Global standards - Barcodes and serialisation

Ulrike Kreysa, Vice-President Healthcare, GS1 Global Office
DCVMN, 25th September 2017, Seoul, Korea
Barcodes...part of our daily life

**Barcode** - a symbol that encodes data into a machine readable pattern of adjacent, varying width, parallel, rectangular dark bars and pale spaces.
Why standards?

Missing standards are in daily life inefficient and annoying...
..in Healthcare it is dangerous and inefficient!

- Multiple bar codes on one package – which one to scan?
- Different types of bar codes – inconsistency; incompatibility

Still often there is NO barcode – need to bar code; re-package; re-label
The Need for Global standards in Healthcare

Diverging country requirements = Manufacturing headaches

CUSTOMIZED ACTIONS CAUSE ADDITIONAL COSTS!!
GS1 by the numbers

1 million
over 1 million companies worldwide use GS1 standards

150 countries
25 industries served across 150 countries

6 billion
Barcodes scanned more than 5 billion times per day globally

112 MOs
112 Member Organisations around the world
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.

1 August 2011
Global automatic identification standards

GS1 Standards ...
6 billion ‘beeps’ per day

Product identification in Healthcare should be as universal as it is in the retail and grocery industries
Voluntary, Global Healthcare User Group

To lead the healthcare sector to the successful development and implementation of **global standards** by bringing together **experts** in healthcare to enhance **patient safety** and **supply chain efficiencies**.
The vision of GS1 Healthcare is to be the **recognised, open and neutral** source for regulatory agencies, trade organisations and other similar stakeholders seeking **input** and **direction** for **global standards** in healthcare for

- **patient safety**
- **supply chain security & efficiency**
- **traceability**
- **product data**
GS1: global system of standards to ensure visibility

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 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/Shipment Tracking
- Traceability
- Product Recall/Withdrawal
- Pedigree
- Purchase Order/Despatch Advice/Invoice

The Global Language of Business
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AIDC – Automatic Identification & Data Capture
Automatic Identification & Data Capture (AIDC)

“Automatic Identification and Data Capture (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).”

Wikipedia, 2009
## Manual versus automated data entry

<table>
<thead>
<tr>
<th>Manual</th>
<th>Automated</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 error in 350 Thousand (350,000)</td>
<td>1 keystroke (input) error in 350 Thousand (350,000)</td>
</tr>
</tbody>
</table>

1 keystroke (input) error in every 300 to 500 keystrokes
GS1 Identification Numbers

Product identifier = GTIN
Global Trade Item Number

Logistics unit identifier = SSCC
Serial Shipping Container Code

Location identifier = GLN
Global Location Number

And there are more …
Products
Foundation of the GS1 System...

GS1 Identification Numbers

Provide access to information held in computer files – Information about company/location, package, product, price, etc.

1234567891234

They are unique, non-significant and global
GTIN – Global Trade Item Number

...used on any item upon which there is a need to retrieve pre-defined information and that may be priced, or ordered, or invoiced at any point in any supply chain.

GTIN is an umbrella term for all GS1 “trade item” identification numbers. As noted a Global Trade Item Number may use the GTIN-8, GTIN-12, GTIN-13, or GTIN-14 numbering structure.
Anatomy of a GTIN-14...an example

- **C** = GS1 Country code for India
- **C** = GS1 Company code
- **I** = Indicator
- **P** = Item Number
- **C** = Check Digit
- 890 = GS1 Global Company prefix

Assigned by GS1 Global Office

Assigned by GS1 India

Assigned by Brand Owner

Calculated
How to get a company prefix?

• If you start to barcode your product you need a company prefix
• You can get that from any GS1 Member Organisation in the world
• Most organisations choose to license the company prefix from their local GS1 organisation or where they have their manufacturing site
• https://www.gs1.org/contact/overview
GS1 Application Identifiers...

...enable to encode additional information besides the product identification into a barcode.

The GS1 General Specification includes 100+ “Application Identifiers” (“Key Attributes” or “AI’s”) for various use cases & sectors, in Healthcare the general agreement is for these four:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>GTIN (Global Trade Item Number)</td>
</tr>
<tr>
<td>10</td>
<td>Batch / Lot</td>
</tr>
<tr>
<td>17</td>
<td>Expiry 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 AI’s is *not significant and should not be mandated*. 
The need to capture the product item ID and more information...

Linear GS1-128 barcode

2D GS1 DataMatrix barcode
Scanning & AIs in action...

ERP Entries

GTIN:   SERIAL:

EXPIRATION:  NYFUL01

BATCH/LOT:  192837

(01)10857674002017  10857674002017
(17)141120  20 Nov 2014
(10)NYFUL01  NYFUL01
(21)192837  192837
Serialisation

- **Serialisation is the assigning of unique, traceable numbers to individual items**
- While the GTIN allows you to identify a product as such, serialisation will allow you to identify each single package of this product!
- So far used from secondary packaging level upwards.
- But – it requires changes of packaging lines and processes (e.g. IT, quality, etc.) – which is costly and complex
- Nevertheless – it is the trend in regulations worldwide as it enables traceability
Serialisation of pharmaceuticals

= country developing requirement or requiring serial number
GS1 DataMatrix on pharmaceuticals

country developing requirements or requiring DataMatrix and/or using DataMatrix in pilots
Different packaging levels require different GTIN’s.
Ideally - identifiers and barcodes at all packaging levels

NOTE: Data carriers shown are for illustration purposes only!

Note: Images shown are for illustration example only, refer to local regulations and/or the latest version of the GS1 General Specification for more detail.
Allocation of GTIN’s

Brand owners (the vaccine manufacturer) allocate GTIN’s based on standardised allocation rules, for example:

- 1 GTIN = 1 product
- 1 product = 1 GTIN
- Different GTIN for each packaging level
- Some examples:
  - Change GTIN when pack of 20 becomes pack of 25
  - Add language, same GTIN
  - Change language, new GTIN
- **Never re-allocate a GTIN to another product!**
Special scanners are needed in Healthcare due to specific barcodes

Camera-based barcode scanners are needed in HC!!
Can read linear and 2D bar codes
Results: Of the 1832 successful scans performed in this evaluation, zero produced incorrect data. Five-millimeter barcodes were the slowest to scan, although only by 0.5 seconds on average. Barcodes with up to 50% fading had a 100% success rate, but success rate deteriorated beyond 60% fading. Curved barcodes took longer to scan compared with flat, but success rate deterioration was only observed at a vial diameter of 10 mm. Light conditions did not affect success rate or scan time between 500 lux and 20 lux. Conditions below 20 lux impeded the device's ability to scan successfully. Variability in scan times were observed across devices in all trials performed.
Locations
Global Location Number (GLN)

- The GLN can be 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.
- Some regulations require the manufacturer to identify e.g. their production place with a GLN.
- The GLN is constructed as follows from the same company prefix as the products:

<table>
<thead>
<tr>
<th>GS1 Company Prefix</th>
<th>Location reference</th>
<th>Check Digit</th>
</tr>
</thead>
<tbody>
<tr>
<td>N₁ N₂ N₃ N₄ N₅ N₆ N₇ N₈ N₉ N₁₀ N₁₁ N₁₂</td>
<td>N₁₃</td>
<td></td>
</tr>
</tbody>
</table>
GLNs in Symbols

• In business operations, GLNs are meaningless if they are not associated with a particular function or purpose.
• The specific Application Identifier indicates the particular function of the location number represented in the bar code symbol like e.g.

- "Ship to – Deliver to" GS1 Global Location Number (AI 410)
- “Bill to – Invoice to” GS1 Global Location Number (AI 411)
- GS1 Global Location Number to identify a physical location (AI 414)
- GS1 Global Location Number of the invoicing party (AI 415)
Logistic item
The SSCC is assigned for the life time of the **transport item** using Application Identifier (00)

The SSCC is constructed as:

<table>
<thead>
<tr>
<th>Extensio n Digit</th>
<th>GS1 Company Prefix</th>
<th>Serial reference</th>
<th>Check Digit</th>
</tr>
</thead>
<tbody>
<tr>
<td>$N_1$</td>
<td>$N_2 \ N_3 \ N_4 \ N_5 \ N_6 \ N_7 \ N_8 \ N_9 \ N_{10} \ N_{11} \ N_{12} \ N_{13} \ N_{14}$</td>
<td>(N_{15} \ N_{16} \ N_{17})</td>
<td>$N_{18}$</td>
</tr>
</tbody>
</table>

The SSCC is a crucial number for traceability, it uniquely identifies each distributed logistic unit and its content.
Standards in Access and humanitarian aid in the developing world

Rehana Wolfe
Director, Global Developing World Vaccines, Pfizer
Regulatory requirements and global developments
Barcodes as first step for traceability

1. Unique identification
   - Products
   - Logistics units
   - Locations & legal entities
   - Etc.

2. Data capture
   - Bar codes
   - EPC/RFID

3. Links management
   - Physical flow
   - Information flow

4. Data communication
   - Share data
   - Retrieve data

The Global Language of Business

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Harmonisation around the identification of pharmaceuticals

- Green = country accepts GTIN
- Orange = no input available

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The Unique Identifier in the Delegated Regulation (EU) 2016/161

The UI - Composition

- The UI will contain:
  - **Product code:** ISO-compliant (ISO 15459); < 50 characters; globally unique; issued by ISO-compliant coding agencies;
  - **Serial number** (max 20 characters; randomised)
  - A national reimbursement or identification number (optional)
  - **Batch number**
  - **Expiry date**

- UI also ISO-compliant (ISO 15418; ISO 15434).

Illustrative example – not binding

(01)09876543210982(21)12345AZRQF1234567890(10)A1C2E3G4I5(17)180531
Recommendation for Coding of Pharmaceuticals in Europe

Data Matrix – Coding proposal derived from GS1 standards
(EAN 128 syntax with Application Identifiers; DataMatrix ECC200)

Manufacturer Product Code (GTIN): 14 digits
Unique Serial Number (randomized): up to 20 alpha-numeric characters
Expiry Date: 6 digits (YYMMDD)
Batch Number: up to 20 alpha-numeric characters

+ minimum requirements on quality of randomisation

Example:

GTIN: (01) 07046261398572
Batch: (10) TEST5632
Expiry: (17) 130331
S/N: (21) 19067811811

Specifications provided in EFPIA’s: “European Pack Coding Guidelines”
USA – 2015, 2017, 2023
Drug Supply Chain Security Act (DSCSA)

Scope: Pharmaceuticals (prescription drugs)
Purpose: Traceability, combat counterfeit

Requirements:
- Packaging level: saleable units and homogeneous cases
- Data elements: NTIN, Expiry date, lot/batch number, serial number
- Data carrier: 2D DataMatrix
- Deadlines - Full track & trace after 10 years (2023)
  • First phase lot based (2015) – delayed to 1 March 2016 for dispensers
  • Serialisation (SNI) after four years (Nov. 2017)

Traceability Model: First lot based traceability, full track & trace in 10 years

Open point(s)/upcoming dev: US FDA points to EPCIS as one of possible way for exchange of traceability data in their draft guidance, industry alignment

NEW GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability (R1.2)
Traceability with GS1 standards in Turkey

• The main challenge in Turkey was to ensure and guarantee the reliable supply of drugs to patients
• The solution is traceability, which is defined as full, end to end, actionable visibility of finished pharmaceuticals in healthcare globally, from point of production to point of use.
• Results of Turkey’s efforts have been tremendous, and in these five areas alone, the nation is seeing savings of 1 billion US dollars annually.


Prof. Özkan Ünal, President of Turkish Medicines and Medical Devices Agency since December 2014.
Many achievements and benefits

- Safe medicines, prevents counterfeiting
- Prevents resale of medicine
- Expedites recalling of medicine
- Prevents sale of expired medicine
- Preventing drug shortages
- Quality data for insurances
- Provides statistics to develop policies on Rational Medicine Use
- Enables pharmacovigilance and strategic planning

RIGHT PRODUCT

RIGHT TIME

RIGHT PLACE

LOW COST
Supply chain in developing countries

Often the supply chain is broken
- Drugs are expired or not stored correctly
- Products are not available when needed
- Inventory management is not optimal
- Traceability is not achievable
- Responsibility towards donors not fulfilled
WHO and USAID/UNFPA

- 2015 Generic Preferred Product Profile for Vaccines (PSPQ2) recommends barcodes with GS1 standards (GTIN, lot number and expiry date) on all packaging levels used by manufacturers, with the exception of primary packaging


- USAID and UNFPA requirements for reproductive health products will be put into action now – same approach: GTIN, lot number, expiry date – later serialisation

https://www.ghsupplychain.org/news-type/innovations
Pilot projects

**Pilot project in Tanzania**
- Proving the benefits of bar coding for vaccines has been launched in region of Arusha with one vaccine from Pfizer
- Other vaccines manufacturer deliver now also vaccines according to specification
- Very positive feedback from first phase – now looking at scaling up across the country and with other products
- Project led by PATH and supported by GAVI

**Pilot project in Nicaragua**
- Main objective 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
- Very positive results – MoH wants to extend to ALL vaccines

**Similar projects in Pakistan, Ghana, Gambia and more?**

**Ethiopia is looking into development of policy and regulation for GS1 standards adoption, designing and implementing a national level track and trace system.**
Initial user feedback has been promising

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%)

"Improves my work by reducing time used to count the stock during receiving or dispatching of vaccines."

"Reduces the emergency trips which is usually caused by inadequate vaccine record keeping."

"The improvement of quality of data could be significant when assessing movement of stock (time) from higher levels to low levels."

Source: Presentation Brian Taliesin, PATH at GS1 Healthcare conference in Dubai, April 2016
We believe we need a world in which...

...in the future any country, multilateral organization, and donor in the world can track the movement of vaccines and other healthcare products from manufacturer to recipient through the use of inexpensive, easily usable, and reliable barcode technology.
Summarising...

• Barcoding technology and global standards are valuable tools to improve patient safety, fight counterfeits and increase visibility in the supply chain and with that the efficiency

• A globally harmonized approach will be less complex and costly

• Regulations across the world as well as requests from buying organisations will sooner or later require your action for compliance – get ready now!
How to start

- Check your ability to print barcodes – linear and 2D
- Is your print quality checked and satisfying?
- Do you have customers in countries which are developing regulations/requirements?
- If you do not print barcodes yet – get started!
- If you print only linear barcodes today – look into the possibilities to upgrade your package lines to 2D DataMatrix printing including serialisation
- Start a project – seek management support – this will consume time and money. But will allow your organisation to be compliant and provide many benefits.
We are all patients!
Contact Details

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