Government and regulatory body ThinkTank

Day 1: Learning from donor agencies on procurement and the support of local regulation

GS1 Healthcare African Conference
8 May 2018, Addis Ababa, Ethiopia

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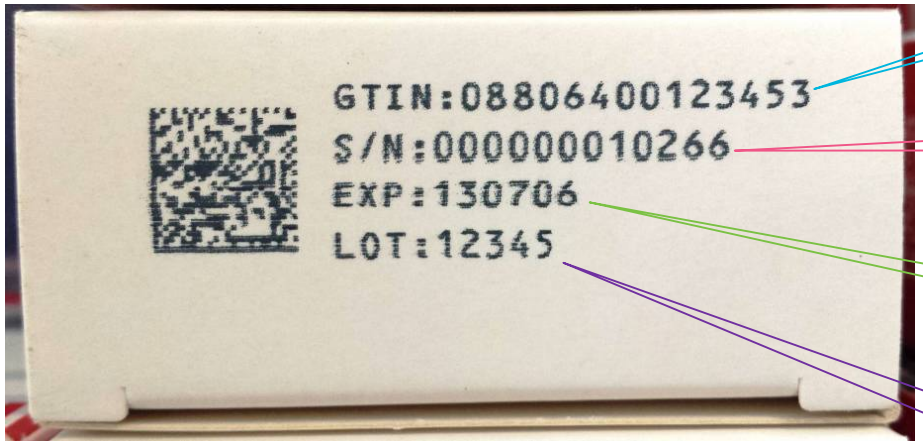
14.30 – 15.00 *(30 minutes)*	Opening and introduction of participants *Facilitator: Géraldine Lissalde-Bonnet, Public Policy Director, GS1 Global Office, Belgium*
15.00 – 15.15 *(15 minutes)*	EFMHACA : working with donor agencies and initiating regulatory dev. *Speaker: Yehulu Denekew, Director General, Food Medicine Health Care Administration and Control Authority, Ethiopia*
15.15 – 15.45 *(15 minutes)*	Discussions Facilitator: *Géraldine Lissalde-Bonnet, Public Policy Director, GS1 Global Office, Belgium*
15.45 – 16.15	Coffee Break
16.15 – 16.25 *(10 minutes)*	Introduction to USAID Pharmaceutical Traceability initiative *Speaker: Dr. Ramy Guirguis, Senior Information Technology Advisor, USAID, U.S.A.*
16.25 – 16.35 *(10 minutes)*	USAID draft Implementation Guidance for Pharmaceutical Traceability Leveraging Global Standards *Speaker: Kaitlyn Roche, Manager for Global Standards, USAID, U.S.A.*
16.35 – 16.50 *(15 minutes)*	Discussions *Facilitator: Géraldine Lissalde-Bonnet, Public Policy Director, GS1 Global Office, Belgium*
16.50 – 17.05 *(15 minutes)*	ISG - collaborating to improve donor procurement guidelines Speaker: *Lisa Hedman, Technical Officer, Procurement and Supply Chain Management, World Health Organisation (WHO), Switzerland*
17.05 – 17.20 *(15 minutes)*	Discussions Facilitator: *Géraldine Lissalde-Bonnet, Public Policy Director, GS1 Global Office, Belgium*
17.20 – 17.30 *(10 minutes)*	Closing *Facilitator: Géraldine Lissalde-Bonnet, Public Policy Director, GS1 Global Office, Belgium*

Traceability in Healthcare for

- Preventing counterfeiting
- Enabling effective product recalls
- Traceability down to the patient and correct patient records
- Enabling regulatory compliance

- Enhancing business processes (e.g. inventory management, optimized supply chain efficiency, eProcurement)

IDENTIFY and CAPTURE
4 identification attributes in a GS1 DataMatrix



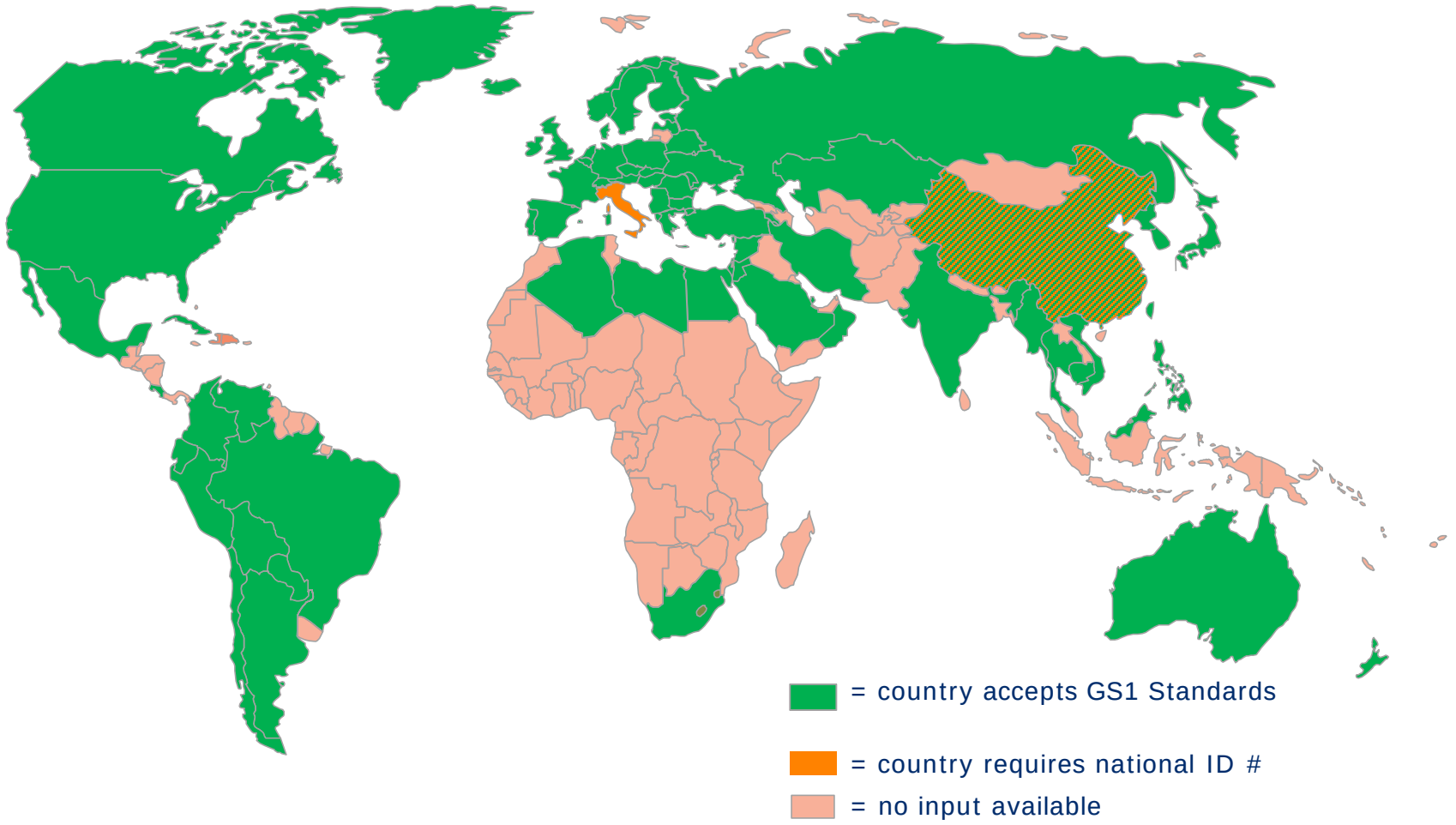
Product Identifier (GTIN)

Serial Number

Expiry date

Lot/Batch number

Identification of pharmaceuticals using GS1



SHARE
Different type of data for traceability

Master Data refers to data that is associated with the product (GDSN):

- GTINs
- Brand Owner identification (GLNs)
- Product descriptions
- Product classification

Transactional Data refers to data that is shared between two trading parties in the sale/purchase process.

Event Data refers to activities that a product goes through as it moves through the supply chain (EPCIS). An event has four dimensions:

- What (GTIN)
- When (GLN)
- Where (date and time stamp)
- Why (business step)

Different actors, functions and results

Supply Chain Dialog

Manufacturers

Logistic Providers

Customs

Distributors

Pharmacy/ Hospital /Clinic Dispensers

Regulators

Traceability Functions

Identify | Verify | Track | Trace | Report

Results

Supply Chain Visibility | Product Protection | Recall Improvement | Returns, Shipment accuracy and efficiency | Reimbursement management

Government Think Thank

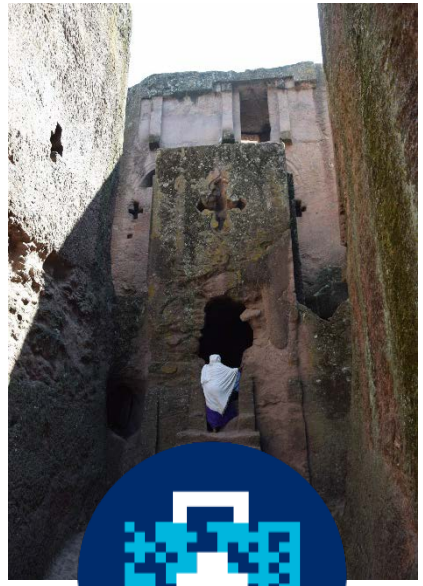
Strengthening the pharmaceutical supply chain to deliver quality medicines in Ethiopia and across Africa

COLLABORATION WITH DONOR AGENCIES

Mr. Yehulu Denekew

Director General, Ethiopian Food, Medicine and Healthcare Administration and Control Authority

GS1 Healthcare Conference, Addis Ababa, May 2018



About EFMHACA

- **Mission:**

"To promote and protect the public health by ensuring the safety and quality of health services and products through registration, licensing and inspection of Health professionals, pharmaceuticals, food establishments, and health and health related institutions and provision of up-to-date regulatory information while Promoting rational medicines use."

- **Vision:**

"Quality health services and products to all citizens."

Government: Where to start?

Recognize challenges and define objectives

Find support that aligns with these objectives – and keeps global developments in account

- **<u>Needs highlighting</u>**: importance of donors for securing essential medicines in many countries. Implementation of traceability helps many donors get visibility in movement of their procured items.

UNFPA

JSI

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PEPFAR
U.S. President's Emergency Plan for AIDS Relief

AIDSFree
Strengthening High Impact Interventions for an AIDS-free Generation

Collaboration

Important:

- Align **objectives** and set **expectations**
- Decide on **roles** and **responsibilities**
- Set a **timeline** for support
- Ensure **engagement**, especially on **management** level
- Provide **sustainable** support, make sure it is **temporary**, plan for the **future**
- Train people **locally**, and use **local expertise** (use of short term consultancy is a temporary solution)

Donor support

How can donors support?

- **Make a plan**
  - What are my challenges and objectives? (fake products – secure supply chain)
  - What do I need to implement to achieve these objectives? (traceability)
  - Which activities do I have to undertake to achieve implementation? (build traceability system – ensure standard implementation – train stakeholders, etc.)

- Find **expertise** to execute this plan**:**

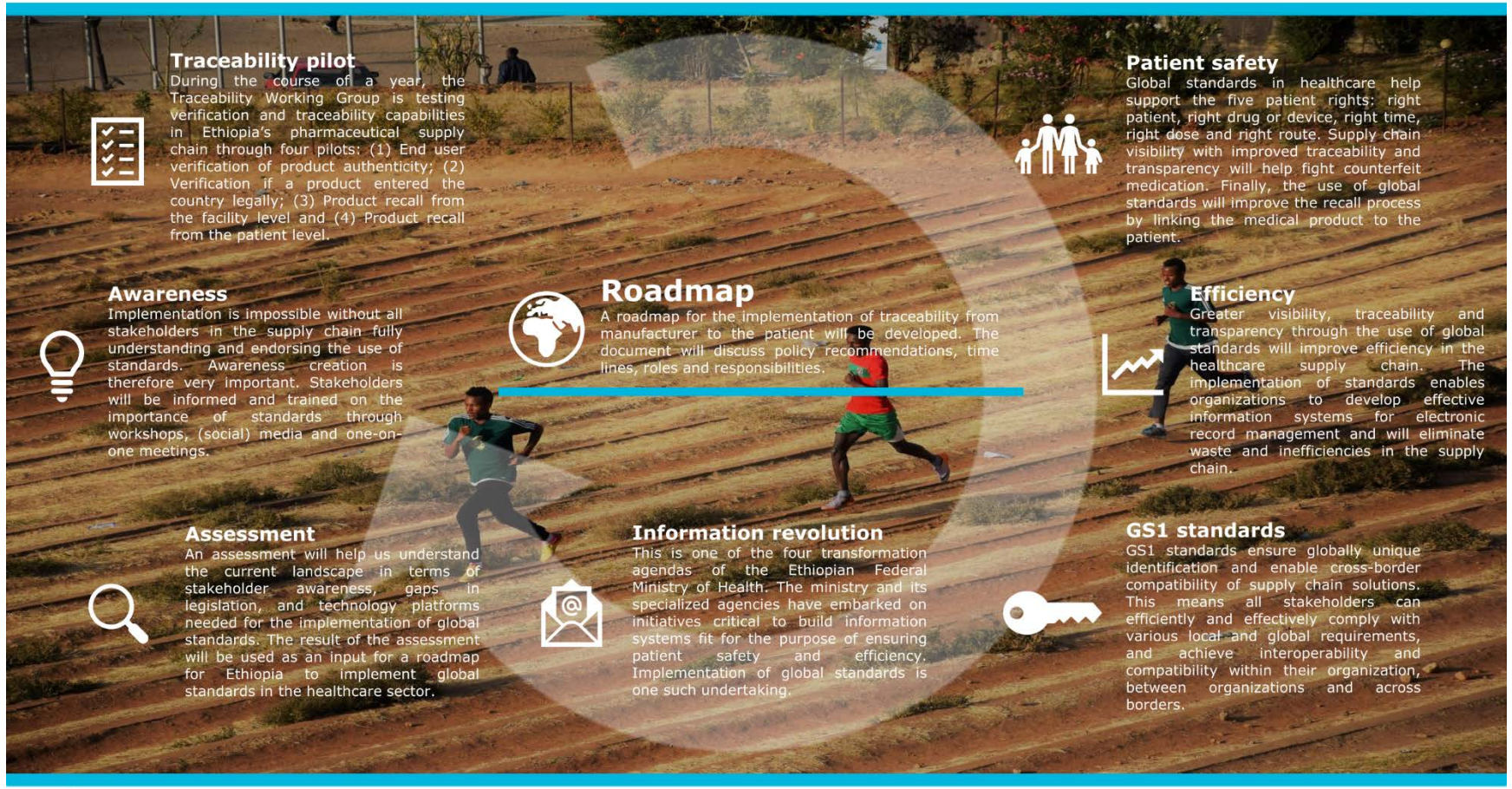
  - **Technical knowledge**: GS1 standards, traceability, building technical infrastructure
  - **Regulatory**: draft national regulation - ensure alignment with worldwide developments
  - **Communication & Training**: support for supply chain stakeholders

➢ **Government ownership is essential!**

How is support arranged in Ethiopia?

Ethiopia's journey toward traceability

for patient safety and efficiency in the healthcare supply chain



100 million inhabitants, one of the oldest nations in the world, over 82 languages, more than 79 ethnicities and home to Lucy, a human fossil believed to have existed over 3 million years ago.

About 20 percent of pharmaceuticals are locally manufactured. This number is expected to grow significantly in the coming years. The public sector has approximately 340 hospitals, 3,500 health centers and 16,000 health posts providing health services.

Important stakeholders including the government, manufacturers, and healthcare providers are supporters of the initiative to develop a roadmap for the implementation of global standards.

Questions

- How do I find support organizations that might be interested in supporting me?
- What are the biggest challenges in the partnership?
- How can we make sure support is sustainable?

What EFMHACA would like to hear from participants:

- What are your experiences?

Thank you for your attention!

We remember GS1's words: "It's a marathon, not a sprint!"

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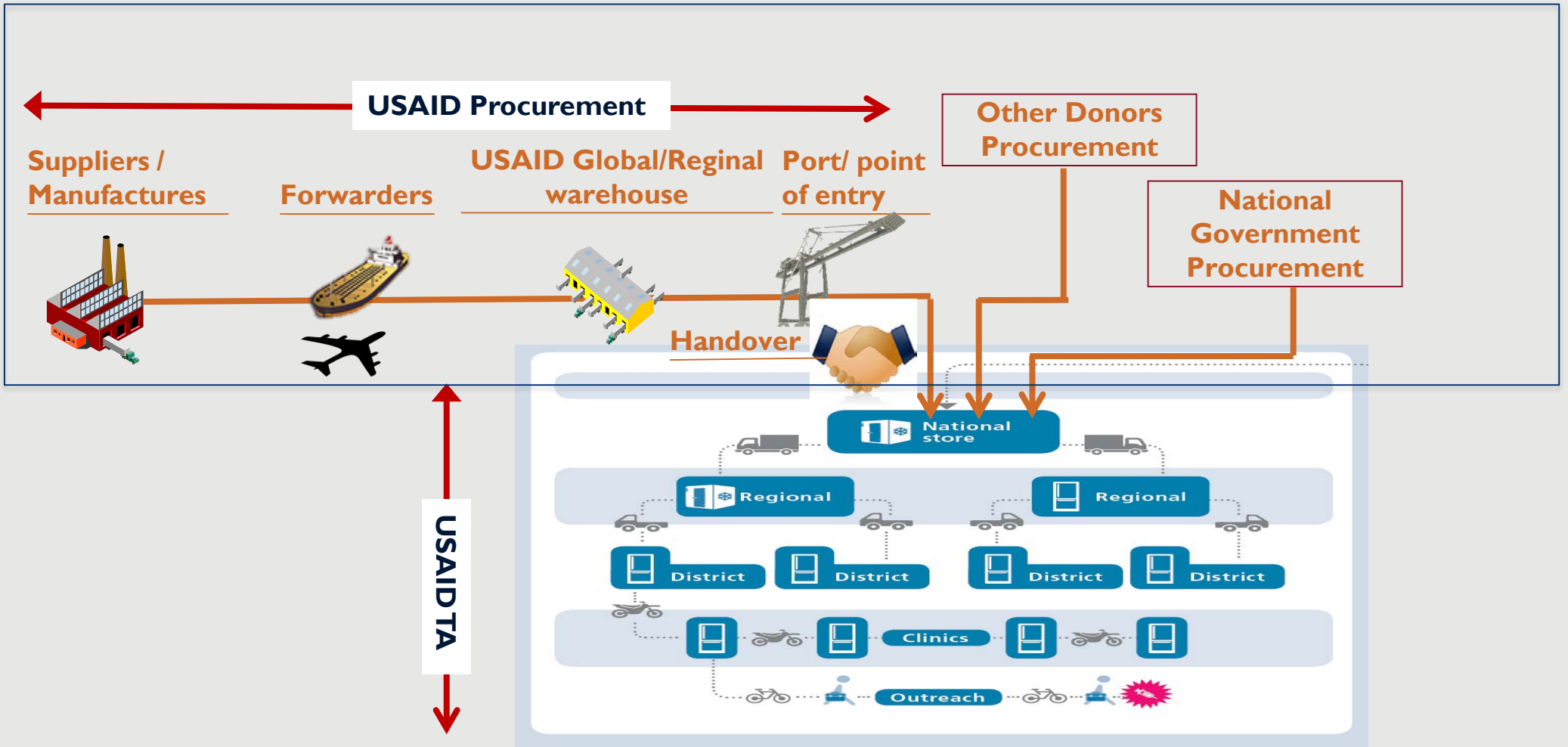
Introduction to USAID Pharmaceutical Traceability Initiative

GS1 Global Healthcare Conference

May 09 , 2018

Ramy Guirguis, Ph.D.
Senior Information Technology Advisor
USAID | Bureau for Global Health
rguirguis@usaid.gov

Commodity Flow in USAID Supply Chain

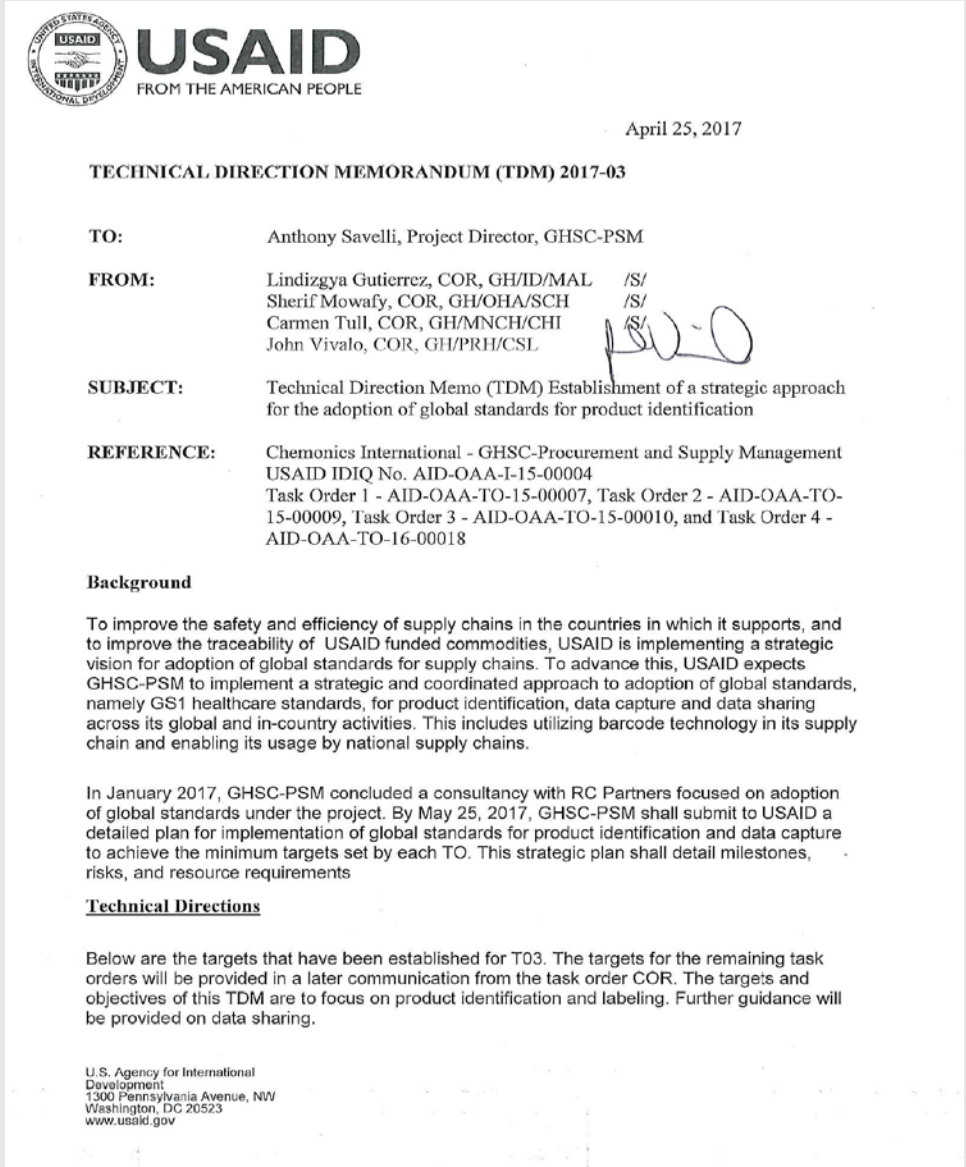


Goals through adoption of global standards

- To identify and implement supply chain efficiencies
- Enable end-to-end data visibility
- To ensure supply chain security
- To increase patient safety

USAID Technical Directive

In April 2017, USAID issued a Technical Directive to the Global Health Supply Chain (GHSC) Procurement and Supply Management (PSM) Project to establish a strategic approach for the adoption of global standards for product identification, data capture, and data sharing for procurement and supply chain assistance.



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April 25, 2017

TECHNICAL DIRECTION MEMORANDUM (TDM) 2017-03

TO: Anthony Savelli, Project Director, GHSC-PSM

FROM: Lindizgya Gutierrez, COR, GH/ID/MAL /S/
Sherif Mowafy, COR, GH/OHA/SCH /S/
Carmen Tull, COR, GH/MNCH/CHI /S/
John Vivalo, COR, GH/PRH/CSL

SUBJECT: Technical Direction Memo (TDM) Establishment of a strategic approach for the adoption of global standards for product identification

REFERENCE: Chemonics International - GHSC-Procurement and Supply Management USAID IDIQ No. AID-OAA-I-15-00004
Task Order 1 - AID-OAA-TO-15-00007, Task Order 2 - AID-OAA-TO-15-00009, Task Order 3 - AID-OAA-TO-15-00010, and Task Order 4 - AID-OAA-TO-16-00018

Background

To improve the safety and efficiency of supply chains in the countries in which it supports, and to improve the traceability of USAID funded commodities, USAID is implementing a strategic vision for adoption of global standards for supply chains. To advance this, USAID expects GHSC-PSM to implement a strategic and coordinated approach to adoption of global standards, namely GS1 healthcare standards, for product identification, data capture and data sharing across its global and in-country activities. This includes utilizing barcode technology in its supply chain and enabling its usage by national supply chains.

In January 2017, GHSC-PSM concluded a consultancy with RC Partners focused on adoption of global standards under the project. By May 25, 2017, GHSC-PSM shall submit to USAID a detailed plan for implementation of global standards for product identification and data capture to achieve the minimum targets set by each TO. This strategic plan shall detail milestones, risks, and resource requirements

Technical Directions

Below are the targets that have been established for T03. The targets for the remaining task orders will be provided in a later communication from the task order COR. The targets and objectives of this TDM are to focus on product identification and labeling. Further guidance will be provided on data sharing.

U.S. Agency for International Development
1300 Pennsylvania Avenue, NW
Washington, DC 20523
www.usaid.gov

GHSC-PSM Procurement Requirement

- In May 2017, as a result of USAID Technical Directive Memo, GHSC-PSM issued an announcement of their intention to implement GS1 global standards for USAID procured health commodities.
- PSM developed a five year (2017 - 2022) implementation strategy that phases requirements for identification, labelling, and data exchange.

Announcement of Intention to Implement Global Standards for Product Identification, Labeling, and Data Exchange

Announcement during Family Planning Summit – July 2017

- On July 11, policymakers, donors, and advocates from around the world gathered at the Family Planning Summit in London, UK, to discuss efforts to reach our Family Planning 2020 goals and ensure that more women and girls around the world are able to plan their families and their futures.
- Adoption of global data standards (GS1) was listed as one of the group initiatives for supply chain strengthening.

Adoption of GS1 Global Standards

Adoption of Global Data Standards (GS1)

The adoption of global standards for product identification and for the capture and exchange of supply chain data is a key enabler of the global and in-country VANs. More widely, standards-driven interoperability between different information systems is critical to facilitate coordination between the various supply chain systems that provide family planning commodities. Data standards also help to ensure patient safety (through product traceability from manufacture to use) and lower supply chain costs (through driving efficiencies). USAID and UNFPA have worked over the past year with contraceptive manufacturers to develop a roadmap and timeline for the adoption of GS1 standards (the leading standards in the healthcare industry) in labeling contraceptive products.

Interagency Supply Chain Group (ISG) Position Paper – August 2017

- The ISG is an informal partnership of 15 major actors involved in providing supply chain support to countries: Bill and Melinda Gates Foundation, DFID, Global Affairs Canada, the Global Drug Facility, KfW, the Global Fund, Gavi, NORAD, UNDP, UNFPA, UNICEF, USAID, World Bank, WFP and WHO.
- In August 2017, ISG published a position paper on the adoption of GS1 standards. The ISG has committed to the process of transitioning to include established, global data standards as part of their procurement requirements and support country uptake of these standards.

From the Interagency Supply Chain Group:

Visibility for Health Systems: Adoption of Global Data Standards (GS1)

About the ISG

The broad purpose of the Interagency Supply Chain Group (ISG) is to share information and seek greater alignment across supply-chain investments to bring more impact to individual agency supply chain strategies. The group promotes coordination both globally across programs, and locally through national leadership with the overall aim of improving the efficiency and effectiveness of in-country supply chains. The ISG is an informal partnership of 15 major actors involved in providing supply chain support to countries: Bill and Melinda Gates Foundation, DFID, Global Affairs Canada, the Global Drug Facility, KfW, the Global Fund, Gavi, NORAD, UNDP, UNFPA, UNICEF, USAID, World Bank, WFP and WHO.

Boxes of medical supplies are sorted before being distributed among the mobile health brigades at the Chicuaicuale District hospital in Maputo, Mozambique, in July 2016. ©UNICEF/Rich.

Background

Medicines supply chain execution and responsiveness require synchronization of supply and demand, as well as the orchestration of three flows of commerce, that are the movement of goods, information and funds, across an increasing number of logistics and trading partners, spanning a wide (if not global geographic) region. Whilst the implementation of traceability systems has been identified by National Regulatory Authorities as a useful and efficient tool to combat falsification and illicit distribution of medical products, only some countries have issued progressive traceability regulation. Many have not, and are still assessing various implementation mechanisms, alternatives or otherwise have not approached this topic at all[1]. The international community has recognized the need to support countries in determining what these best approaches are. Since 2014, the international development community has promoted the use of global data standards (GS1) to provide a wider and harmonized framework for supply chain visibility, strengthening anti-counterfeiting measures and sharing of data between parties. The Interagency Supply Chain Group recognizes the value for advocating for both effective and sustainable solutions to enable traceability and safe passage of medicines through national supply chains and have committed to strengthening this response accordingly.

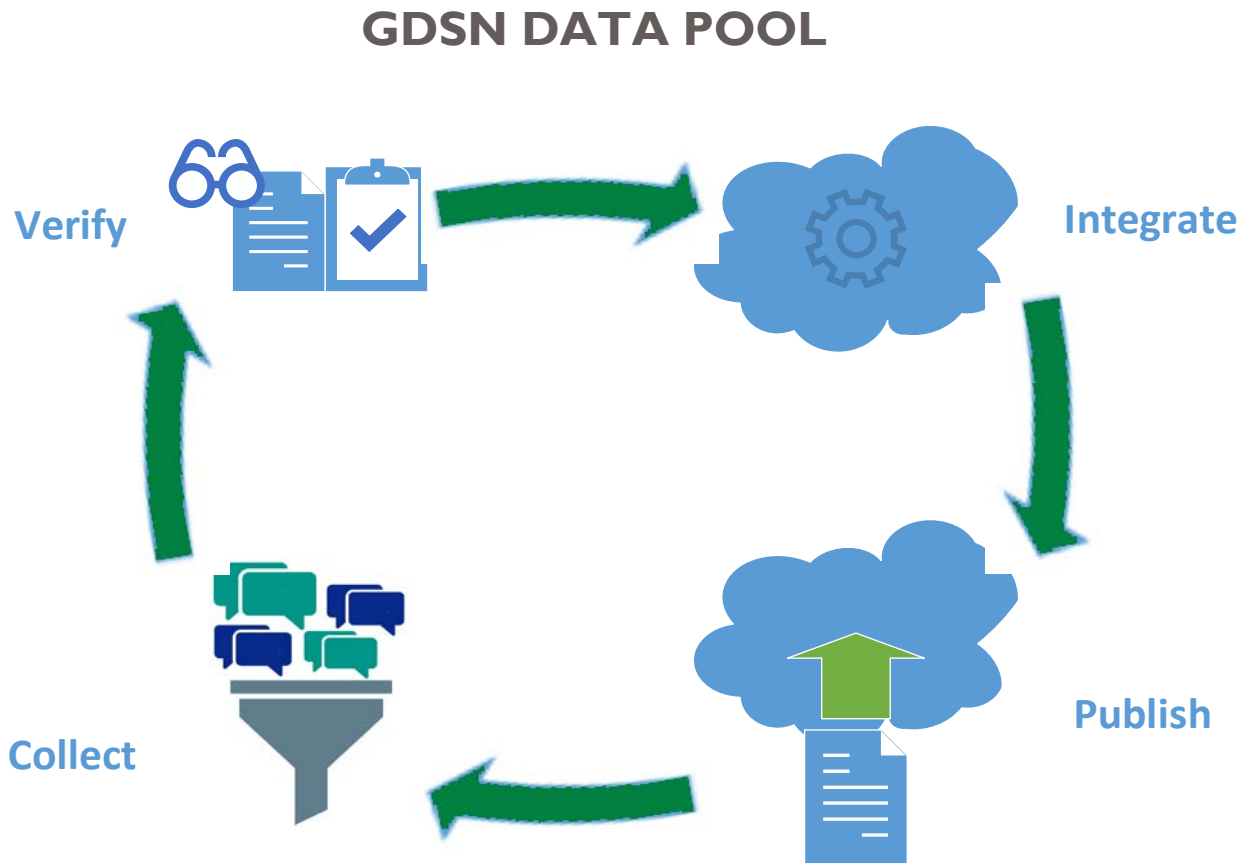
Current activities of the ISG

- Strengthen global and country advocacy for the adoption of GS1 standards and traceability systems with countries, in collaboration with other relevant stakeholders.
- Accelerate the understanding and adoption of an open and global supply chain standard, globally, through technical support, education, and collaboration with manufacturers.
- Collaborate to improve donor procurement guidelines, including the requirement for the use of GS1 standards for identification and barcoding on the different packaging levels, and coordinate with manufacturers on an implementation timeline.
- Develop a roadmap & timeline for the adoption of GS1 standards in labeling all health commodities and products.
- Provide technical assistance to several countries in defining parameters necessary to implement National Traceability Systems. These include development and finance implementation plans for barcoding of health commodities for member states. e.g. support to the Government of Ethiopia to implement a nation-wide adoption of barcoding technology.

[1] Fourth meeting of the member state mechanism on substandard/spurious/falsely-labelled AR/SIM/D falsified/counterfeit medical products, 13 November 2015, provisional agenda item 4C. Existing technologies and 'track and trace' models in use and to be developed by member states. Draft document submitted by Argentina.

Product Master – Data Pool

1. Product Master Data represent a major challenge for both the global supply chain and country supply chain
2. Data Pool/GDSN is an opportunity to solve the product master challenges where:
    1. Supplier registers with GS1 and obtains a prefix
    2. Supplier assigns GTINs to its products
    3. Supplier registers with a GDSN data pool provider
    4. Supplier provides product attributes through their GDSN Data Pool



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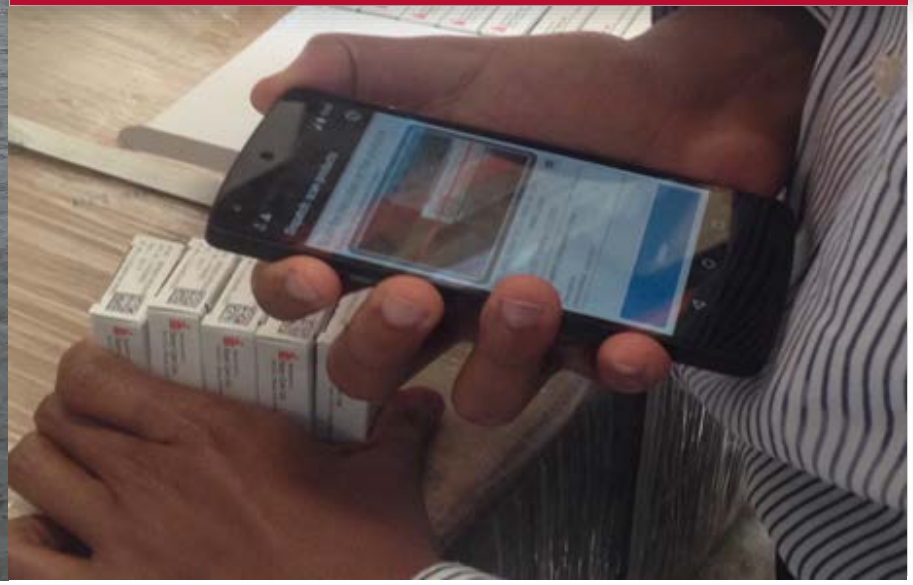

Implementation Guidance for Pharmaceutical Traceability Leveraging Global Standards

USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

Procurement and Supply Management

USAID FROM THE AMERICAN PEOPLE

PEPFAR U.S. President's Emergency Plan for AIDS Relief

USAID FROM THE AMERICAN PEOPLE CDC

U.S. President's Malaria Initiative

Executive Summary

The intent of this document is to provide guidance to country programs on how to systematically organize the work of operationalizing and executing the vision/strategy for pharmaceutical traceability by:

- Providing an sample of stakeholder group, illustrative implementation roadmap, and architecture model
- Summarizing key takeaways, lessons learned, and good practices
- Supporting the development of the vision, strategy, and ultimately country-specific implementation roadmap
- Drawing attention to the key questions that should be considered for a successful country-specific implementation

DRAFT

Document Structure

Education & Awareness

Investing in key stakeholders to provide a baseline understanding of global standards, traceability, and what it takes to implement it.

Vision & Strategy

Identifying the problem statement to develop a declaration of the reason for implementing traceability, it's short-term and long-term objectives and goals.

Architecture

Data and systems models to enable implementation of the stated vision.

Policy

Supporting policies that enable implementation of the stated vision.

Implementation Plan

A management tool that details the critical strategic steps, milestones, and resources required to execute on the vision.

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Education & Awareness

Establishes a baseline understanding of traceability and global standards, including opportunities and challenges for implementation, among key country stakeholders to inform the vision and strategy developed for country implementation

Vision & Strategy

Outlines high-level vision for what the country expects to achieve through traceability and the documentation and messaging necessary to clearly define the strategic, overarching purpose the initiative and how it will be implemented in collaboration with key stakeholders. Underscores the importance of mutually agreed upon priorities, clarity of purpose, and well-defined scope.

Global Standards

Documents the global standards for product and location identification, data capture, and data sharing to be leveraged to enable implementation of traceability in the health supply chain.

Regulatory

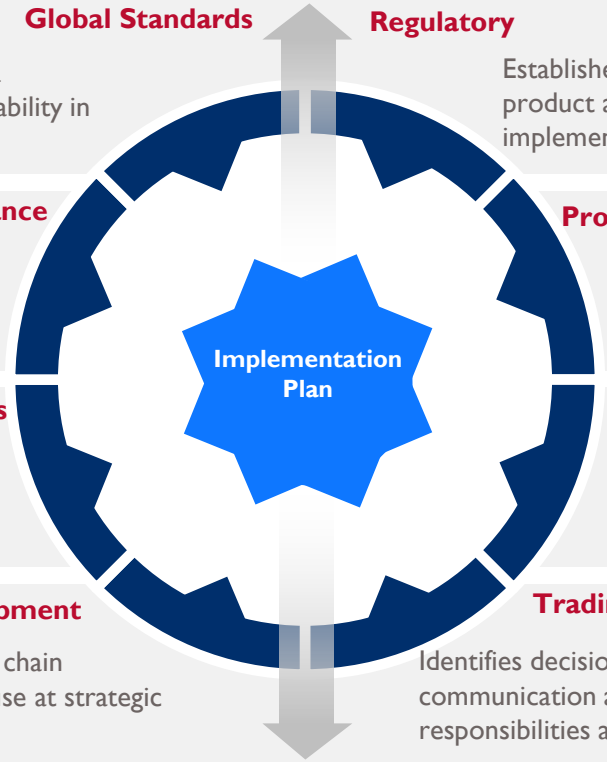
Establishes the regulations that supply chain trading partners need to adhere to for product and location identification, data capture, and data sharing to enable implementation of the country's traceability vision.

Ownership and Governance

Outlines the governance structure, distribution of roles and activities, decision-authority, reporting lines, and high-level relationship between the various stakeholders responsible for traceability implementation.

Procurement

Establishes the requirements criteria to be included in national procurements and communications protocols to disseminate information on these requirements to trading partners.



Supply Chain Operations

Identifies and provides guidance and procedural norms for processes and systems use across the supply chain operations including importation, warehousing, inventory management, and distribution.

Information Systems

Identifies supply chain systems requirements, data flows, and architectures to support traceability implementation across supply chain partners. Defines norms and good practices for their use.

Workforce Development

Identifies key areas and requirements for capacity building within the supply chain workforce to enable implementation of established processes and systems use at strategic points in the supply chain.

Trading Partners

Identifies decisions that need to be made to establish relationships and appropriate lines of communication and engagement with trading partners. Determines the division of responsibilities and scope boundaries for the government vis-à-vis their trading partners.

Performance Management

Defines the key metrics and measurement processes to determine the performance and ability of the implementation plan to deliver stated objectives.

Pilot

Identifies the pilot activities that should be conducted at each step of implementation to identify any roadblocks and inform viability and strategy to scale.

Scale

Identifies the steps to scale, including key required documentation to codify established policies, processes, and structures for governance and ownership.

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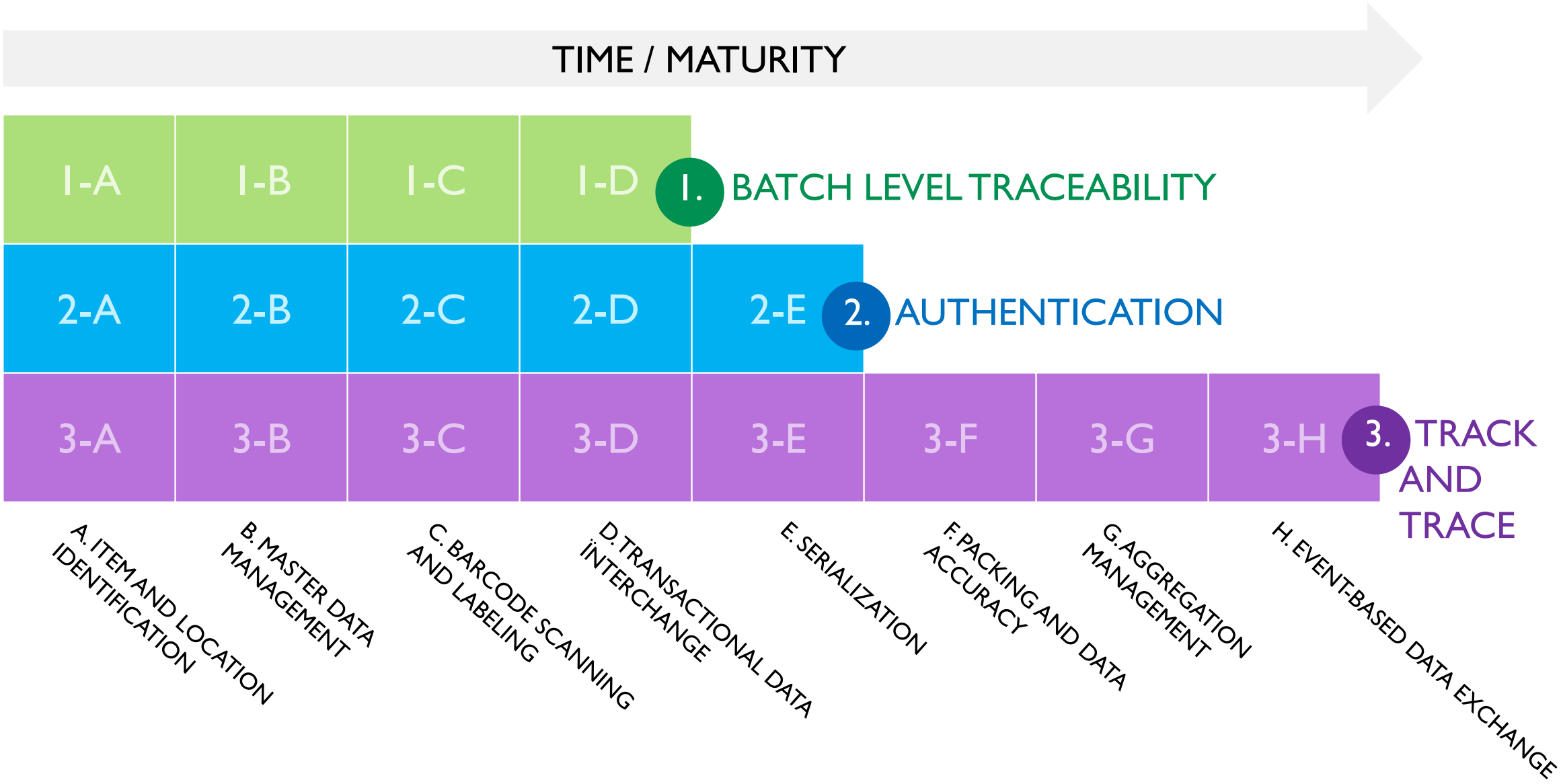
Illustrative Implementation Roadmap



Supporting Work Products

- Education & Training Materials
- Visioning Workshop Structure
- Vision & Strategy Templates
- Architecture Models
- Data Reference Models
- Guidance Document for National Stakeholders on Developing Policies that are Inclusive of Local Manufacturers

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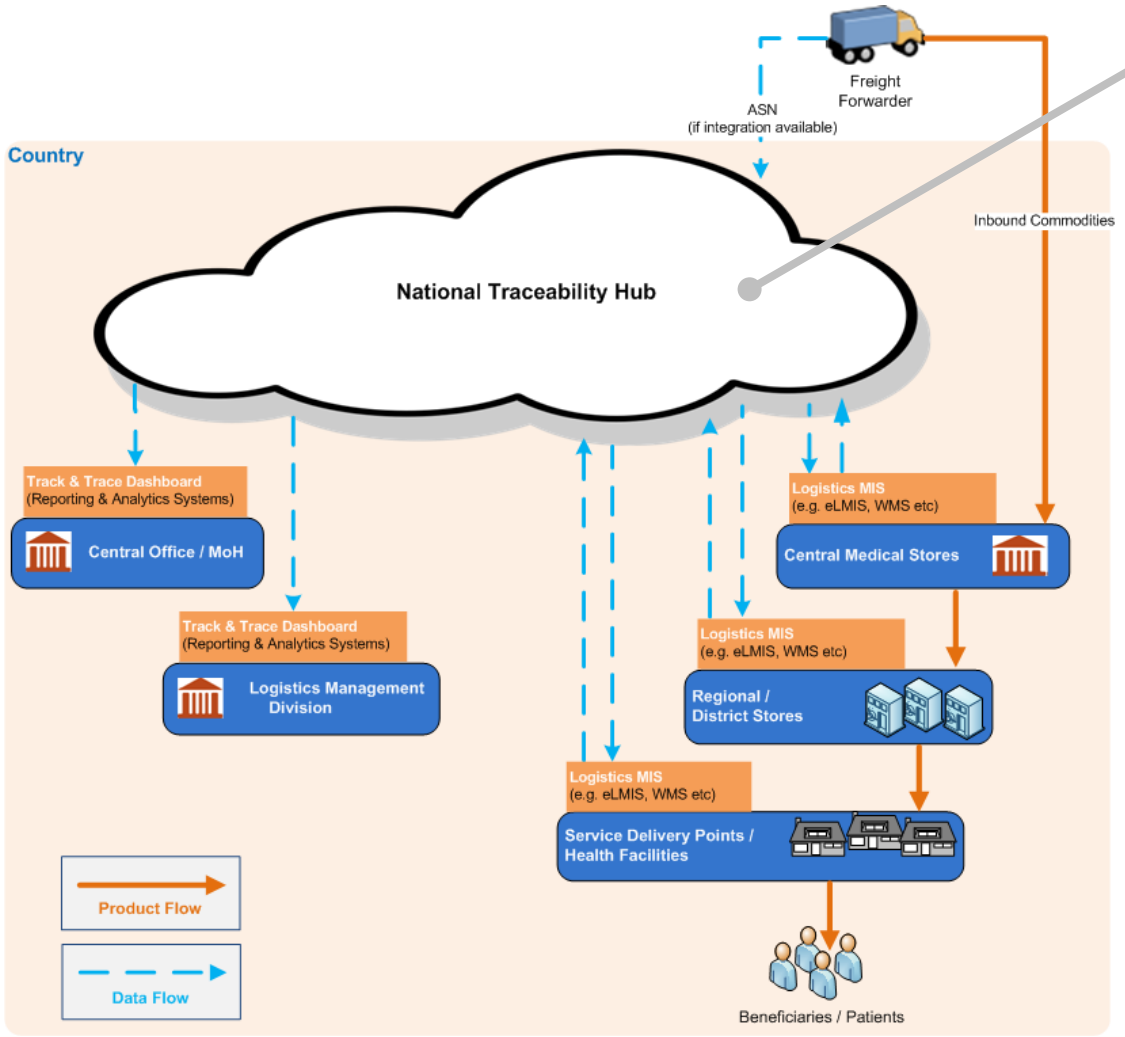
Centralized Model: Leverages Existing Tech Landscape



Batch Level Traceability

Current ERP, LMIS or WMS can be leveraged, if following capabilities exist

- Ability to manage product and facility master data
- Ability to capture batch numbers
- Ability to capture batch level events that move products within facilities in-country

Authentication

Current ERP, LMIS or WMS can be leveraged, if following capabilities exist

- Ability to retain inbound event data as commodities enter the country & the traceability hub
- Ability to validate batch/serial #s against the retained event data

Track and Trace

Current ERP, LMIS or WMS can be leveraged, if following capabilities exist

- Ability to manage product and facility master data
- Ability to capture batch numbers & serial numbers
- Ability to capture serial number level events that move products within facilities in-country

Discussion

- How do you anticipate you could use this tool?
- Does this approach cover all the key areas where you will need preliminary support?
- Are there any key stakeholder groups missing?
- What work products listed will be the most important for your country? What are the gaps where additional support will be needed?

Closing remarks

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