

The utilization of many systems lacking of a coordinated approach makes the supply chain system inefficient and data collected inaccurate; this incurs cost and confusion in the healthcare business, threatening quality of care and patient safety. In a time where the country wants to achieve more for less, there is a need for the development of global standards which provide simplicity and consistency by enabling the identification of business items and communication of data about these items in ways that can be used in any industry, in any country and with any trading partner.

This document entitled "Rwanda National Vision and strategy for pharmaceutical traceability " is presenting priority orientations that will guide the development of a comprehensive operational plan which is going to help Rwanda to be among the top african countries that implement the full traceability of the health commodities.

The Ministry of Health would like to appreciate and thank all development partners and individuals who have been involved in the preparation of this valuable document.

Dr. Diane GASHUMBA
Minister of Health

EXECUTIVE SUMMARY

This Pharmaceutical Traceability Strategy was developed in support of the goals of The National Pharmaceutical Sector Strategic Plan (NPSSP) 2018 – 2024, which outlines strategic objectives for the pharmaceutical sector. Two of the NPSSP objectives are to "build and enforce a Quality Assurance system to ensure safety, effectiveness and efficacy of health commodities and technologies from manufacturers to consumers" as well as "strengthen the national health commodities and technologies supply system in order to ensure regular supply of essential Health commodities and technologies at all times in sufficient quantities to all health facilities".

In support of these NPSSP goals, in June 2018, the Rwanda Ministry of Health (MOH) hosted a collaborative workshop to launch the pharmaceutical traceability initiative. The workshop was attended by government and private sector stakeholders involved in the pharmaceutical sector in Rwanda. This multi-disciplinary team established the vision, objectives, and activities for implementing pharmaceutical traceability in Rwanda through the use of global standards.

The implementation of pharmaceutical traceability policies, processes, and systems aims to create an environment that:

- Decreases the presence of substandard and falsified (SF) medications
- Ensures the quality and desired efficacy of pharmaceuticals
- Promotes trust in the pharmaceutical sector and healthcare system
- Provides visibility of product status across the supply chain
- Creates supply chain efficiencies from manufacturers to patient receipt
- Increases patient safety

To achieve these outcomes, Rwanda will collaborate across government agencies and the private sector to carry out the following strategic objectives.

- Objective 1: Establish a governance structure to lead the strategy, collaboration, outreach, and oversight of traceability implementation
- Objective 2: Strengthen the regulatory environment to include policies that enable traceability
- Objective 3: Create efficiencies in the public health supply chain through automated data capture and reporting
- Objective 4: Build and sustain technology to support implementation of traceability and interoperability of health systems for increased data visibility

This document introduces traceability and global standards, outlines the vision established during the pharmaceutical traceability workshop, and defines the 20 key activities that were identified to support Rwanda's vision for pharmaceutical traceability implementation and the use of global standards.

INTRODUCTION

The Government of Rwanda (GOR), through the MOH, has underwritten its commitment to ensuring access to quality, affordable and sufficient medicines to its population through the development of key policy and strategic documents to guide the national pharmacy sector. The vision of the Health Sector is:

To pursue an integrated and community-driven development process through the provision of equitable, accessible, and quality health care services.

In 2016, the government published the National Pharmacy Policy (NPP) to address challenges in the pharmaceutical sector. The plan includes a series of strategic initiatives such as establishing the Rwanda Food and Drug Authority (RFDA), incentivizing and enabling local manufacturing of pharmaceuticals, regulating pricing for health commodities, and increasing use of technologies in the private sector. The vision for the Pharmacy Sector from the NPP is:

Rwandan population's health is improved through sustainable provision and rational use of equitably accessible and affordable essential quality health commodities and technologies.

The NPSSP 2018 – 2024 details the strategic objectives and interventions for the sector in the coming 7 years. Through this current NPSSP, the MOH aims to consolidate and harmonize all strategic plans for the pharmaceutical sector and align all strategies with the policy and strategic objectives of the NPP. The NPSSP outlines priority issues to be addressed in the areas of policy, legislation and governance, regulation and quality assurance (QA), rational medicines use and pharmacovigilance, supply chain, antimicrobial resistance (AMR), access to pharmaceutical products and health technologies, public private partnership, human resources and pharmaceutical information systems.

Despite these efforts, including establishment of registration and QA requirements for suppliers and importers, the occurrence of substandard or falsified (SF) products in private and public-sector markets is still a risk. Thus, Strategic Objective 21 of the NPSSP seeks to address the following issues:

- Establish overarching process(es) to ensure that any quality failures are detected, and systematically shared with central authority and addressed.
- Address poor compliance with pharmacy code of ethics policy especially in private pharmacies in districts, operating without presence of pharmacist and dispensing prescription-only medicines without prescriptions.
- Build capacity to track and trace health commodities from manufacturers, storage locations down to end users. This impacts the recall process as well as monitoring quality compliance in ensuring quality products flow through the supply system.

[1] NPS SP Page 20

- Regularly collect data and develop key performance indicators (KPIs) for monitoring adherence to medicine quality standard operating procedures (SOPs).
- Enforce ethical advertising procedures for all products regulated by Rwanda FDA.
- Availability of pharmaceutical products and health technologies in private health facilities not meeting acceptable packaging.[2]

THE LAUNCH OF THE PHARMACEUTICAL TRACEABILITY INITIATIVE IN RWANDA

In support of these goals, in June 2018, the MOH, with the support of the United States Agency for Intentional Development (USAID) Global Health Supply Chain – Procurement and Supply Management (GHSC-PSM) Project, hosted a workshop to launch the pharmaceutical traceability initiative. The event was attended by a range of stakeholders, including:

- MOH, General Directorate of Clinical and Public Health Services
- MOH, Directorate of Clinical and Public Health Services, Health Policies and Regulation Unit
- MOH, General Directorate of Planning, Health Financing and Information Systems
- Rwanda Biomedical Center (RBC)
- Medical Procurement and Production Division (MPPD)
- Rwanda Social Security Board (RSSB)
- Rwanda Information Society Authority (RISA)
- Rwanda National Police (RNP)
- Private Sector Federation (PSF)
- Referral Hospitals (RHs)
- Bureau des Formations Médicales Agrées du Rwanda (BUFMAR)
- District Pharmacies (DPs)
- USAID
- United Nations Population Fund (UNFPA)
- Management Sciences for Health (MSH)
- Clinton Health Access Initiative (CHAI)
- World Health Organization (WHO)
- United Stated Center for Disease Control (CDC)
- GS1 Kenya

The workshop was intended to build education and awareness among stakeholders on the benefits of traceability and the existing global standards used in the healthcare industry to enable traceability across the supply chain, in the context of supporting integration of the operational, tactical and strategic functions of supply chain through improved interoperability and ultimately, end-to-end visibility. Through a collaborative process, the group worked to establish the vision for

[2] NPSSP page 21

pharmaceutical traceability in Rwanda leveraging GS1 global standards and through a process of assessing the current state and identifying gaps, defined a roadmap for implementation, focusing on key activities required over the next 3-6 months . This document summarizes the output of those activities and is intended to be a starting point to drive implementation across the health sector, recognizing that it will be a "living document" that is updated over time as the long-term objectives and requirements become more defined.

BACKGROUND

Traceability enables visibility into the movement of prescription drugs or medical devices across the supply chain. You can **trace backwards** to identify the history of the transfers and locations of a product, from the point of manufacture onwards. And you can **track forwards** to see the intended route of the product towards the point of care.[3] Traceability can support many healthcare objectives, including to :

- Address substandard, falsified or stolen product detected in the legitimate supply chain
- Address substandard, falsified or stolen product that is obtained by the patient / end user
- Address theft or diversion of products from the legitimate supply chain
- Improve accuracy and efficiency of procurement operations
- Improve efficiency of inventory management and distribution
- Improve efficiency of "reverse" logistics processes (e.g. those used for returns, recalls)
- Improve visibility of product "status" (e.g. expired or about to expire product, previously recalled product)
- Improve efficiency of payment and payment monitoring processes
- Improve pharmacovigilance and control of outcome of treatments
- Enable visibility of where the product is within the supply chain
- Enable visibility to decrease or eliminate reimbursement fraud
- Enable harmonized trade/customs clearance procedures for pharmaceutical products

TRACEABILITY MODELS

Fundamental to any traceability model is that in parallel with the flow of product, there has to be a flow of data about that product. A traceability system maintains the flow of data about the product, including the master, transaction, and event information related to an item in the supply chain. However, the design and scope of any given traceability system implementation is dependent on the specific context and what that country seeks to achieve. Traceability systems generally take on one of the three models – verification, track and trace, or both.

[3] https://www.gs1.org/traceability -healthcare

A verification model refers to checking at a single point in the supply chain that the identification data held in the barcode is assigned by the manufacturer of the product. Countries that implement this model must clearly identify whether the scope of verification is point of dispense (e.g. check at hospital, retail, or pharmacy) or end consumer / point of use (e.g. check by the patient).

A track and trace model refers to capturing data from trading partners as the product moves through the supply chain, from the manufacturer to the end user. Countries that implement this model must clearly identify whether the scope of track and trace is chain-of-ownership (e.g. reporting by entities that currently have / have had legal title to the product) or chain-of-custody (e.g. reporting by entities that currently have / have had physical possession of the product). Integral to track and trace is the availability of master, transaction, and event data associated with the product at each point of the supply chain in scope.

While many countries implement a single traceability system, there are instances of countries who implement both in a phased approach. Because verification is technically more straightforward, countries can consider implementing this approach in the initial phase and building out additional track and trace capabilities at various points in the supply chain over a longer period of time.

In addition to the traceability model, countries need to identify which IT infrastructure model[4] will be implemented to support the established reporting requirements. In general, there are three models to be considered:

- *Centralized:* All event data from all supply chain parties is stored in one central repository. The repository will manage the data authentication between a user and/or a system, the authorization of the user or system and the access control for the user or system, for all supply chain parties. All event-storing and event-retrieving is managed by a separate service of the central repository. This model is being implemented in Turkey, Argentina, and China.
- *Semi-centralized:* All event data for a given item and its instances is stored in one repository. The repository will be populated with data from the item owner, who is commonly the brand owner/manufacturer. Only events and event data identified to be important for other supply chain partners are stored in the repository. Each supply chain party may operate their own repository, which may contain data about more events as well as more data about a shared event. This model is being implemented in the European Union.
- *Distributed:* The event data is stored by each data owner of the event data in its own repository. The data owner then decides which event data they want to share with other parties. The data owner will then make information available for other supply chain parties.

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[4]For more information on the various traceability models, please see the APEC Track and Trace Systems Workshop materials, part of the APEC Supply Chain Security Toolkit: http://www.ni fds.go.kr/apec/SupplyChain/A PEC_SupplyChainToolkit_170317.pdf

The data owner will also be able to control which supply chain party can see what data, putting the data owner in control of the data. This model is being implemented in the United States.

Each model comes with its own benefits and limitations that are often based on the structure of the national supply chain and role of different partners in trading health commodities and delivering health services. These IT infrastructure models need to be considered in context and evaluated based on traceability goals and feasibility of implementation.

THE ROLE OF GLOBAL STANDARDS IN TRACEABILITY

While the traceability models may differ, the foundation for all traceability implementation is adopting a common business language – a global standard – that can be used by all trading partners, from manufacturer to dispenser, to identify, capture, and share information about pharmaceuticals and their movement in the supply chain.

Identify

Products and locations must be globally uniquely identified. This includes assignment of a globally unique identification number for each trade item (i.e. a unique number by manufacturer, formulation, dose, pack size, etc.), logistic unit, and legal entity or location that will have custody or ownership of a product at some point in the supply chain. Note that unique product identification alone does not ensure an item is authentic, but it is a tool that paired with additional processes, security features, and data exchange can enable traceability and verification with the manufacturer.

Additional information can be included as a component of item identification. The global regulatory environment has largely aligned around including batch/lot, expiration date, and serial number as the necessary identification features required to secure the supply chain. A serial number is a numeric or alphanumeric code assigned to an individual instance of an item for its lifetime. The combination of the globally unique product identifier plus serial number uniquely identifies an individual item and can be used as needed to identify that item in supply chain transactions, supply chain communications, and internal systems.

Capture

Data capture refers to the methods of reading the data encoded into a data carrier and automatically entering that data directly into computerized systems without human involvement. This is generally done through the use of barcodes or other data capture technologies such as radio frequency identification devices (RFID). Identification keys unlock access to information held in computer files, including information about companies, locations, packages, products and price.[5]

Share

When items and locations are uniquely identified, information about these items and locations must be shared across the supply chain to enable traceability. There are three types of data that need to be shared, including master data, transaction data, and event data.

Master data is information that describes attributes or characteristics of an item, entity or location that is created by the owner of that item or entity (e.g. shelf-life, dimensions, weights, quantity). Master data is required by item recipients to perform basic operational processes, but also to make strategic decisions across the supply chain, from marketing authorization and strategic sourcing to service delivery. Thus, access to consistent, quality master data across the supply chain is necessary to enable traceability.

Transaction data is information about production, purchasing, selling, and other transactions that occur through the supply chain (e.g. units sold, stock on hand, stock on order, forecasted units).

Event data is information about the physical movement and status of products as they move through the supply chain (e.g. commissioning, shipping, receiving, picking, packing, decommissioning). Each event in an item's lifecycle has four main dimensions:

- What physical objects were involved (e.g. serialized product identifier in a data carrier)?
- When did the event take place (e.g. timestamp)?
- Where did the event take place (e.g. location identifier)?
- Why did the event take place? What business process step was being carried out (e.g. receiving, shipping)?

THE GS1 SYSTEM OF STANDARDS

GS1 is a not-for-profit organization that develops and maintains global standards for business communication. The best known of these standards is the barcode, a symbol printed on products that can be scanned electronically. GS1 barcodes are scanned more than six billion times every day – largely in the retail sector – and used by more than 1.5 million companies globally.

In 2005, GS1 Healthcare was formally launched, with a vision to be the recognized, open and neutral source for regulatory agencies, trade organizations and other similar stakeholders seeking input and direction for global standards in healthcare for patient safety, supply chain security and efficiency, traceability, and product data. The GS1 standards for healthcare are developed in consultation with members of GS1, including manufacturers, logistics companies, solution providers, and hospital networks.

The benefit of working with GS1 standards in the healthcare sector is that the standards are developed to address the healthcare supply chain holistically, to be across all trading partner

functions, to identify, capture, and share relevant product information. This section details the specific standards that are commonly used in healthcare.[6]

Identify

GS1 Global Trade Item Number (GTIN). The GTIN is the GS1 standards-based, globally unique identifier for "trade items" (i.e., products that may be priced, ordered or invoiced). The GTIN enables supply chain partners to use the same standards-based identifier to identify products in a standardized data format in all supply chain transactions, supply chain communications, and internal systems. Because they are standardized, GTINs can be encoded in barcodes to identify products as they move through the supply chain and be read and interpreted in the same way by all trading partners. Additional information like batch/lot number, expiration date, and serial number can also be encoded along with the GTIN.[7]

Serial Number. A serial number is a numeric or alphanumeric code assigned to an individual instance of an entity for its lifetime. Using GS1 standards, the combination of a GTIN plus serial number uniquely identifies an individual item and can be used as needed in supply chain transactions, supply chain communications, and internal systems. For example, if hypothetical GTIN 00361414567894 is assigned to identify a 100-count bottle of XYZ tablets, then the combination of GTIN 00361414567894 plus a serial number would identify a specific 100-count bottle of XYZ tablets. All bottles of XYZ tablets would have the same GTIN, but each bottle would be assigned a unique serial number.8

Serial Shipping Container Code (SSCC). The SSCC is the GS1 standards-based, identifier for "logistics units" (i.e., any combination of trade items packaged together for storage and/or transport purposes). The SSCC enables supply chain partners to track individual logistics units (e.g. pallets or cases) for efficient order and transport management in a standardized data format. The SSCC also enables companies to link information about a logistics unit between the physical package and its contents (i.e. GTINs and serial numbers) and the associated transaction documents (i.e. purchase order (PO), packing list, advanced ship notice (ASN), commercial invoice, etc.).9

GS1 Global Location Number (GLN). The GLN is the GS1 standards-based, globally unique identifier for supply chain parties and locations. The GLN enables supply chain partners to use the

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[6] For a complete list of standards and the technical specifications for implementation, please refer to the GS1 General Specification: https://www.gs1.org/docs/barcodes/GS1_General_Specifications.pdf

[7] GS1 US (September 2017). An Introduction to Global Trade Item Number (GTIN).

[8] GS1 US (2016). Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability.

[9] GS1 US (2017). (SSCC).

same standards-based identifier to identify parties and locations in a standardized data format. Supply chain partners can use GLNs to identify parties and locations in all supply chain transactions, supply chain communications, and internal systems.10

Capture

GS1 128 Linear Barcode. A GS1 128 barcode is linear barcode symbology using bars and spaces in one dimension. A linear barcode can be concatenated (i.e., represent all elements of a data string in a single barcode) or non-concatenated (i.e., represent individual elements of a data string over two or more barcodes).

GS1 DataMatrix. A GS1 DataMatrix is a two-dimensional matrix symbology that is made up of square modules arranged within a perimeter finder pattern. DataMatrix symbols are read by two-dimensional imaging scanners or vision systems.

RFID. RFID uses electromagnetic fields to automatically identify and track tags attached to objects. The tags contain electronically-stored information. Unlike a barcode, the tag need not be within the line of sight of the reader, so it may be embedded in the tracked object. In healthcare, RFID is not used as a standalone method for data capture but can be used in combination with the barcode for various functions in the supply chain.

Share

GS1 Global Data Synchronization Network™ (GDSN). The GDSN® is the GS1 standard for master data exchange. The GDSN enables organizations to establish one, authoritative source of product information from which all systems in the organization can pull. In addition, the GDSN provides a highly efficient automated process for ensuring that the information in that central source is reliable, accurate, properly formatted, and up-to-date. With the GDSN, organizations can establish a "single source of truth" or all product information to feed all of their systems with the same reliable information used by all of their suppliers and supply chain partners.[11]

Electronic data interchange (EDI). EDI is the GS1 standard for transaction data exchange. GS1 EDI provides global standards for electronic business messaging that allow automation of business transactions commonly occurring across the entire supply chain. It covers order and delivery and financial settlement management, as well as transport and warehouse management. The main business partners in scope for this are retailers, manufacturers, material suppliers and logistic service providers.[12]

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[10] GS1 US (September 2017). An Introduction to the Global Location Number (GLN).

[11] GS1 US (March 2012). GS1 US Healthcare Supplier Toolkit: Global Data Synchronization Network™ (GDSN®).

[12] https://www.gs1.org/standards/edi

Electronic Product Code Information Services (EPCIS) and Core Business Vocabulary (CBV). EPCIS and CBV are the GS1 standards for event data exchange. EPCIS is a GS1 standard that enables trading partners to share information about the physical movement and status of products as they travel throughout the supply chain – from business to business and ultimately to consumers. It helps answer the "what, where, when and why" questions to meet consumer and regulatory demands for accurate and detailed product information. The goal of EPCIS is to enable disparate applications to create and share visibility event data, both within and across enterprises. This sharing is aimed at enabling users to gain a shared view of physical or digital objects within a relevant business context. EPCIS is intended to be used in conjunction with the GS1 CBV, which provides definitions of data values that may be used to populate the data structures defined in the EPCIS standard. The use of the standardized vocabulary provided by the CBV standard is critical to interoperability and critical for querying of data by reducing the variation in how different businesses express common intent.[13]

TRACEABILITY VISION

The Rwanda NPSSP outlines interventions to increase and ensure access to quality and affordable pharmaceutical products and health technologies in Rwanda. This includes building and enforcing a quality assurance system that ensures safety, effectiveness and efficacy of health commodities and technologies from manufacturers to consumers.

To meet this objective, Rwanda seeks to implement pharmaceutical traceability that is supported by the use of GS1 global standards. The implementation of pharmaceutical traceability policies, processes, and systems will create an environment that:

- Decreases the presence of SF medications
- Ensures the quality and desired efficacy of pharmaceuticals
- Promotes trust in the pharmaceutical sector and healthcare system
- Provides visibility of product status across the supply chain
- Creates supply chain efficiencies from manufacturers to patient receipt
- Increases patient safety

Achieving these outcomes requires an environment that includes proper processes, execution, and oversight. Rwanda will collaborate across government agencies and the private sector to meet the following strategic objectives:

Objective 1: Establish a governance structure to lead the strategy, collaboration, outreach, and oversight of traceability implementation

Objective 2: Strengthen the regulatory environment to include policies that enable traceability

[13] https://www.gs1.org/standards/epcis

Objective 3: Create efficiencies in the public health supply chain through automated data capture and reporting

Objective 4: Build and sustain technology to support implementation of traceability and interoperability of health systems for increased data visibility

Successfully achieving these strategic objectives requires strong leadership, supporting resources, and accountability in executing supporting activities to implement of traceability in Rwanda.

STRATEGIC INITIATIVES

Ministry of Health and its stakeholders identified an immediate need to put in place controls to address the risk of SF medicines in the supply chain, while developing capabilities for greater supply chain data visibility over time. As a result, there is a strong interest in pursuing a phased approach to traceability implementation, starting with verification of medicines to secure the supply chain and implementing full track and trace capabilities over a longer period of time. In the near term, the traceability model and IT infrastructure will need to be defined with greater specificity, weighing the risks and benefits of various approaches as they related to the needs of Rwanda's health sector.

This section outlines the supporting activities that Rwanda will need to undertake to specify their traceability model and begin to implement traceability in the public health supply chain. These activities are put in place to support the strategic objectives set forth to carry out the vision for pharmaceutical traceability in Rwanda. To achieve the desired outcomes, collaboration must exist across stakeholders to establish strong governance and partnerships, create policies and regulations that support traceability, and enhance supply chain operations, data, and systems that support reaching full traceability across the public health supply chain.

Objective 1: Establish a governance structure to lead the strategy, collaboration, outreach, and oversight of traceability implementation

Establishing strong organization and governance will provide the framework for implementation across the health sector. The collaboration between government agencies and private sector health partners will align the needs of different stakeholders to reach a shared vision and commitment to implementing traceability in Rwanda. This governance structure will provide the overall direction and guidance for achieving the traceability outcomes. These activities will define the governance structure, roles and relationships between the various stakeholders responsible for traceability implementation. The proposed owner for this objective is the MOH

Activity 1.1: *Endorse Rwanda Pharmaceutical Traceability Strategy*

The Ministry of Health and its stakeholders will review the *Rwanda Pharmaceutical Traceability Strategy* document to provide feedback and submit to the Ministry of Health for endorsement. This activity will mark the formal launch of all subsequent activities identified and detailed in the remainder of the document.

Activity 1.2: *Identify sponsor and establish governance framework*

An executive sponsor will be identified for the traceability implementation. A collaborative team of stakeholders across public and private sector organizations will be created and will establish a governance framework to provide strategic direction, decision-making authority, and oversight of implementation activities to achieve Rwanda's vision for traceability and global standards. If necessary, any new committees or technical working groups (TWGs) should be established to oversee traceability implementation, or existing TWGs will modify their terms of reference to include traceability in their mandate.

Activity 1.3: *Engage strategic implementation partners and define stakeholder roles and responsibilities*

Implementation of traceability will rely on shared responsibility and input from public and private institutions. Partners may include other government entities, educational institutions, international organizations, and private companies such as manufacturers, solutions providers, and trade associations. Implementation requires defining the role and responsibilities of each of these stakeholders in achieving the vision for traceability. The responsibility of each organization will align with carrying out the traceability implementation and governance framework.

Activity 1.4: *Review other countries' traceability implementations*

Globally, countries have approached traceability implementations differently, with different objectives and timing of outcomes. Each country serves as an example approach to traceability implementation using global standards and can be further examined to inform Rwanda's own approach. The implementation plan and lessons-learned for feasible alternatives will be evaluated and used as possible input for creating Rwanda's phased-implementation plan.

Activity 1.5: *Establish specifications for Rwanda's traceability model*

This workshop built consensus on the need for global standards in the health sector and the vision for pharmaceutical traceability. A sub-group of stakeholders will develop further technical expertise on the various considerations described in the Background section of this document to determine the most appropriate traceability and IT infrastructure models for Rwanda's public health environment. The proposed model will be detailed and distributed among stakeholders to build consensus around feasibility and impact towards achieving the traceability vision for the health sector.

Activity 1.6: *Develop detailed implementation plan*

The plan for implementing the traceability model will be clearly defined with phased outcomes over a period of time (5-10 years) until the full vision is achieved. The requirements will be shared with stakeholders for input and feedback to ensure they are achievable by internal and external trading partners. This phased approach, to include scalable pilots, will allow Rwanda to recognize value of using global standards as the traceability implementation progresses and adjust through iterative implementation to ensure that the strategy and approach continues to align with achieving the vision.

Activity 1.7: *Conduct situational analysis, develop risk framework, and create a monitoring plan*

A situational analysis should be conducted to assess strengths, weaknesses, opportunities, and threats to the successful implementation of the plan. Any implementation will face risks and a framework will identify the critical path to success, provide a structure for monitoring progress against timeline, and establish an approach for capturing and mitigating risks.

Activity 1.8: *Assess financial needs, prepare budget, and identify resources*

Once the traceability model and implementation plan is developed, an evaluation will assess the costs of the proposed implementation approaches, timelines, and technology requirements. A plan will be created to identify resource needs, develop a budget, advocate for funding, and secure funding for the duration of the implementation timeline.

Activity 1.9: *Provide ongoing education and support capacity building in global standards*

A communication plan and supporting training material will be created to ensure ongoing outreach to identified stakeholders. Education, knowledge building, and communication is a continuous activity to be carried out to create awareness and ensure stakeholders are engaged and informed of the latest developments throughout implementation.

Objective 2: Strengthen the regulatory environment to include policies that enable traceability

A strong regulatory framework will provide the basis to define and enforce requirements for traceability across the supply chain. These activities establish the regulations that supply chain trading partners will need to adhere to for product and location identification, data capture, and data sharing to enable the implementation of Rwanda's traceability vision. The proposed owner for this objective is the Rwanda FDA .

Activity 2.1: *Assess existing supplier compliance to standards*

A review of the local, regional, and global organizations supplying pharmaceuticals to Rwanda will help to identify current capabilities for using standardized item and local identification. A gap analysis will be conducted to understand manufacturers' capabilities against minimum requirements and describe the needs of the industry to comply with regulatory requirements. An intention will be issued to manufacturers to understand current capabilities, request feedback on Rwanda's implementation, and solicit feedback on requirements and timelines to inform policy development.

Activity 2.2: *Promote regional harmonization*

Given the open trade policy in the East African Community (EAC), promoting pharmaceutical traceability implementation across the region is beneficial in order to achieve Rwanda's goals. Rwanda will collaborate with other regulatory authorities in the EAC to understand current state of traceability initiatives, use of global standards, and common objectives upon which the community can work to achieve together through harmonized policy and systems implementations (e.g. Pharmaceutical Regulatory Information Management System (PRIMS)). Analysis will be done in collaboration with regional partners to understand legal frameworks and requirements to be established to carry out traceability implementation across the EAC.

Activity 2.3: *Develop regulations to support traceability implementation*

An assessment will be conducted to understand current regulations and guidelines for product labeling leveraging GS1 global standards for identification and data capture. Based on this assessment, required actions will be outlined to revise or create new regulations that support the traceability implementation. New regulatory guidelines will need to be prepared, and/or existing guidelines will need to be revised, in order to outline requirements for traceability implementation. This will include regulations for product identification and labeling; submission of master, transaction, and event data; and the responsibilities of different trading partner roles across the supply chain.

Activity 2.4: *Establish mechanisms for enforcing regulations*

Once regulations are established, the regulatory body will need to outline how to monitor and enforce the requirements as defined.

Objective 3: Create efficiencies in the public health supply chain through automated data capture and reporting

Public and private supply chain partners need to develop additional capabilities to gain the benefits of automation through barcode scanning and to implement traceability. These activities will provide guidance and processes for implementation across supply chain operations including procurement, importation, warehousing, inventory management, and distribution. The proposed owner for this objective is MOH.

Activity 3.1: *Assess readiness for global standards implementation across supply chain operations*
It is important to understand the capabilities of different supply chain partners and their ability to implement GS1 requirements. This will assess current state of procurement, warehousing, and distribution requirements related to use of GS1 standards, including GTINs and barcode technology, and identify gaps in these processes that need to be addressed in implementation.

Activity 3.2: *Conduct an audit of existing products in Rwanda market for adherence to GS1 standards*

An audit of existing products in the supply chain will support a better understanding of the current state of GS1 adoption by suppliers to identify and label products on the Rwanda market, determine gaps that exist with the current supply base to meet requirements, and support prioritization of products and supplier outreach to address at risk product categories.

Activity 3.3: *Implement barcode scanning in public sector warehouses*

A gap analysis will be conducted to understand the current capabilities for barcode use for warehouse operations (e.g. receiving, picking, packing, shipping) and inventory management to create a plan for barcode implementation in public sector warehouses in the near-term.

Objective 4: Build and sustain technology to support implementation of traceability and interoperability of health systems for increased data visibility

Rwanda's traceability vision is supported by the implementation of standardized data and interoperable systems for traceability of pharmaceuticals throughout the supply chain.
These activities will define the scope and requirements for information systems to implement the chosen traceability model(s), including supply chain systems requirements, data flows, and architectures to support implementation across all trading partners (e.g. public, private) in scope. The proposed owner of this objective is the MOH.

Activity 4.1: *Conduct traceability technology needs assessment*

The needs assessment will assess the current e-Health architecture in Rwanda to determine opportunities to leverage existing systems to support traceability and determine any gaps that need to be addressed. A report will be developed to detail recommendations based on current capabilities, identify areas for increased interoperability, and recommend requirements for a

future-state architecture to support traceability implementation. The technology will need to support global standards for item identification, data capture, and data sharing for master, transaction, and event data, and be accessible by all trading partners in scope for traceability implementation.

Activity 4.2: *Define systems architecture*

Once the technical requirements are defined, an architecture will be created for data exchange and interoperability of health systems. This will define the system roles in collection, managing and sharing of data as well as application use to meet the traceability objectives.

Activity 4.3: *Develop national product registry for product master data*

To improve interoperability among systems and progress towards standardized product master data, a national product registry will be developed to create a single source of all product master data across Rwanda's health information systems. An assessment will be conducted to determine which existing systems can be leveraged to collect, manage, and maintain this data and a data governance mechanism will be developed to support this function.

Activity 4.4: *Develop and sustain traceability infrastructure*

The technology to support the traceability implementation and objectives will be designed and developed. Activities will need to take place in order to build the technical infrastructure and support strategic priorities for traceability aligning with the phased implementation approach.

ROADMAP

The roadmap is a time-phased focus on the supporting activities that Rwanda will undertake to achieve traceability objectives.

Objectives and Activities	Timeframe			Owner
	May-July19	Aug.-Oct.19	Nov. 19-Jan.20	
OBJECTIVE 1: ESTABLISH A GOVERNANCE STRUCTURE TO LEAD THE STRATEGY, COLLABORATION, OUTREACH, AND OVERSIGHT OF TRACEABILITY IMPLEMENTATION				
Activity 1.1: Endorse Rwanda Pharmaceutical Traceability Strategy	X			MOH
Activity 1.2: Identify sponsor and establish governance framework	X			MOH
Activity 1.3: Establish specifications for traceability model Develop the TORs for the TWG for traceability model and its implementation plan Conduct meeting (s) with stakeholders to discuss the establishments of TWG Validation of the TORs for the TWG for the traceability model and its implementation plan Develop a detailed implementation roadmap with cost of each intervention Develop communication and collaboration plan to support continuous education and capacity building in global standards		X		MOH

Activity 1.4: Develop detailed implementation plan Desk review Review other countries' traceability implementations- Establish specifications for traceability model Develop detailed implementation (operational) plan Distribute the proposed model to the stakeholders for validation Conduct a workshop for the validation of the strategic and operational (implementation) plan		X		
Activity 1.5: Conduct situational analysis, develop risk framework, and create a monitoring plan Develop a concept note and for the situation analysis including activities to be conducted such as workshops, face-to-face discussions, site visits and a questionnaire for different stakeholders Engage strategic implementation partners and define stakeholder roles and responsibilities Assess financial needs, prepare budget, and identify resources Assess existing supplier compliance to standards Promote regional harmonization (assess)		X		

Assess readiness for global standards implementation across supply chain operations Conduct an audit of existing products in Rwanda market for adherence to GS1 standards				
Activity 1.6: Provide ongoing education and support capacity building in global standards	X	X	X	
OBJECTIVE 2: STRENGTHEN THE REGULATORY ENVIRONMENT TO INCLUDE POLICIES THAT ENABLE TRACEABILITY				
Activity 2.1: Develop regulations to support traceability implementation	X			Rwanda FDA
Activity 2.2: Establish mechanisms for enforcing regulations	X			
OBJECTIVE 3: CREATE EFFICIENCIES IN THE PUBLIC HEALTH SUPPLY CHAIN THROUGH AUTOMATED DATA CAPTURE AND REPORTING				
Activity 3.1: Define the technical requirements for the traceability implementation			X	MOH
Activity 3.2: Create the architecture for data exchange and interoperability of health systems and define the system roles in collection, managing and sharing of data as well as application use to meet the traceability objectives			X	
ctivity 3.3: Develop technical expertise on the various considerations of the traceability			X	
Activity 3.4: Determine the most appropriate traceability and IT infrastructure models for Rwanda's public health environment.			X	
Activity 3.5: Implement barcode scanning in public sector warehouses			X	

OBJECTIVE 4: BUILD AND SUSTAIN TECHNOLOGY TO SUPPORT IMPLEMENTATION OF TRACEABILITY AND INTEROPERABILITY OF HEALTH SYSTEMS FOR INCREASED DATA VISIBILITY				
Activity 4.1: Conduct traceability technology needs assessment			X	MOH
Activity 4.2: Define systems architecture			X	
Activity 4.3: Develop national product registry for product master data Develop the SOW for Product Registry The current landscape around product master data management will be assessed and challenges will be identified that impact transactional processing across the supply chain and across various SC systems Master Data Management capabilities within e-LMIS/RTVN and other tools will be evaluated to determine options that can address the challenges Roadmap will be developed for effective management of product master data within Rwanda Identify the firm to develop and implement the National Product Registry	X			
Activity 4.4: Develop and sustain traceability infrastructure			X	