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FEDERAL MINISTRY OF HEALTH

NIGERIA NATIONAL PHARMACEUTICAL TRACEABILITY STRATEGY

MAY 2020

**FEDERAL
MINISTRY OF HEALTH**

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CONTENTS

ACRONYMS

3PL	Third-Party Logistics
ACPN	Association of Community Pharmacists of Nigeria
ADR	Adverse Drug Reporting
AHAPN	Association of Hospital and Administrative Pharmacists of Nigeria
APIN	Association of Pharmaceutical Importers of Nigeria
CBV	Core Business Vocabulary
DHPRS	Department of Health Planning, Research, and Statistics
EDI	Electronic Data Interchange
EPCIS	Electronic Product Code Information Services
FDS	Food and Drug Services
GDSN	GS1 Global Data Synchronisation Network™
GHSC	Global Health Supply Chain Program
GLN	Global Location Number
GTIN	Global Trade Item Number
HS	Harmonized Commodity Description and Coding System
IPMIN	Indian Pharmaceutical Manufactuers and Importers in Nigeria
IT	Information Technology
KPI	Key Performance Indicator
FMOH	Federal Ministry of Health
FGON	Federal Government of Nigeria
MAS	Mobile Authentication Service
M&E	Monitoring and Evaluation
MO	Member Organization
MOU	Memorandum of Understanding
NAFDAC	National Agency for Food and Drug Administration and Control
NCS	Nigeria Customs Service
NDDG	National Drug Distribution Guideline
NHIS	National Health Insurance Scheme
NIROPHARM	Nigeria Representation of Overseas Pharmaceutical Manufacturers
NITDA	National Information Technology Development Agency
NPC	National Product Catalogue

NPHCDA	National Primary Healthcare Development Agency
NSCIP	Nigeria Supply Chain Integration Project
NSHDP	National Strategic Health Development Plan
PCN	Pharmacists Council of Nigeria
PMGMAN	Pharmaceuticals Manufacturing Group of the Manufacturers Association of Nigeria
PPP	Public-Private Partnership
PSM	Procurement and Supply Management
PSN	Pharmaceutical Society of Nigeria
RFID	Radio Frequency Identification Device
SF	Substandard or Falsified Medical Products
SOP	Standard Operating Procedure
SON	Standards Organization of Nigeria
SSCC	Serial Shipping Container Code
TOR	Terms of Reference
TWG	Technical Working Group
USAID	United States Agency for International Development

Traceability Driving Committee to identify, assign, and drive the work required to develop an enabling environment for implementation of global standards to drive pharmaceutical traceability within the supply chains of the nation's health sector system. .

The Nigerian Government is committed to ensuring traceability and tracking of all commodities in circulation in the country and seeks the continued support of all stakeholders towards this.

Dr. E. Osagie Ehanire MD, FWACS
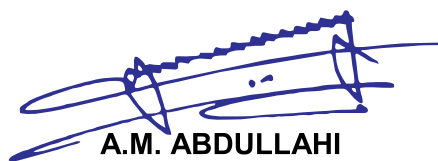Honourable Minister of Health

PREFACE

The Government of Nigeria, with the support and collaboration from our 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.

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 pharmaceuticals 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 enable them to track and trace pharmaceuticals delivery from the source to the patient and back through the supply chain.

The utilization of health commodity data across systems lack a coordinated approach, which results in data quality challenges that affect the efficiency of the supply chain; this incurs cost and confusion in the healthcare sector, 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 implementation of existing global standards which provide simplicity and consistency by enabling the identification of items and locations, automated data capture, and exchange 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 the *Nigeria National Pharmaceutical Traceability Strategy* presents our priority objectives that will guide the development of a comprehensive operational plan. This strategy is the first step in positioning Nigeria to be a leader in driving traceability of pharmaceuticals in Africa.

The Federal Ministry of Health would like to express sincere gratitude to USAID/GHSC-PSM, GS1 International, GS1 Nigeria, and other stakeholders including NAFDAC, PCN, other FMOH agencies and other development partners, who supported the preparation of this valuable document.

A.M. ABDULLAHI
Permanent Secretary
Federal Ministry of Health

FOREWORD

I am delighted to write the foreword to the maiden edition of the Nigeria National Pharmaceutical Traceability Strategy.

The Federal Government of Nigeria, is committed to ensuring sustainable access to quality, affordable medicines to its population through the development and implementation of key strategies and actions that guide the national health sector. The guiding principle being the central goal of the vision of the National Health Policy: "To strengthen Nigeria's health system, particularly the Primary Health Care subsystem, to deliver quality, effective, efficient, equitable, accessible, affordable, acceptable and comprehensive health care services to all Nigerians"

In line with two of the NSHDP II objectives to "improve availability and functionality of health infrastructure required to optimize service delivery at all levels" as well as "ensure that quality medicines, vaccines, and other health commodities and technologies are available, affordable and accessible to all Nigerians. There is need to use standards to support identification and verification of commodities dispensed to end-users at service delivery points in the public and private sectors. Healthcare is not complete and ideal without availability of good quality and affordable medicines and there is need for end to end product visibility within the supply chain pipeline.

This informed the hosting, in June 2019, of a collaborative workshop to launch the pharmaceutical traceability initiative by the Nigeria Federal Ministry of Health (FMOH) and with the support of the United States Agency for International Development (USAID). The workshop was attended by government, private sector, and development partner/stakeholders involved in the pharmaceutical sector in Nigeria. This multi-disciplinary team established the vision, strategy, and a roadmap for implementing pharmaceutical traceability in Nigeria through the use of global standards to create an environment that provides visibility of product status from plant to patient, promotes trust in the pharmaceutical sector and healthcare system, provides increased opportunity for trade of domestically manufactured pharmaceuticals, increases quality of data to support pharmacovigilance, decreases the presence of substandard and falsified (SF) medications, enables efficiency across the supply chain; and ultimately Increases patient safety.

This document describes the vision and strategy for Nigeria, inclusive of the perspective of stakeholders across the health sector, and represents a starting point to organize and operationalize the foundational work that needs to be undertaken to support a traceability implementation. It is intended for use by the Global Standards and Pharmaceutical

EXECUTIVE SUMMARY

This strategy was developed in support of the goals of the second National Strategic Health Development Plan (NSHDP II), which outlines strategic objectives for the pharmaceutical sector. Two of the NSHDP II objectives are to "improve availability and functionality of health infrastructure required to optimize service delivery at all levels" as well as "ensure that quality medicines, vaccines, and other health commodities and technologies are available, affordable and accessible to all Nigerians."

In support of these NSHDP II goals, in June 2019, the Nigeria Federal Ministry of Health (FMOH) and NAFDAC hosted a collaborative workshop to launch the pharmaceutical traceability initiative. The workshop was attended by government, private sector, and development partner stakeholders involved in the pharmaceutical sector in Nigeria. This multi-disciplinary team established the vision, strategy, and a roadmap for implementing pharmaceutical traceability in Nigeria through the use of global standards to create an environment that:

- Provides visibility of product status from plant to patient;
- Promotes trust in the pharmaceutical sector and healthcare system;
- Provides increased opportunity for trade of domestically manufactured pharmaceuticals;
- Increases quality of data to support pharmacovigilance;
- Decreases the presence of substandard and falsified (SF) medications;
- Enables efficiencies across the supply chain; and ultimately,
- Increases patient safety.

To achieve these outcomes, we will collaborate across health sector stakeholders to carry out the following strategic objectives.

- **Strategic Objective 1:** Establish a governance structure to lead the strategy, advocacy, collaboration, resource mobilization, and oversight of global standards and traceability implementation.
- **Strategic Objective 2:** Strengthen the regulatory environment to include legal frameworks that enable traceability of quality pharmaceuticals through the legitimate supply chain.

- **Strategic Objective 3:** Create efficiencies in the public and private health supply chains through standardized identification, automated data capture, and reporting.
- **Strategic Objective 4:** Build and sustain technology to support interoperability of health information systems and implementation of traceability to improve data visibility.
- **Strategic Objective 5:** Enable use of standards to support identification and authentication of commodities dispensed to end-users at service delivery points in the public and private sectors.

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

ACKNOWLEDGEMENT

The **NIGERIA NATIONAL PHARMACEUTICAL TRACEABILITY STRATEGY** is the outcome of dedicated efforts by some individuals and organisations.

Such organisations and individuals are greatly acknowledged, appreciated and listed below:

Honourable Minister of Health

The Permanent Secretary (FMOH)

Director, Department of Food and Drugs Services (FMOH)

Director General, NAFDAC

The Registrar (PCN)

National Agency for Food and Drug Administration and Control (NAFDAC)

Standard Organisation of Nigeria (SON)

Pharmacist's Council of Nigeria (PCN)

National Primary Healthcare Development Agency (NPHCDA)

Federal Ministry of Science and Technology

Nigeria Customs Services (NCS)

National Health Insurance Scheme (NHIS)

GS1 Standard, Nigeria

GS1 International

United States Agency for International Development (USAID)

Global Health Supply Chain-Product Supply Management (GHSC-PSM)

Africa Resource Centre for Supply

Chemonics International

The Global Fund (TGF)

National Product Supply Chain Management Programme (NPSCMP)

Pharmaceutical Society of Nigeria

Pharmaceutical Manufacturing Group of Manufacturing Association of Nigeria (PMG-MAN)

Indian Pharmaceutical Manufacturers and Importers in Nigeria (IPMIN)

Nigeria Representative of Overseas Manufacturers (NIROPHARM)

Association of Hospital and Administrative Pharmacists of Nigeria (AHAPIN)

Association of Community Pharmacists of Nigeria (ACPN)

Association of Pharmaceutical Importers of Nigeria (APIN)

Family Health International 360 (FHI 360)

Clinton Health Access Initiative (CHAI)

Association of Pharmaceutical Importers of Nigeria

National Information Technology Development Agency (NITDA)

Worldwide Commercial Ventures Limited (WWCVL)

Biovaccine Nigeria Limited

IQVIA Nigeria

MDS Logistics Limited

Sproxil

Pharma Science

Pharmaceutical Wholesales and Distribution Association of Nigeria.

INTRODUCTION

The Federal Government of Nigeria, through FMOH, is committed to ensuring sustainable access to quality, affordable medicines to its population through the development of key strategies and actions that guide the national health sector. These decisions are guided by the central goal of the vision of the National Health Policy:

> *"To strengthen Nigeria's health system, particularly the Primary Health Care subsystem, to deliver quality, effective, efficient, equitable, accessible, affordable, acceptable and comprehensive health care services to all Nigerians"*

The NSHDP II provides a roadmap for the health sector to move towards the accomplishment of the National Health Policy goals. It outlines the health sector priorities and actions that will continue the progress and strengthening of Nigeria's health sector. The mission for the NSHDP II is:

> *"To ensure that the Nigerian populace have universal access to comprehensive, appropriate, affordable, efficient, equitable and quality essential health care through a strengthened health care system"*

The NSHDP II outlines pillars, priority areas, goals, and objectives to accomplish this mission in support of the National Health Policy. This *National Pharmaceutical Traceability Strategy* supports this mission, specifically the priority of commitment to a strengthened health system *"including medicines, vaccines and other health technologies and supplies",* which includes goals:

> *"To improve availability and functionality of health infrastructure required to optimize service delivery at all levels and ensure equitable access to effective and responsive health services throughout the country"*

and

> *"To ensure that quality medicines, vaccines, and other health commodities and technologies are available, affordable and accessible to all Nigerians"*

This *National Pharmaceutical Traceability Strategy* directly supports these goals by providing a plan of action to leverage global standards to enable pharmaceutical traceability to support the commitment to strengthen the health system by optimizing delivery of health commodities and enabling access to safe, effective, and quality medicines.

THE LAUNCH OF THE PHARMACEUTICAL TRACEABILITY INITIATIVE IN NIGERIA

In support of these goals, in June 2019, the FMOH and NAFDAC, with the support of the United States Agency for International 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:

- FMOH, Food and Drug Services (FDS)
- FMOH, Department of Health Planning, Research, and Statistics (DHPRS)
- NAFDAC
- Association of Community Pharmacists of Nigeria (ACPN)
- Association of Hospital & Administrative Pharmacists of Nigeria (AHAPN)
- Association of Pharmaceutical Importers of Nigeria (APIN)
- Federal Ministry of Science and Technology
- GS1 Nigeria
- Indian Pharmaceutical Manufacturers and Importers in Nigeria (IPMIN)
- National Health Insurance Scheme (NHIS)
- National Information Technology Development Agency (NITDA)
- National Primary Healthcare Development Agency (NPHCDA)
- Nigeria Customs Services (NCS)
- Nigeria Representation of Overseas Pharmaceutical Manufacturers (NIROPHARM)
- Nigeria Supply Chain Integration Project (NSCIP)
- Pharmacists Council of Nigeria (PCN)
- Pharmaceutical Manufacturers Group of Nigeria (PMGMAN)
- Pharmaceutical Society of Nigeria (PSN)
- Standards Organization of Nigeria (SON)
- USAID

The workshop was intended to build education and 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 group worked collaboratively to establish the vision for pharmaceutical traceability in Nigeria leveraging GS1 global standards and, through a process of assessing the current state and identifying gaps, defined a roadmap for implementation that focuses on key activities required over the next 3-6 months (i.e. July – December 2019). 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.

SCOPE

This document describes the vision and strategy for Nigeria, inclusive of the perspective of stakeholders across the health sector, and represents a starting point to organize and operationalize the foundational work that needs to be undertaken to support a traceability implementation. It is intended for use by the Global Standards and Pharmaceutical Traceability Steering Committee to identify, assign, and drive the work required to develop an enabling environment for implementation of global standards to drive pharmaceutical traceability in the public and private sector supply chains.

It is recognized that there are a number of other dependencies for a successful implementation of traceability in Nigeria, including successful implementation of the Pharmacy Bill currently under review, effective implementation of the National Drug Distribution Guideline (NDDG), control of the "grey market" for pharmaceuticals and closure of open drug markets, and stronger control over or closure of certain high-risk porous border points. This document is not intended to cover these other on-going regulatory measures, which are included under the broader mandate of NAFDAC's mission.

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.[1] Traceability can support many healthcare objectives, including:

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

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

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 three models – verification, track and trace, or both.

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.

A track and trace model supports the capture of data from trading partners as the product moves through the supply chain, from the manufacturer to the end user. 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 information technology (IT) infrastructure model[2] will be implemented to support the established reporting requirements. Considering the Nigeria context and the goals of Nigeria's traceability implementation, a centralized model will be used. In a centralized traceability model, 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.

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[2]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.nifds.go.kr/apec/SupplyChain/APEC_SupplyChainToolkit_170317.pdf

THE ROLE OF GLOBAL STANDARDS IN TRACEABILITY

The foundation for all traceability implementations 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.

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.[3]

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). 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).

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[3] http://gs1.org/healthcare
 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

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).

THE GS1 SYSTEM OF STANDARDS

GS1 is a not-for-profit organization that develops and maintains global standards for business communication. This section details the specific GS1 standards that are commonly used in healthcare.[4]

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. Additional information like batch/lot number, expiration date, and serial number can also be encoded along with the GTIN.[5]

Serial Number. A serial number is a numeric or alphanumeric code assigned to an individual instance of an entity for its lifetime. The combination of a GTIN plus serial number uniquely identifies an individual item.[6]

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 as well as link information about a logistics unit between the physical package and its contents (i.e. GTINs and serial numbers).

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

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[4] 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

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

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

partners to use the same standards-based identifier to identify parties and locations in a standardized data format.[7]

Capture

GS1 128 Linear Barcode. A GS1 128 barcode is linear barcode symbology using bars and spaces in one dimension.

GS1 Data Matrix. A GS1 Data Matrix is a two-dimensional matrix symbology that is made up of square modules arranged within a perimeter finder pattern. Data Matrix 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. 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 Synchronisation 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.[8]

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.[9]

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. EPCIS is intended to be used in conjunction with the GS1 CBV, which provides definitions of data values that may be used to the data structures defined in the EPCIS standard

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

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

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

TRACEABILITY VISION

Traceability is defined as the ability to identify, track and trace and measure all the stages that led to a particular point in a process that consists of a chain of interrelated events.

The Nigeria NSHDP II outlines interventions to increase and ensure access to quality and affordable pharmaceutical products and health technologies in Nigeria. This aim is supported by NAFDAC's mandate to "compile standard specifications and guidelines for the production, importation, exportation, sale and distribution of food, drug, cosmetics, medical devices, bottled water and chemicals."

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

- Provides visibility of product status from plant to patient;
- Promotes trust in the pharmaceutical sector and healthcare system;
- Provides increased opportunity for trade of domestically manufactured pharmaceuticals;
- Increases quality of data to support pharmacovigilance;
- Decreases the presence of SF medications;
- Enables efficiencies across the supply chain; and ultimately,
- Increases patient safety.

Achieving these outcomes requires an environment that includes strong governance, collaborative execution, and accountability through measurement of outcomes against goals. Nigeria will collaborate across government agencies and the private sector to meet the following strategic objectives:

- **Strategic Objective 1:** Establish a governance structure to lead the strategy, advocacy, collaboration, resource mobilization, and oversight of global standards and traceability implementation.
- **Strategic Objective 2:** Strengthen the regulatory environment to include legal frameworks that enable traceability of quality pharmaceuticals through the legitimate supply chain.

- **Strategic Objective 3:** Create efficiencies in the public and private health supply chains through standardized identification, automated data capture, and reporting.
- **Strategic Objective 4:** Build and sustain technology to support interoperability of health information systems and implementation of traceability to improve data visibility.
- **Strategic Objective 5:** Enable use of standards to support identification and authentication of commodities dispensed to end-users at service delivery points in the public and private sectors.

STRATEGIC INITIATIVES

This section outlines the supporting activities that Nigeria will need to undertake to begin to implement traceability across the health sector. These activities are put in place to support the strategic objectives set forth to carry out the vision for pharmaceutical traceability in Nigeria. 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 health sector.

STRATEGIC OBJECTIVE 1: ESTABLISH A GOVERNANCE STRUCTURE TO LEAD THE STRATEGY, COLLABORATION, OUTREACH, AND OVERSIGHT OF GLOBAL STANDARDS AND 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 Nigeria. 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.

Activity 1.1: Endorse National Pharmaceutical Traceability Strategy

Workshop stakeholders will review the *National Pharmaceutical Traceability Strategy* to provide feedback and submit to FMOH and NAFDAC for endorsement. Endorsement of the document will mark the formal launch of all subsequent activities identified by workshop participants and detailed in the remainder of the document.

Activity 1.2: Establish a Global Standards and Traceability Steering Committee[10]

A collaborative team of stakeholders across public and private sector organizations will be created and will establish their terms of reference (TOR) to provide strategic direction, decision-making authority, resource mobilization, and oversight of implementation activities to achieve the strategic objectives outlined in this document. Technical Working Groups (TWGs) may be established under the TOR to support the Steering Committee in implementing specific strategic objectives.

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[10] Recommended representatives at a minimum include FMOH, NAFDAC, PCN, PSN, PMGMAN, NIROPHARM, NAIP, ACPN, GS1, GHSC-PSM

Activity 1.3: Establish agreement between SON and GS1 Nigeria on definition, implementation, and use of global standards in the Nigeria context

With support and input from the Steering Committee, SON and GS1 Nigeria will document respective roles and responsibilities in supporting use of global standards in the Nigeria context through a Memorandum of Understanding (MOU) or similar document.

Activity 1.4: Identify strategic implementation partners and define stakeholder roles and responsibilities

Implementation of pharmaceutical traceability will rely on shared responsibility and input from public and private institutions. Partners may include other government entities, educational institutions, international organizations, standards organizations, pharmacists, consumers and private companies such as manufacturers, solutions providers, and trade associations. Through this activity, identification for opportunities to leverage public-private partnerships (PPPs) will be established. A successful implementation will depend on understanding the landscape of stakeholders and their respective role and responsibilities in achieving the vision for traceability.

Activity 1.5: Develop a plan for communications, advocacy, and awareness of Nigeria's traceability initiative, global standards, and pharmaceutical traceability concepts

Document communications, advocacy and awareness plan to identify how stakeholders throughout the value chain will be informed and engaged on strategy implementation. This includes continuous education for all stakeholders ranging from manufacturers to the healthcare workforce on foundational concepts of global standards and traceability, and ensuring that direct stakeholders and the public are engaged and informed of the latest developments throughout implementation.

Activity 1.6: Establish specifications for Nigeria's traceability model

The June 2019 National Pharmaceutical Traceability Workshop established consensus on the need for global standards in the health sector, the vision for pharmaceutical traceability, and a path forward through this roadmap. 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 scope traceability model (e.g. verification, track and trace), IT infrastructure (e.g. centralized, semi-centralized, etc) to support it, and define scope parameters (e.g. products, trading

partners). 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 1.7: Provide guidance to supply chain stakeholders on hardware/software requirements and qualified solution providers[11]

Supply chain stakeholders will rely on solution providers for support through implementation, particularly domestic manufacturers to identify, label, and share data on their commodities. Stakeholders have requested guidance to provide specifications on infrastructure needed and visibility into vetted or certified solution providers who can provide them with hardware, software, and services that will support them in implementing the traceability mandate in accordance with the selected standards and specifications.

Activity 1.8: Conduct situational analysis risk mitigation plan

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

Activity 1.9: Develop 5-year costed implementation plan

The plan for implementing the traceability model will be clearly defined with phased outcomes over 5 years until the full vision is achieved. This phased approach, to include scalable pilots in each phase, will enable stakeholders 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.

In parallel with the development of the implementation plan, an evaluation will assess the costs of the proposed implementation approaches, timelines, human resources, and technology requirements against each phase. The plan will be shared with stakeholders for input and feedback to ensure they are achievable by internal and external trading partners and used as a tool to mobilize resources from funding partners.

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[11] For reference, a similar program has been implemented by GS1 US: https://www.gs1us.org/what-we-do/partners/find-gs1-us-solution-partner

Activity 1.10: Create a monitoring and evaluation (M&E) plan

To measure the impact of the investment in global standards and traceability against the projected vision and strategy, an M&E plan will be developed to establish key performance indicators (KPIs). The M&E plan will take into account projected value drivers across all key stakeholder groups and establish an early baseline against which implementation can be measured.

STRATEGIC OBJECTIVE 2: STRENGTHEN THE REGULATORY ENVIRONMENT TO INCLUDE LEGAL FRAMEWORKS THAT ENABLE TRACEABILITY OF QUALITY PRODUCTS THROUGH LEGITIMATE SUPPLY CHANNELS

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 implementation of Nigeria's traceability vision.

Activity 2.1: Assess existing deployment to global standards across to-be regulated parties and identify gaps

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

Activity 2.2: Assess cost/benefit and alignment between current state of verification (e.g. mobile authentication service (MAS)) and to-be traceability solution

NAFDAC has already undertaken extensive efforts to reduce presence of SF medicines in Nigeria for antimalarial and antibiotic medicines. To implement this program, a number of investments were required by various stakeholders including NAFDAC, manufacturers, and solution providers to implement and while metrics are reported on incidents, full impact of the program may not be fully quantifiable to date. Health sector stakeholders are supportive with moving forward to expand beyond verification in pursuit of a solution that

can be more broadly applied across product categories and scalable in its benefits, however, there is a desire to more clearly understand how Nigeria's traceability effort builds on or replaces MAS, and the value proposition throughout the value chain in light of this new initiative. This activity will document that anticipated progression and high-level cost/benefits for stakeholders throughout the supply chain in light of the new traceability model.

Activity 2.3: Develop regulations to support traceability implementation

2.3.1: An assessment will be conducted to understand current regulations and guidelines for product labelling 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.

2.3.2: 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 labelling; submission of master, transaction, and event data; and the responsibilities of different trading partner roles across the supply chain.

Activity 2.4: Create strategy for monitoring compliance to requirements and appropriate enforcement or punitive mechanisms for non-compliance

Once regulations are established, NAFDAC will need to define how they intend to enforce the requirements as defined, monitor for compliance, and punitive measures for non-compliance.

Activity 2.5: Strengthen collaborative efforts between NCS and NAFDAC to support coordination and alignment around product identification and reporting

To successfully implement traceability, especially monitoring and enforcement, there is a need to strengthen the relationship between NCS and NAFDAC to ensure roles and responsibilities are appropriately defined, and that reporting and escalation paths are clearly documented so that both agencies are operating in a synchronised manner towards achieving the vision.

STRATEGIC OBJECTIVE 3: CREATE EFFICIENCIES IN HEALTH SUPPLY CHAINS THROUGH STANDARDIZED IDENTIFICATION, 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, with a focus on driving efficiencies.

Activity 3.1: Private sector preparation for traceability implementation

As the requirements for the traceability model and implementation timelines are defined, health sector stakeholders will undertake the necessary work to assess current capabilities and prepare for implementation. This includes registering with a GS1 Member Organization (MO), manufacturer identification and labelling of commodities in accordance with global standards for healthcare, gathering and validating master data, and implementing barcode scanning where feasible in the supply chain.

Activity 3.2: Implement barcode scanning at public/private sector medical stores (including Coordinated Wholesale Centers , CWC)

A gap analysis will be conducted to understand the current capabilities for barcode use for public/private sector medical stores operations (e.g. receiving, picking, packing, shipping, inventory management) and their third-party logistics (3PL) partners to create a plan for barcode implementation in the near-term. This activity will include establishing a baseline for current-state efficiency metrics and track improvements in medical stores operations through introduction of standards and automation, with a goal to demonstrate both qualitative and quantifiable benefits from implementation to share more broadly to inform other stakeholders' implementations.

Activity 3.3: Implement barcode scanning with NCS at ports of entry

A gap analysis will be conducted to understand the current capabilities for barcode scanning at NCS in identifying pharmaceuticals for importation to develop a plan to implement barcode scanning in the near-term. This plan will include training on standards,

required changes to standard operating procedures (SOPs), access to master data (including notably, Harmonized Commodity Description and Coding System (HS) Codes for appropriate capture of revenue), assessment of systems capabilities for data capture, and other technology requirements.

Activity 3.4: Identify future-state supply chain traceability requirements and develop prototype system for supply chain partners to pilot reporting data

Supply chain stakeholders have a keen interest to undertake a pilot to inform the work that needs to be done to support traceability implementation. Through a rapid pilot, the supply chain stakeholders seek to identify high-level future-state requirements and develop a prototype database and instructions to pilot and test reporting mechanisms, identify opportunities to inform final guidance, and address any barriers to implementation.

STRATEGIC OBJECTIVE 4: BUILD AND SUSTAIN TECHNOLOGY TO SUPPORT INTEROPERABILITY OF HEALTH SYSTEMS AND IMPLEMENTATION OF TRACEABILITY TO IMPROVE DATA VISIBILITY

Nigeria'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 in-scope trading partners.

Activity 4.1: Develop national product catalogue (NPC) for product master data

To improve interoperability among systems and progress towards standardized product master data, a NPC will be developed to create a single source of all product master data across Nigeria's health information systems. To inform implementation, an assessment will be conducted to determine what catalogues exist today; priority attributes for products and trade items; and requirements for a future state cross-enterprise platform that can be integrated with priority systems; and data governance considerations required to support this function.

Activity 4.2: Conduct traceability technology needs assessment, taking into account capabilities and gaps in existing systems

The needs assessment will assess the current e-health architecture in Nigeria 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 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 4.3: Define future-state traceability systems architecture and requirements, taking into account integrations with stakeholders and connectivity by remote locations

Once the technical requirements are defined, 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 4.4: Develop a comprehensive traceability data strategy

Through implementation, stakeholders recognize the increase in requirements around data generation, sharing, and use in order to achieve the traceability vision. To support implementation, a comprehensive traceability data strategy will be developed that covers in-scope master, transaction, and event data; key components of data governance including management, access, and use; and outlines data security measures to ensure that the systems support achievement of the vision.

Activity 4.5: Develop and sustain traceability system 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.

STRATEGIC OBJECTIVE 5: ENABLE USE OF STANDARDS TO SUPPORT IDENTIFICATION AND VERIFICATION OF COMMODITIES DISPENSED TO END-USERS AT SERVICE DELIVERY POINTS IN THE PUBLIC AND PRIVATE SECTORS

Through this traceability strategy, Nigeria seeks to leverage the benefits of standards to expand on current authentication initiatives to increase the ability to identify and verify a broader set of pharmaceuticals at service delivery points. These activities describe the work to be undertaken to leverage global standards for these purposes at the last mile.

Activity 5.1: Review current state reporting and stock / record keeping mechanisms to capture a standard set of data made available through global standards

There are a number of government-mandated forms of record keeping and reporting in place across service delivery points - particularly in the public sector - but also inclusive of the private sector with mechanisms such as yellow forms for adverse drug reporting (ADR). A review will be undertaken of common reporting forms (both paper and systems-based) to assess where standards-based identification can replace or supplement existing information to provide better data quality in support of visibility and traceability.

Activity 5.2: Support implementation of policies through deployment of barcode scanning at the last mile and development of supporting SOPs and training for healthcare workers

For both verification of commodities and track and trace from "plant to patient," a fundamental requirement will be capturing data on pharmaceuticals at the point of dispense. This will require a people, process and technology intervention that includes defining SOPs required to meet the regulatory mandate, deploying appropriate technologies for data capture, and training the workforce for implementation. This will not be a onetime intervention, but require continuous monitoring to ensure adherence to protocols and support closing gaps in compliance where they may exist.

Activity 5.3: Support the development of mobile apps for consumers to scan and access data about issued commodities

Through the workshop, there were a number of benefits identified for consumers that can be enabled by global standards, ranging from e-leaflets to access to product information

through master data provided by the national product catalogue, in addition capabilities for verification of a broader range of medicines. To support access to this data, applications will need to be developed for consumers to scan or manually enter data on these commodities from their mobile phones.

ROADMAP

Objectives and Activities	Timeframe			Owner
	<6 mo.	6-18mo.	>18mo.	
OBJECTIVE 1: Establish a governance structure to lead the strategy, collaboration, outreach, and oversight of global standards and traceability implementation				
Activity 1.1: Endorse National Pharmaceutical Traceability Strategy	X			
Activity 1.2: Establish a Global Standards and Traceability Steering Committee	X			
Activity 1.3: Establish agreement between SON and GS1 Nigeria on definition, implementation, and use of global standards in the Nigeria context	X			
Activity 1.4: Identify strategic implementation partners and define stakeholder roles and responsibilities	X			

Activity			
Activity 1.5: Develop a plan for communications, advocacy, and awareness of Nigeria's traceability initiative, global standards, and pharmaceutical traceability concepts	X		
Activity 1.6: Establish specifications for Nigeria's traceability model	X		
Activity 1.7: Provide guidance to supply chain stakeholders on hardware/software requirements and qualified solution providers	X	X	
Activity 1.8: Conduct situational analysis risk mitigation plan			X
Activity 1.9: Develop 5-year costed implementation plan		X	
Activity 1.10: Create a M&E plan			X
OBJECTIVE 2: Strengthen the regulatory environment to include legal frameworks that enable traceability of quality products through legitimate supply channels			

Activity			
Activity 2.1: Assess existing deployment to global standards across to-be regulated parties and identify gaps			X
Activity 2.2: Assess cost/benefit and alignment between current state of verification (e.g. MAS) and to-be traceability solution			X
Activity 2.3: Develop regulations to support traceability implementation		X	X
Activity 2.4: Create strategy for monitoring compliance to requirements and appropriate enforcement or punitive mechanisms for non-compliance	X	X	
Activity 2.5: Strengthen collaborative efforts between NCS and NAFDAC to support coordination and alignment around product identification and reporting		X	
OBJECTIVE 3: Create efficiencies in health supply chains through standardized identification, automated data capture, and reporting			
Activity 3.1: Private sector preparation for traceability implementation		X	

Activity			
Activity 3.2: Implement barcode scanning at public sector medical stores	X		
Activity 3.3: Implement barcode scanning with NCS at ports of entry	X		
Activity 3.4: Identify future-state supply chain traceability requirements and develop prototype system for supply chain partners to pilot reporting data		X	
OBJECTIVE 4: Build and sustain technology to support interoperability of health systems and implementation of traceability to improve data visibility			
Activity 4.1: Develop NPC for product master data	X		
Activity 4.2: Conduct traceability technology needs assessment, taking into account capabilities and gaps in existing systems		X	
Activity 4.3: Define future-state traceability systems architecture and requirements, taking into account integrations with stakeholders and connectivity by remote locations	X		

Activity	Col 1	Col 2
Activity 4.4: Develop a comprehensive traceability data strategy	X	
Activity 4.5: Develop and sustain traceability system infrastructure		X
OBJECTIVE 5: Enable use of standards to support identification and verification of commodities dispensed to end-users at service delivery points in the public and private sectors		
Activity 5.1: Review current state reporting and stock / record keeping mechanisms to capture a standard set of data made available through global standards	X	
Activity 5.2: Support implementation of policies through deployment of barcode scanning at the last mile and development of supporting SOPs and training for healthcare workers		X
Activity 5.3: Support the development of mobile apps for consumers to scan and access data about issued commodities		X