Global Standards for Supply Chain Data Visibility

USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM
Procurement and Supply Management
Objectives

- To raise awareness of and sensitize stakeholders to GS1 standards for health care
- To understand the relevance of GS1 standards across the health care supply chain
- To understand the relevance of GS1 standards to enabling pharmaceutical traceability
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<th>Slide</th>
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<td>GS1 Global Standards Introduction</td>
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</table>
Foundations of Global Standards
Public Health Supply Chains Are Challenged by …

• Poor data visibility, because items and products are identified in non-standard ways
  o Proprietary identification numbers that are reassigned at various points in the supply chain
  o Identification that is inconsistent across procurement agencies and supply chain stakeholders to the end user

• Lack of standardization in processes and operations, because of inconsistent packaging labels
  o Multiple barcodes
  o Different types of barcodes
  o No barcodes

... WHICH RESULT IN RISK TO SUPPLY CHAIN SECURITY.
GS1 Standards in the Health Care Value Chain

- GS1 standards are enabling health care providers to uniquely identify products, patients, caregivers, assets, and locations for transparent processes across the health care value chain.

- Global standards — a common language for identification, data capture, and data exchange — are the basis for global trade, verification, and traceability.

- Use of GS1 standards in health care supports traceability of products from the manufacturer to the patient, contributes to detect counterfeit products, helps to prevent medication errors, enables effective recalls, and supports clinical processes.
Lack of Standards in Daily Life Is Inefficient and Annoying
In Health Care, It Is Inefficient and Dangerous!

- Multiple bar codes on one package: Which one to scan?
- Different types of bar codes: inconsistent, incompatible.
- No bar code: Need to bar code, repackage, relabel.
Our Reality Is That We Operate in a Global Environment

Source: APEC Toolkit
So, How Are Global Standards Relevant?

• 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 sector by having one reference code to associate items or products across different stakeholder groups.
GS1 Global Standards Introduction
The Need for Global Standards in Health Care

Diverging country requirements
Manufacturing headache

“CUSTOMIZED ACTIONS MEAN COSTS!!
Harmonisation of regulatory requirements and data standards will enable efficiency of a global product offering. Otherwise, complexity and cost will continue to raise.”

— Senior executive, MD company

Content Source: GS1 Global Office
GS1 — an International Standards Organization

- More than 1 million companies worldwide use GS1 standards.
- 25 industries are served across 150 countries.
- Barcodes are scanned more than 6 billion times per day globally.
- 115 member organizations around the world.

Content Source: GS1 Global Office
GS1 has Recognized Non-Governmental Organization Status by the United Nations

Dear NGO Representative,

I am pleased to inform you that the Economic and Social Council (ECOSOC) at its Substantive Session of July 2011 adopted the recommendation of the Committee on Non-Governmental Organizations (NGOs) to grant Special consultative status to your organization “GS1”. On behalf of all staff of the Non-Governmental Organizations Branch, please accept our heartfelt congratulations.
GS1 Standards for Health Care

Identify: GS1 Standards for Identification

Capture: GS1 Standards for Barcodes & EPC/RFID

Share: GS1 Standards for Data Exchange

Content Source: GS1 Global Office
GS1 Standards Across the Entire Supply Chain

- Improved production planning, packaging, and supply processes
- Simplification and accuracy improvement in warehousing, distribution, and logistics processes
- Automatic verification in dispensing and administration processes, which reduces medical errors
- More accurate and efficient supply chain management
- Enabling traceability and authentication (counterfeiting, product recalls, etc.)
- Enabling regulatory compliance
- Improving patient safety and supply chain efficiency!
Product Labeling and Identification
Automatic Identification & Data Capture (AIDC)

AIDC refers to the methods of *automatically identifying* objects, *collecting data* about them, and *entering that data* directly into computer systems (i.e., without human involvement).
The Vision of AIDC for Health Care

EVERY item has
ONE set of key identification data carried in
ONE data carrier
that is able to be scanned by EVERYONE
at every key process step …
Barcode Scanning in the Supply Chain Improves Data Quality

Manual vs. automated data entry

1 keystroke (input) error in every 300-500 keystrokes

versus

1 error in 350,000 on the low end (linear symbology)

to

1 error in 10,500,000 on the high end (2D/Matrix symbologies)
Position — GS1 DataMatrix vs. GS1 QR Code

**GS1 Healthcare 2D Data Carrier Recommendation Summary**

<table>
<thead>
<tr>
<th>GS1 Keys for:</th>
<th>GS1 DataMatrix</th>
<th>GS1 QR Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Trade Item Identification</td>
<td>![Checkmark]</td>
<td>![X]</td>
</tr>
<tr>
<td>• GTIN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• GRAI</td>
<td>![Checkmark]</td>
<td></td>
</tr>
<tr>
<td>• GIAI</td>
<td>![Checkmark]</td>
<td></td>
</tr>
<tr>
<td>• SSCC*</td>
<td>![Checkmark]</td>
<td></td>
</tr>
<tr>
<td>b) Other Identification use cases</td>
<td>![Checkmark]</td>
<td>![Checkmark]</td>
</tr>
<tr>
<td>• GLN</td>
<td>![Checkmark]</td>
<td>![Checkmark]</td>
</tr>
<tr>
<td>• GDTI</td>
<td>![Checkmark]</td>
<td>![Checkmark]</td>
</tr>
<tr>
<td>• GSRN</td>
<td>![Checkmark]</td>
<td>![Checkmark]</td>
</tr>
<tr>
<td>• ...etc.</td>
<td>![Checkmark]</td>
<td>![Checkmark]</td>
</tr>
</tbody>
</table>

*NOTE: This paper discusses use of GS1 2D/Matrix Data Carriers and does not alter present policy on use of 1D/Linear. At present SSCC is only used with the GS1-128 1D/Linear Data Carrier. SSCC is included above for future use when applicable.
The Foundation: GS1 Identification Keys

- Unique
- Non-significant
- International
- Secure
- Foundational

Global Trade Item Number (GTIN)
   Item Identifier

Serial Shipping Container Code (SSCC)
   Logistics Unit Identifier

Global Location Number (GLN)
   Location Identifier

And there are more …

Content Source: GS1 Global Office
Global Trade Item Number (GTIN)

- Used to identify any item upon which there is a need to retrieve pre-defined information that may be priced, ordered, or invoiced at any point in any supply chain.
- GTIN is an umbrella term for all GS1 “trade item” identification numbers.
- A GTIN may use the GTIN-8, GTIN-12, GTIN-13, or GTIN-14 numbering structure, but GTIN-14 is becoming more common for health care.
Anatomy of a GTIN-14 … an Example

- **I** = Indicator
- **C** = Check Digit
- **P** = Item Number
- **C** = GS1 Company Code
- **C** = GS1 Country Code for Pakistan
- **I** = GS1 Global Office
- **C** = GS1 Global Office
- **C** = GS1 Global Office

**Assigned by GS1 Global Office**

**Assigned by GS1 Pakistan**

**Assigned by Brand Owner**

Content Source: GS1 Global Office
Different Trade Item Packaging Levels Require Different GTINs

Content Source: GS1 Global Office
Additional GS1 Application Identifiers (AI)

- Enable encoding of additional information other than the product identification into a barcode
- The GS1 General Specification includes 100+ AIs for various use cases and sectors
- In health care, these are the four most used data elements:

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>GTIN</td>
</tr>
<tr>
<td>10</td>
<td>Batch/Lot Number</td>
</tr>
<tr>
<td>17</td>
<td>Expiration Date</td>
</tr>
<tr>
<td>21</td>
<td>Serial Number</td>
</tr>
</tbody>
</table>

*Note: Other than certain efficiency recommendations within the GS1 General Specifications, the order of AIs is not significant and should not be mandated.*
Item Identification and Select Other Item Information Must Be Captured in a Data Carrier

**GS1 128-Linear Barcode**

![GS1 128-Linear Barcode Image]

- GTIN-14: 1022222233334
- Expiry Date: 091231
- Batch Number: A1345B
- Serial Number: 1234

**GS1 2D DataMatrix Barcode**

![GS1 2D DataMatrix Barcode Image]

- (01) 20887511007346
- (17) 150331
- (10) A1B2C3D4E5
- (21) 123456789
The Globally Harmonized Approach

*Example from secondary pack*

*Data Matrix — Coding proposal derived from GS1 standards*

- Global Product Code assigned by manufacturer (GTIN): 14 digits
- Unique serial number (randomized): up to 20 alphanumeric characters
- Expiry date: 6 digits (YYMMDD)
- Batch number: up to 20 alphanumeric characters

GTIN: (01) 08699546010011  
Batch: (10) TRT08E3  
Expiry: (17) 151228  
S/N: (21) 583053774154
• India Director General for Foreign Trade seeks to ensure quality and protect brand image of pharmaceutical products exported from India.

• With effect from 10 January 2015, all drugs with manufacturing date on or after 10 January 2015 can be exported only if both the tertiary and secondary packaging carry barcoding as applicable.

• This means that pharmaceuticals imported from India already should be compliant!
As a Result, Many Trade Items in Countries Are Already Compliant

**Tertiary Pack Examples**

![Tertiary Pack Example Image]

**Secondary Pack Examples**

![Secondary Pack Example Image]
Scanning and Identification Keys in Action

ERP Entries

- GTIN: [Blank]
- EXPIRATION: [Blank]
- BATCH/LOT: [Blank]

GTIN: 0110857674002017
BATCH/LOT: 123456
SERIAL: 123456

Content Source: GS1 Global Office
Product Master Data Enables Use of GTIN (ex. Central Medical Stores)

<table>
<thead>
<tr>
<th>GTIN Number</th>
<th>Central Medical Stores Product Code</th>
<th>Description</th>
<th>Shelf Life</th>
<th>UOM</th>
<th>Length</th>
<th>Length UOM</th>
<th>Width</th>
<th>Width UOM</th>
<th>Height</th>
<th>Height UOM</th>
</tr>
</thead>
<tbody>
<tr>
<td>58904093822198</td>
<td>FP00XX</td>
<td>Ethinylestradiol/Levonorgestrel 0.03/0.15 mg Tablet, Blister, 28 Tablet, Case [Mylan] [Zinnia F]</td>
<td>36</td>
<td>CS</td>
<td>0.50</td>
<td>m</td>
<td>0.30</td>
<td>m</td>
<td>0.15</td>
<td>m</td>
</tr>
</tbody>
</table>

*illustrative and simplistic

Content Source: GS1 Global Office
Product Master Data Enables Use of GTIN (ex. Facility)

<table>
<thead>
<tr>
<th>Field</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>GTIN</td>
<td>18904093822190</td>
</tr>
<tr>
<td>Description</td>
<td>Ethinylestradiol/Levonorgestrel 0.03/0.15 mg Tablet, Blister, 28 Tablet, Each</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Mylan Laboratories Ltd.</td>
</tr>
<tr>
<td>Manufacturer GLN</td>
<td>8906000990018</td>
</tr>
<tr>
<td>Brand Name</td>
<td>Zinnia F</td>
</tr>
<tr>
<td>Market Authorization</td>
<td>FDAXX.00</td>
</tr>
<tr>
<td>ATC/DDD Code</td>
<td>G03AB03</td>
</tr>
<tr>
<td>Reimbursement Price</td>
<td>USD 26</td>
</tr>
</tbody>
</table>
Global Location Number (GLN)

- The GLN is used to identify physical locations and legal entities
- GLNs are used when there is a need to retrieve pre-defined information to improve the efficiency of communication with the supply chain
- GLNs are a prerequisite for data sharing using the GS1 standard
- The GLN is constructed as follows, and can be from the same company prefix as the GTIN:

```
GS1 Company Prefix  Location reference  Check Digit
N₁  N₂  N₃  N₄  N₅  N₆  N₇  N₈  N₉  N₁₀  N₁₁  N₁₂  N₁₃
```

Content Source: GS1 Global Office
GLNs in Barcodes

• In business operations, GLNs are meaningless if they are not associated with a particular function or purpose.

• The specific AI indicates the particular function of the location number that is represented in the bar code symbol, e.g.:
  – (AI 410) “Ship to – Deliver to” GS1 GLN
  – (AI 411) “Bill to – Invoice to” GS1 GLN
  – (AI 414) GS1 GLN to identify a physical location
  – (AI 415) GS1 GLN of the invoicing party

• GLNs are used in regulations on traceability!
  – Argentina, Turkey, Egypt, etc.
The GLN in Use ... an Example

Company Prefix 60312345

Warehouse
GLN: 60301234500001

Clinic
GLN: 6031234500065

Pharmacy
GLN: 6031234500017

Community Health Post
GLN: 6031234500005
Master Data Management
GS1 Standards for Sharing Supply Chain Data

**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
- GSIN Global Service Relation Number

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

- **GS1 Barcodes**
  - EAN/UFC
  - GS1-128
  - ITF-34
  - GS1 DataBar
  - GS1 DataMatrix
  - GS1 QR Code
- **GS1 EPC/RFID**
  - GS1 Composite Barcode
  - 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)

**Interoperability**

- Item Master Data
- Location Data
- Item/Shipments Tracking
- Traceability
- Product Recall/Withdrawal
- Pedigree
- Purchase Order/Ship/Advice/Invoice

Content Source: GS1 Global Office
# Three Kinds of Shared Data in Health Care Supply Chains

<table>
<thead>
<tr>
<th>SUPPLY CHAIN INFORMATION DATA TYPES</th>
<th>DEFINITION</th>
<th>EXAMPLES OR DESCRIPTION</th>
</tr>
</thead>
</table>
| **MASTER DATA**                    | ITEM: product identifiers and associated descriptive attributes  
  LOCATION: facility (legal entity) identifiers and associated descriptive attributes | ITEM: Manufacturer, brand name, item description, unit of measure, net content, shelf life  
  LOCATION: Address, contact information, role |
| **TRANSACTION DATA**               | Information about production, planning ordering, delivering, paying, and other transaction-related processes that occur through the supply chain | Order quantity, units sold, stock on hand, forecasted units, price |
| **EVENT DATA**                     | Information about the physical movement and status of products as they move through the supply chain | Commissioning, shipping, receiving, decommissioning |
What Is Master Data?

• Item-, entity-, or location-related data that is created by the owner of that item or entity.
• The data that is needed by the recipient to perform operational and commercial processes.
• Product-related data or characteristics are referred to as ATTRIBUTES.
• Unique reference numbers* are the keys that are used to access master data across multiple systems, applications, or processes.
• Hierarchies are the magic behind health care analytics — the ability to define roll-up and drill-downs of information.

*For items, Global Trade Item Number (GTIN)
*For entities, Global Location Number (GLN)
Content Source: GS1 Global Office
Where Do We Use Master Data?

- Planning
- Manufacturing
- Logistics
- Warehouse
- Clinic
- Pharmacist
- Procurement
- Regulatory
- Customs
- Distribution
- Insurance
# Data Errors in Health Care

## U.S. Department of Defense Study

<table>
<thead>
<tr>
<th>% of Total Data Error</th>
<th>Manufacturer</th>
<th>Distributor</th>
<th>GPO</th>
<th>Health Care Provider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Missing Middle Levels of Packaging</td>
<td>15-20%</td>
<td>1-4%</td>
<td>20-25%</td>
<td>15-25%</td>
</tr>
<tr>
<td>Hard “Packaging Quantity” Errors</td>
<td>1%</td>
<td>1%</td>
<td>2%</td>
<td>2-5%</td>
</tr>
<tr>
<td>Unit of Measure Confusion/Misuse</td>
<td>2-6%</td>
<td>1-3%</td>
<td>2-5%</td>
<td>Unknown</td>
</tr>
<tr>
<td>Missing Packaging — Not Middle Level</td>
<td>3-8%</td>
<td>3-8%</td>
<td>3-7%</td>
<td>5%</td>
</tr>
<tr>
<td>Manufacturer Name Problems</td>
<td>NA</td>
<td>2-5%</td>
<td>1-4%</td>
<td>30%</td>
</tr>
<tr>
<td>Obsolete Products</td>
<td>1-4%</td>
<td>2-5%</td>
<td>1-8%</td>
<td>5-15%</td>
</tr>
<tr>
<td>Missing Product Brand Names</td>
<td>2-5%</td>
<td>5-10%</td>
<td>5-10%</td>
<td>20-25%</td>
</tr>
<tr>
<td>Incomplete Item Descriptions</td>
<td>5-15%</td>
<td>3-12%</td>
<td>5-15%</td>
<td>10-20%</td>
</tr>
<tr>
<td>Wrong Customer Unit Prices</td>
<td>Unknown</td>
<td>1-2%</td>
<td>NA</td>
<td>1-2%</td>
</tr>
<tr>
<td>Customer Paid More Than Lowest Contract Price</td>
<td>NA</td>
<td>Unknown</td>
<td>NA</td>
<td>3-6%</td>
</tr>
</tbody>
</table>

Source: [https://www.gs1.org/docs/healthcare/events/291105/KG_HUG_301105.pdf](https://www.gs1.org/docs/healthcare/events/291105/KG_HUG_301105.pdf)
The Cost of Data Errors

Catalog Disparities
- Incorrect Item Data: 30%
- Costs: US$60 to $80 per error to correct
- Time Lost: 25 minutes/SKU/year

Invoice Errors
- 60% invoices with errors, of which, 43% have deduction costs
- To Correct: US$40 to $400 to reconcile

Lost Business
- Product Roll-in: About 4 weeks
- Lost Sales: 3.5% due to inaccurate data

- Source: Supply Chain Management Review — Synchronization: a cure for bad data (INNOVATIONS: New ways of thinking about supply chain management)
- Link to GDSN cases studies: http://www.gs1.org/standards/gdsn/case-studies
Products vs. Trade Items

Product
An object with a defined set of attributes or characteristics

Trade Item
Individual instances of a product with some unique characteristics (e.g., manufacturer, brand name, pack configuration/design)

Why differentiate?
Managing price, quality, distribution, and recalls needs to happen at the item level!
What Is Master Data Management (MDM)?

• MDM is, at its most basic, the process of linking identity data and reference data across multiple IT systems into a single, consistent point of reference. That single point of reference could be an item, location, or patient code.

• A more formal, all-encompassing definition of master data management is this:
  – MDM comprises the processes, governance, policies, standards, and tools that consistently define and manage the critical data of an organization to provide a single point of reference.

• Managing codes or identifiers is the foundation of MDM. If you can’t do that well, you won’t be able to succeed in the complex task of managing reference data.

• MDM seeks to ensure that an organization does not use multiple versions of the same reference data in different application systems or parts of its operations.

• Global Health Supply Chain Program–Procurement and Supply Management (GHSC-PSM) project Product Master Data Reference Guide: https://www.ghsupplychain.org/PMDMReferenceGuide

Important! MDM is not an IT function. It is a business strategy that can be optimized with the appropriate use of enabling technologies.

Source: Health Catalyst
Why Do We Care About MDM?

• Large organizations with a multitude of processes and systems to process transactions are often faced with the challenge of not having a “Source of Truth” for their master data.

• Data is an enterprise asset that is used to make strategic decisions across the supply chain, from registration to service delivery.

• 80 percent of data in transactions is master and reference data.

• Alignment of master data is the basis for trade and traceability.
### Foundational Pillars of an MDM Program

<table>
<thead>
<tr>
<th>Data Governance</th>
<th>Data Architecture</th>
<th>Data Quality Mgt.</th>
<th>Data Storage and Operations</th>
<th>Data Security</th>
<th>DI&amp;I</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Data Governance Strategy</td>
<td>- Reference Data Model</td>
<td>- Data Quality Audits</td>
<td>- Data Lifecycle Management</td>
<td>- Data Sharing Agreements</td>
<td>- Architectural Standards</td>
</tr>
<tr>
<td>- Data Governance Operations</td>
<td></td>
<td>- Data Validation Rules and Reasonability Checks</td>
<td>- Data Auditing, Logging, and Reporting</td>
<td></td>
<td>- Integration and Data Sharing</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Historical Data, Archiving, and Retention</td>
<td></td>
</tr>
</tbody>
</table>

GS1 Master Data Standards

- GS1 Barcodes
- GS1 EPC/RFD

**Company & Location**
- Global Location Number (GLN)

**Product**
- Global Trade Item Number (GTIN)
- Globalized Global Trade Item Number (GGTIN)

**Logistics & Shipping**
- Global Shipping Container Code (GSCC)
- Global Shipment Identification Number (GSIN)
- Globalized Shipment Identification Number for Consignment (GSINC)

**Assets**
- Global Individual Asset Identifier (GAI)
- Global Retumetric Asset Identifier (GRAI)

**Services & More**
- Global Service Relation Number (GSRN)
- Global Document Type Identifier (GDTI)
- Global Coupon Number (GCM)

**Master Data**
- Global Data Synchronization Network (GDSN)

**Transactional Data**
- eCom (EDI): EANCOM, GS1 XML

**Event Data**
- SEC Information Services (EPCIS)

Content Source: GS1 Global Office
Opportunities for Global Data Synchronization Network (GDSN)

• Single source of truth on master data: the supplier!
• Get a consistent set of attribute data from all trading partners
• Near real-time updates if product data changes
• Opportunity to receive registration (marketing authorization) information in a standard and consistent manner
• GHSC-PSM will have the same identifying data as United Nations Populations Fund (UNFPA), Global Fund, and others, improving cross-agency procurement analytics
The GDSN Is the GS1 Standard for Master Data Exchange

- 39 certified GDSN data pools
- 2.1+ million health care products
- 3,500+ suppliers
- Published to 96 target markets
The GDSN Opportunity for Global Health

GS1 Global Data Synchronisation Network™ (GDSN®)

Manufacturers are able to provide data to all kinds of databases and all kinds of customers (hospitals, distributors, wholesalers, GPOs) simultaneously, with a single connection.
Data Integration and Interoperability (DI&I)

DI&I Platform Architectural Approach

DI&I Integration and Data Sharing

DI&I Architectural Standards

DI&I Historical Data, Archiving, and Retention
Traceability Overview
Holistic Approach
### GS1 Standards Support a Number of Supply Chain Objectives

<table>
<thead>
<tr>
<th>ADDRESS</th>
<th>Supply Chain Security</th>
<th>Supply Chain Efficiency</th>
<th>Data Visibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF or stolen product detected in the legitimate supply chain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Theft or diversion of products from the legitimate supply chain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SF or stolen product that is obtained by the patient/end user</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accuracy and efficiency of procurement operations</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Efficiency of “reverse” logistics processes (e.g., those used for returns, recalls)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visibility of product “status” (e.g., expiry, recalls)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Efficiency of inventory management and distribution</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Efficiency of payment and payment monitoring processes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacovigilance and control of treatment outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visibility into where the product is within the supply chain</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Visibility to decrease or eliminate reimbursement fraud</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harmonized trade/customs clearance procedures for pharmaceutical products</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Content Source: GS1 Global Office
## GS1 Standards Enable Traceability of Items in the Supply Chain

<table>
<thead>
<tr>
<th>Feature</th>
<th>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>X</td>
<td>X</td>
<td></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>

Content Source: GS1 Global Office
Different Approaches to Achieving These Objectives

Safe and Secure Supply Chain

Verification
- Is the item that is 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?

Content Source: GS1 Global Office
Understanding Traceability

Traceability is the ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application, or location of the item under consideration.

The scope of a traceability implementation will depend on the maturity and vision of a specific implementation. Traceability can be implemented at the batch/lot or at the serialized trade item level. In either case, fundamental to traceability is the concept that, in parallel with the flow of the physical product, there has to be a flow of information about the product!
Understanding Verification

Product verification refers to checking at any single point in the supply chain that the unique identifier that is printed on the item is assigned by the product manufacturer. Countries can implement verification as part of a traceability mandate or as a point-of-dispense (e.g., check at a service delivery point) and/or point-of-use (e.g., check by the consumer or the patient) model at an end point in the supply chain.

Content Source: GS1 Global Office
Electronic Product Code Information Services (EPCIS): A GS1 “Share” Standard

Content Source: GS1 Global Office
What Is EPCIS?

• A GS1 standard that enables trading partners to share information about events — physical movement and status of products — through the supply chain.

• It does not replace enterprise resource processing (ERP), warehouse management system (WMS), or Track-and-Trace system; it is a complementary layer that offers interoperability between disparate systems.

• EPCIS is intended to be used in conjunction with the GS1 Core Business Vocabulary (CBV) standard. The CBV 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 to provide for querying of data by reducing the variation in how different businesses express common intent.
EPCIS Is an Open GS1 and ISO Standard

- Defines framework data model and interfaces for sharing data
- Enables services and solutions for supply chain visibility
- Data-carrier-neutral: works with Barcodes and/or RFID
- Approved as ISO/IEC 19987
- EPCIS is an open standard, not a product or service for sale
- U.S. Federal Drug Administration draft guidance points to EPCIS as a way to interoperably exchange pharmaceutical traceability data
- GS1 keys identify the what and where of visibility events.

Content Source: GS1 Global Office
Sharing Information on Events

• **WHAT** objects are the subject of event?
  – *Individual objects (SGTIN) or groupings (GTIN + Lot/batch)*

• **WHEN** did this event take place?
  – *Date, time, time zone*

• **WHERE** did this event take place?
  – *GLN of physical location and object’s subsequent whereabouts*

• **WHY** did this event take place?
  – *Business step, disposition, source/destination information*

**All captured in an EPCIS repository!**
EPCIS End-to-end Data Visibility

EPCIS enables tracking and tracing AND easy sharing of event data in real-time among trading partners upstream and downstream.

Content Source: GS1 Global Office
GHSC-PSM’s Global Standards and 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.

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

The “What”

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

The “How”

Check out our full implementation guidance resource on our website:
Illustrative Implementation Roadmap

A Trade Item and Location Identification

B MDM

C Trade Item Barcode Labeling and Scanning

D Transaction Data Exchange

E Logistic Unit Identification, Labeling, and Scanning

F Serial Number Management

G Event-based Data Exchange

Traceability

Verification

Illustrative example only. Each country will develop an implementation plan based on their vision and strategy.

Check out our full implementation guidance resource on our website:
What Does It Take? A Holistic Approach that Includes …

- Governance & Advocacy
- Regulatory & Policy
- Supply Chain Operations
- Systems & Technology
- Service Delivery
GS1 Standards Around the World
Global Identification of Pharmaceuticals

Source: GS1 Canada (as of July 2020)
Overview

- Proving the benefits of barcoding for vaccines has been launched in region of Arusha with one vaccine from Pfizer
- Project led by PATH and supported by GAVI

Initial Findings

- Labor savings foreseen across various business processes:
  - Tracking stock movement, counting, expiry date management, and ordering (50-60%)
  - Demand planning, data cleansing, and synchronization (2-5%)
  - Reverse logistics associated with the location, identification, return, and receipt of recalled health commodities (2-4%)

Source: Presentation Brian Taliesin, PATH at GS1 Healthcare Conference in Dubai, April 2016. Further reading: LINK
Nicaragua Pilot

Overview
• Main objective was to evaluate the benefit of barcode scanning on vaccine tracking and visibility
• Pfizer vaccine with GTIN, lot number, and expiry date in 2D DataMatrix
• On three different levels: from central store to regional to local
• Ministry of Health wants to extend to ALL vaccines

Results
• Adjustments reduces to 1:233 transactions
• 68 percent reduction in time needed for one transaction
• 100 percent stock visibility at all levels of the system
• Improved security with central data repository

Source: Presentation Rehana Wolfe, Pfizer at GSI Healthcare Conference in Berlin, April 2017. Further reading: [LINK]
Kenya — 2014 — Tender
Kenya Medical Supplies Agency Barcoding Requirement

**Status:** Agreement between GS1 Kenya and Kenya Medical Supplies Agency

**Scope:** Medical commodities

**Planned requirements**
- Packaging level: secondary
- Data carrier: Re-labelling by Kenya Medical Supplies Agency with GS1 barcodes

**Open point(s)/upcoming developments**
- Ministry of Health is driving discussions to establish a traceability solution, focusing on post-market surveillance
- Ongoing discussions in the national assembly about the formation of the Food and Drug Authority

Source: Presentation Rehana Wolfe, Pfizer at GS1 Healthcare Conference in Berlin, April 2017. Further reading: [LINK](#)
Rwanda

Scoping Regulation

**Status:** Rwanda national vision and strategy for pharmaceutical traceability endorsed by Minister of Health in June 2019

**Scope:** Pharmaceuticals

**Planned requirements**
- Requirements to be fully aligned to GS1 standard
- Stakeholder endorsement of the centralized track-and-trace model
- Planned implementation of a national product catalog for product master data in 2020

**Open points/upcoming developments**
- Terms of reference developed for the Traceability Steering Committee and supporting working groups
- Currently developing a phased traceability costed implementation plan
- In 2020, seek to establish of traceability architecture based on the chosen model; ongoing discussions around interoperability across existing systems in country
Nigeria Implementation

**Status:** Vision and strategy for traceability developed

**Scope:** Pharmaceuticals

**Planned requirements**
- Ongoing stakeholder engagement
- Ongoing assessment of current regulations and opportunities to incorporate GS1 standards
- Planned implementation of a national product catalogue for product master data in 2020

**Open points/upcoming developments**
- Seeking approval of a four-year Nigeria Pharmaceutical Traceability Work Plan, which comprises a four-phased approach to traceability: enabling environment (governance and policy); MDM; AIDC implementation; and serialized traceability.

Presented at GS1 Healthcare Conference, Nigeria, September 2019
Malawi

Developing Vision and Strategy

**Status:** Vision and strategy for traceability developed and under stakeholder review

**Scope:** Pharmaceuticals

**Planned requirements**
- Ongoing assessment of current regulations and opportunities to incorporate GS1 standards
- Planned implementation of a national product catalog for product master data in 2020

**Open points/upcoming developments**
- Seeking revision and input on the vision and strategy document for pharmaceutical traceability
- Focus on assessing current state of regulations, processes, data, and technology to inform future state and implementation plan

Presented at GS1 Healthcare Conference Nigeria September 2019
Zambia
Policy & Implementation

Status: Vision and strategy for traceability developed and under stakeholder review

Scope: Pharmaceuticals

Planned requirements
• Ministry of Health/ICT seeks to implement national drug registry in 2021, assessing opportunities to use GLN in facility/vendor registries

Open points/upcoming developments
• Received stakeholder feedback on vision and strategy for pharmaceutical traceability; under final review and will seek endorsement from Ministry of Health
• Medical Stores Limited currently implementing internal barcoding system and seeking opportunities to leverage GS1 data carriers from manufacturers
• Opportunity to reassess regulatory frameworks in support of driving standardization
• Zambian Medicine Regulatory Authority has also drafted a policy to include GLNs as a requirement at the point of submission for registration of dossiers that are awaiting signoff by the minister

Presented at GS1 Healthcare Conference, Nigeria, September 2019
Use Case: Ethiopia

Slides from Mr. Teddy Berihun, Senior Health Information Systems Advisor, USAID Ethiopia during GS1 Healthcare Conference in Lagos, 2019
The focus of Ethiopia’s regulatory system and supply chain is to consistently get quality products to people.

“Much of the [world’s] burden of disease can be prevented or cured with known, affordable technologies. The problem is getting drugs, vaccines, information and other forms of prevention, care or treatment—on time, reliably, in sufficient quantity and at reasonable cost—to those who need them.”

— World Health Organization

Infographic Credit: Global Financing Facility
A suite of information systems support the exchange of information throughout the supply chain

An overview of Ethiopia’s supply chain:

- **110+ million** Ethiopians
- **21,000+** unique health commodities
- **3,900+** facilities and **18,000+** health posts
- **194+** unique importers
- **837** unique supplier license holders
- Value of drugs approved for import by local importers **USD 225,744,174**
EFDA is building a technology infrastructure with the **Electronic Regulatory Information System (eRIS)** that support end to end supply chain visibility to provide one unbroken chain of action and information:

- **i-License** – used to apply for a certificate of competency to register and import products.
- **i-Register** – used to manage the market authorization process where an applicant seeks to register a medical product.
- **i-Import** – used to manage the import process for medical products, once registered in Ethiopia.
In addition to technology, traceability is being supported by policy

**Pharmaceutical Products Traceability Directive:**

1. **To protect the public from falsified, substandard, unregistered, expired, recalled or otherwise harmful pharmaceuticals**

2. **To improve efficiency in the pharmaceutical supply chain regulation**

3. **To develop a system in which the identification, authentication and traceability of a pharmaceutical product is guaranteed from manufacturers to importers, wholesalers, healthcare providers and retail outlets, and other points of dispense, and;**

4. **To enforce the mandatory requirements and the implementation of identification, authentication and traceability of pharmaceutical products.**
Scope of the *Pharmaceutical Products Traceability Directive*

- All pharmaceutical products registered in Ethiopia which are intended for human use; and
- All supply chain actors involved in the physical movement of pharmaceutical products, including but not limited to:
  - Manufacturers
  - Importers
  - Wholesalers
  - Healthcare providers
  - Retail outlets and other points of dispensing
The *Pharmaceutical Products Traceability Directive* is being implemented in four phases

**Phase 1**
- Unique identification (GS1) + labelling requirements

**Phase 2**
- Share standardized master product and location data

**Phase 3**
- Batch traceability

**Phase 4**
- Serialization/traceability of unique items

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GTIN 00314141999995
SN  10000000234
EXP 25 JAN 2015
LOT  987654321GFEDCBA
McKinsey Quantifies Supply Chain Issues in Health Care


The report is available at http://www.gs1.org/healthcare/mckinsey
Huge Cost Savings and Patient Safety Benefits When Adopting a Single Global Standard in Health Care

• “Implementing global standards across the entire healthcare supply chain could save 22,000-43,000 lives and avert 0.7 million to 1.4 million patient disabilities.”

• “Rolling out such standards-based systems globally could prevent tens of billions of dollars’ worth of counterfeit drugs from entering the legitimate supply chain.”

• [We] “estimate that healthcare cost could be reduced by $40 billion-$100 billion globally” with the implementation of global standards.

• “Adopting a single set of global standards will cost significantly less than two” — between 10 percent and 25 percent lower cost to stakeholders.

Ultimately, It’s All About …

... PATIENT SAFETY!

Photo credit: Wendy Tactuk, courtesy of CapacityPlus and IntraHealth International

Credit: Maggie Hallahan
Resources
Joint Donor Guidance on Data Standards for Suppliers

- Document is endorsed by Global Drug Facility (Stop Tuberculosis), Global Fund, UNFPA, United Nations Development Programme, and USAID/GHSC-PSM
- Collective group of agencies referred to as international procurement agencies
- Guidance on identification, data capture, and data sharing aligned with global standards
- Agency-specific timelines for implementation are included in Annex C
- Currently disseminated by respective agencies to suppliers through their own channels

Recommended Identification, Capture, and Master Data Sharing Specifications for Long-Lasting Insecticidal Nets

- Currently circulated on social media (Twitter, LinkedIn, etc.)
- Document covers new standards for identification, data capture, and data sharing to which long-lasting insecticidal nets manufacturers will be held accountable

• Guidance on the identification, sharing, and management of accurate product information throughout the product lifecycle in the supply chain.

• Accompanied by a Product MDM Toolkit.

• Contains normative references to standards and good practices of product MDM with a specific focus on GS1 global standards for health care supply chains.

• More information at http://ghsupplychain.org/globalstandards
Human Resources for Traceability Implementation

- The following tools have been designed for country programs and national authorities to adopt and adapt in resourcing in-country traceability implementation strategies:
  - Notional organizational diagram
  - Primary responsibilities and required skill set for the roles identified in the notional organizational diagram
  - Detailed job descriptions for traceability project manager, regulatory specialist, and supply chain MDM specialist roles
- Available in English and French

Available: https://www.ghsupplychain.org/GlobalStandardsRoleDescriptions
GS1 Supply Chain Information System (SCIS) Requirements

- The following tools have been designed for country programs that seek to procure SCISs that are compliant with GS1 standards:
  - GS1SCIS Requirements, including functional and technical requirements that form the basis for how specific SCIS provide GS1 capabilities
  - The GS1 SCIS Requirements Narrative that introduces the SCIS Requirements and how they can be used as a starting place for specific procurements across the SCIS spectrum

Available: [http://www.ghsupplychain.org/GS1SCISReqs](http://www.ghsupplychain.org/GS1SCISReqs)
Global Standards in Low- and Lower-Middle Income Settings: Policy Design Considerations to Address Domestic Manufacturer Needs

- Provides guidance and strategic considerations for national-level policymakers in low- and lower-middle income settings who are developing policies for pharmaceutical traceability to address the needs of domestic pharmaceutical manufacturers.

- Utilizes a case study approach to provide considerations for legislative design for traceability implementation.

- Explores people, process, and technology impact on local manufacturers on traceability implementation.

Business Case for the Implementation of Global Standards

- Document presents the business case for adoption and implementation of global standards product identification, location identification, and product master data.

- Discusses the current approach to product identification, party/location identification, and MDM in the global health supply chain.

- Provides guidance on identification, data capture, and data sharing that is aligned with global standards.

### Global Standards and Traceability Glossary of Terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>automatic identification and data capture (AIDC)*</td>
<td>A technology used to automatically capture data. AIDC technologies include barcodes, smart cards, biometrics, and radio frequency identification devices.</td>
</tr>
<tr>
<td>barcode*</td>
<td>A symbol that encodes data into a machine-readable pattern of adjacent, varying width, parallel, rectangular dark bars and light spaces.</td>
</tr>
<tr>
<td>batch/lot*</td>
<td>The batch or lot number associated with the product that is in production. The manufacturer considers relevant for traceability of the trade item. The data may refer to the trade item itself or to items contained in it.</td>
</tr>
<tr>
<td>brand owner*</td>
<td>The organization that owns the specifications of a trade item, regardless of where and by whom it is manufactured. The brand owner is usually responsible for the management of the GTIN.</td>
</tr>
<tr>
<td>classification</td>
<td>A form of cataloging, or identifying, products that can be defined as a process for grouping products into categories based on an understanding of the essential properties and relationships between them. A classification system is used to group like products such as medical devices versus pharmaceutical drugs. Example classification systems are UNSPC, GPC, eCNS, and HTIC.</td>
</tr>
<tr>
<td>check digit*</td>
<td>A final digit calculated from the other digits of some GTIN identification keys. This digit is used to check that the data has been correctly imprinted. (See GTIN check digit calculation.)</td>
</tr>
<tr>
<td>concatenation*</td>
<td>The representation of several element strings in one barcode.</td>
</tr>
<tr>
<td>data architecture</td>
<td>Data architecture is composed of models, policies, rules, or standards that govern how data is stored, managed, and utilized in an information system.</td>
</tr>
<tr>
<td>data governance</td>
<td>The development, execution, and supervision of policies, programs, and practices that standards, collect, control, protect, deliver, and enhance the value of data and information assets.</td>
</tr>
<tr>
<td>data synchronization</td>
<td>The process of maintaining the consistency and uniformity of data instances across all consuming applications and storing devices.</td>
</tr>
<tr>
<td>Data Matrix*</td>
<td>A stand-alone, two-dimensional matrix symbology that is made up of square modules arranged within a perimeter finder pattern.</td>
</tr>
<tr>
<td>Global Location Number (GLN)*</td>
<td>The GTIN identification key used to identify physical locations or parties. The key comprises a GS1 Company Prefix, location reference, and check digit.</td>
</tr>
<tr>
<td>Global Trade Item Number (GTIN)*</td>
<td>The GTIN identification key used to identify trade items. The key comprises a GS1 Company Prefix, item reference, and check digit.</td>
</tr>
<tr>
<td>GS1</td>
<td>A neutral, not-for-profit, global organization that develops and maintains the most widely used supply chain standards in the world.</td>
</tr>
</tbody>
</table>

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This deck is supported by materials prepared by GS1. GS1 is a not-for-profit organization that develops and maintains global standards for business communication.

The USAID GHSC-PSM project provides commodity procurement and logistics services, strengthens supply chain systems, and promotes commodity security.

We support USAID programs and presidential initiatives in Africa, Asia, Latin America, and the Caribbean, focusing on HIV/AIDS, malaria, and population and reproductive health commodities.
## Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
<th>Acronym</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>AI</td>
<td>GS1 application identifier</td>
<td>GPO</td>
<td>Group Purchasing Organization</td>
</tr>
<tr>
<td>AIDC</td>
<td>automatic identification and data capture</td>
<td>GTIN</td>
<td>global trade item number</td>
</tr>
<tr>
<td>CBV</td>
<td>core business vocabulary</td>
<td>MDM</td>
<td>master data management</td>
</tr>
<tr>
<td>DI&amp;I</td>
<td>data integration and interoperability</td>
<td>SCIS</td>
<td>supply chain information system</td>
</tr>
<tr>
<td>EPCIS</td>
<td>electronic product code information services</td>
<td>SCC</td>
<td>serial shipping container code</td>
</tr>
<tr>
<td>ERP</td>
<td>Enterprise resource processing</td>
<td>UOM</td>
<td>Unit of measure</td>
</tr>
<tr>
<td>GDSN</td>
<td>global data synchronization network</td>
<td>UNFPA</td>
<td>United Nations Population Fund</td>
</tr>
<tr>
<td>GHSC-PSM</td>
<td>USAID Global Health Supply Chain Program—Procurement and Supply Management project</td>
<td>USAID</td>
<td>United States Agency for International Development</td>
</tr>
<tr>
<td>GLN</td>
<td>global location number</td>
<td>WMS</td>
<td>warehouse management system</td>
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</table>