The Intersection of Theory and Action: A Framework for Traceability & Rwanda's Implementation Journey

USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM
Procurement and Supply Management
About Us

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Why do we care about global standards?

- National identification and classification structures do exist, but to interact with external trading partners (e.g. manufacturers, distributors, procurement agents, donors, export clients) you need to speak a common language.

- Within a country, global standards enable interoperability across disparate systems in a given sector by having one reference code to associate items or products across different stakeholder groups.
GS1 standards enable traceability in the healthcare supply chain.

**Identify: GS1 Standards for Identification**

- GLN Global Location Number
- GTIN Global Trade Item Number
- SSCC Serial Shipping Container Code
- GRAI Global Returnable Asset Identifier
- GIAI Global Individual Asset Identifier
- GSRN Global Service Relation Number

**Capture: GS1 Standards for Barcodes & EPC/RFID**

- GS1 Barcodes
  - EAN/UPC
  - GS1-128
  - ITF-14
  - GS1 DataBar
  - GS1 DataMatrix
  - GS1 QR Code
  - GS1 Composite Barcode
- GS1 EPC/RFID
  - EPC HF Gen 2
  - EPC UHF Gen 2

**Share: GS1 Standards for Data Exchange**

- Master Data Global Data Synchronisation Network (GDSN)
- Transactional Data eCom (EDI)
- Event Data EPC Information Services (EPCIS)
Global standards enable traceability of health commodities across the supply chain

**ADDRESS**

- SF or stolen product detected in the legitimate supply chain
- Theft or diversion of products from the legitimate supply chain
- SF or stolen product that is obtained by the patient/end user

**IMPROVE**

- Accuracy and efficiency of procurement operations
- Efficiency of “reverse” logistics processes (e.g., those used for returns, recalls)
- Visibility of product “status” (e.g., expiry, recalls)
- Efficiency of inventory management and distribution
- Efficiency of payment and payment monitoring processes
- Pharmacovigilance and control of treatment outcomes

**ENABLE**

- Visibility into where the product is within the supply chain
- Visibility to decrease or eliminate reimbursement fraud
- Harmonized trade/customs clearance procedures for pharmaceutical products

**Content Source:** GS1 Global Office

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**USAID Global Health Supply Chain Program**
Serialization enables identification with increased precision

<table>
<thead>
<tr>
<th>Feature</th>
<th>Global Trade Item Number (GTIN)</th>
<th>GTIN + Batch/Lot</th>
<th>GTIN + Serial Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low-precision identification</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medium-precision identification</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>High-precision identification</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Item exists in multiple locations at the same time</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Item exists in only one location at the same time</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Enables inventory control</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Enables anti-substandard and falsified (SF) measures</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Enables product recall</td>
<td>All units of a given GTIN</td>
<td>All units of a given GTIN + batch/lot</td>
<td>Specific unit with a matching GTIN + serial number</td>
</tr>
</tbody>
</table>

USAID Global Health Supply Chain Program
There are different approaches to achieving these objectives

Safe & Secure Supply Chain

Verification
- Is the item to be dispensed/used genuine?
- Verify Item
  - Is the item identifier valid?
- Authenticate Item
  - Does the item have the expected overt or covert security features?

Traceability
- Is the chain-of-custody or chain-of-ownership of the item intact?
- Track Item
  - Where is the item now, and where is it going?
- Trace Item
  - Where did the item come from, and who had custody/ownership of it?
Why we developed this framework

- Intended to compliment the GS1 Regulatory Roadmap by providing guidance beyond regulatory and into supply chain
- Targeted for the unique needs of the countries we support:
  - Limited awareness and use of global standards today
  - High risk of sub-standard or falsified (SF) medicines
  - Limited resources and competing priorities for health sector resources
  - Government-owned public-sector supply chains
  - Emerging local manufacturing environment
- Aim to provide step-by-step guidance to support specific investment in workplans and country strategies
USAID GHSC-PSM’s Traceability Planning Framework

**The “Why”**

**Awareness and Advocacy**
Raise awareness of global standards and traceability and what it takes for implementation.

**Vision and Strategy**
Develop a declaration of the reason for implementing traceability, establish short-term and long-term objectives and goals, and identify what strategic initiatives need to be undertaken to launch the work.

**Architecture**
Develop data and system models to enable implementation of the stated vision.

**Policy**
Define and develop policies that enable implementation of the stated vision.

**Implementation Plan**
Use a management tool that details the critical steps, milestones, and resources required to execute on the strategy.

**The “What”**

**The “How”**

USAID GHSC is supporting GS1 + traceability TA in a number of countries
Each country will develop an implementation plan based on their vision and strategy.

Achievable timeframe

1st compliance date

+ 1 to 2 year(s)

+ 2 to 3 years
What does it take? A holistic approach that includes...

- Governance & Advocacy
- Regulatory & Policy
- Supply Chain Operations
- Systems & Technology
- Service Delivery
Rwanda’s Implementation Journey
Our starting point

Mandate from National Pharmaceutical Sector Strategic Plan (NPSSP) 2018 – 2024

- Build and enforce a QA system to ensure safety, effectiveness and efficacy of health commodities and technologies from manufacturers to consumers
- 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

Gap

To improve monitoring of product quality throughout the value chain, it is critical to improve data accuracy, data capture and efficiency in supply chain operations

Intervention

MOH-led initiative to implement global standards for product identification and data capture
Progress to date

The “Why”
- Awareness and Advocacy
  Raise awareness of global standards and traceability and what it takes for implementation.

The “What”
- Vision and Strategy
  Develop a declaration of the reason for implementing traceability, establish short-term and long-term objectives and goals, and identify what strategic initiatives need to be undertaken to launch the work.
- Architecture
  Develop data and system models to enable implementation of the stated vision.
- Policy
  Define and develop policies that enable implementation of the stated vision.

The “How”
- Implementation Plan
  Use a management tool that details the critical steps, milestones, and resources required to execute on the strategy.

Complete
- Awareness and Advocacy

Reviewing
- Vision and Strategy

Drafting
- Architecture
- Policy
- Implementation Plan
Advocacy, awareness & strategy development workshop

- Sponsored by the Minister of Health
- Hosted in June 2018
- Participation from 20 organizations from government, service delivery, private sector, donors, implementing partners, and GS1 Kenya
In May 2019, MOH endorsed the National Vision & Strategy

Through this plan we aim to:

- Decrease the presence of substandard and falsified (SF) medications
- Ensure the quality and desired efficacy of pharmaceuticals
- Promote trust in the pharmaceutical sector and healthcare system
- Provide visibility of product status across the supply chain
- Create supply chain efficiencies from manufacturers to patient receipt
- Increase patient safety
Rapid national healthcare market assessment

- 50% of market from India – already complaint!
- China – no compliance
- EU – partial compliance
- USA – partial compliance
- Kenya
- 25 importers
- 120 wholesalers

Supply Market

- No Existing Requirements for product identification & labelling

Regulatory & Procurement

Information Systems

- PRIMS (DRIS)
- One Network (eLMIS)
- SageL500 (WMS)
- Ishyiga (Ordering / Revenue)

Service Delivery

- 1 Central Medical Store
- 48 hospitals
- 30 district pharmacies
- 542 health centres
Minimizes falsified or stolen medicines in the legitimate supply chain

Provides visibility into custody / ownership throughout the supply chain

Minimized reimbursement fraud

Provides visibility into product status (e.g. expired, recalled)

Enables efficient inventory management at central level & at the point of dispense
Currently establishing a governing body

Rwanda FDA/MOH

Steering Committee (Proposal)
- Rwanda FDA
- MOH Representatives
- Distributors Association
- Pharmacies Association
- Private Sector Federation
- Donor Agencies Representatives

Technical Committee (Proposal)
- Rwanda Public Procurement Authority
- Rwanda Information Systems Authority
- Rwanda Bureau of Standards
- Rwanda Biomedical Centre

Secretary (GHSC-PSM)
Next steps

• Formalize the governance structure for traceability implementation
• Draft legal frameworks and solicit stakeholder input
• Developing a national product catalog for all public health commodities
• Complete health information systems architecture assessment
  — Which systems and technologies in place support track and trace? What are the gaps?
• Develop 3-5 year costed implementation plan
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