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

Country A

(01)12345678912345(17)101230(10)A234VC2

Country B

Country C

(01)30012345678906(17)101230(10)C4324(21)23QA6576P9

Country E

Country D

4 512345 678906 >

18931234567894

CUSTOMIZED ACTIONS CAUSE ADDITIONAL COSTS!!

GS1 by the numbers

1 million	**150 countries**	**6 billion**	**112 MOs**
over 1 million companies worldwide use GS1 standards	25 industries served across 150 countries	Barcodes scanned more than 5 billion times per day globally	112 Member Organisations around the world

Recognised NGO status by UN

UNITED NATIONS   NATIONS UNIES

DEPARTMENT OF ECONOMIC AND SOCIAL AFFAIRS

Office for ECOSOC Support and Coordination – NGO Branch

DC1-1480, 1 UN PLAZA, NEW YORK, N.Y. 10017

Tel: (212) 963-8652 • Fax: (212) 963-9248

www.un.org/ecosoc/ngo

1 August 2011

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.
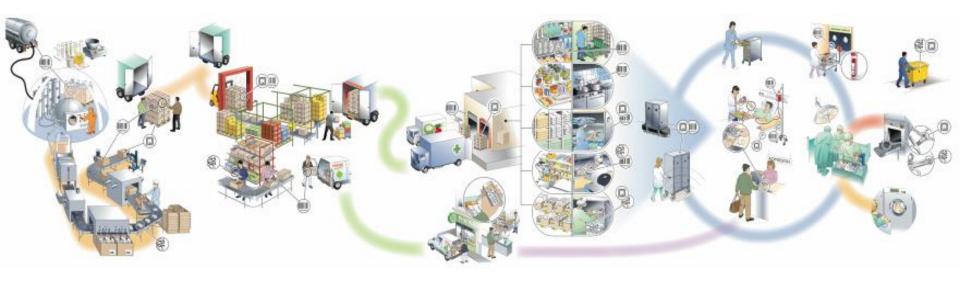
Global automatic identification standards

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**.

Our vision

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

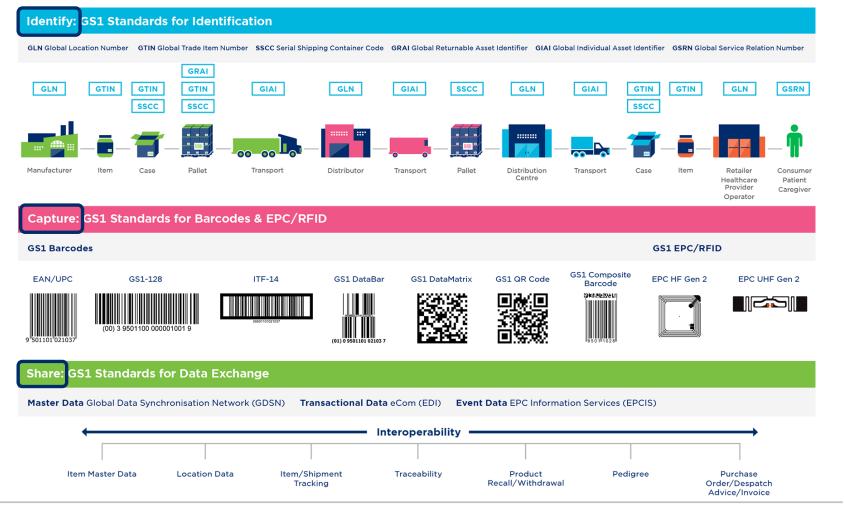supply chain security & efficiency

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

GLN	GTIN GTIN	GRAI GTIN SSCC	GIAI	GLN	GIAI	SSCC	GLN	GIAI	GTIN SSCC GTIN	GLN	GSRN

Manufacturer · Item · Case · Pallet · Transport · Distributor · Transport · Pallet · Distribution Centre · Transport · Case · Item · Retailer Healthcare Provider Operator · Consumer Patient Caregiver

Capture: GS1 Standards for Barcodes & EPC/RFID

GS1 Barcodes   **GS1 EPC/RFID**

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

9 501101 021037

(00) 3 9501100 000001001 9

09501101021037

(01) 0 9501101 021037

9501 1028

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

AIDC –
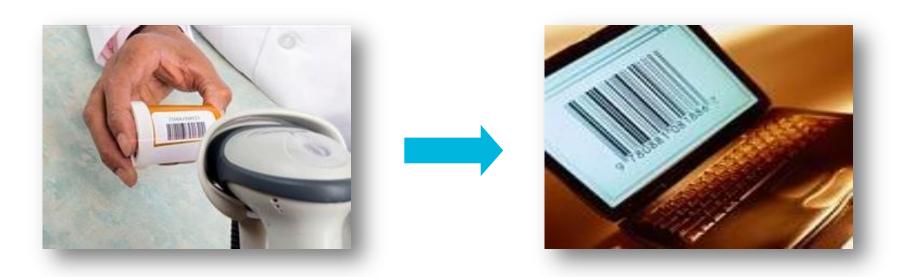# Automatic Identification & Data Capture

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

Manual	Automated **1 error in 350 Thousand (350,000)**
1 keystroke (input) error in every 300 to 500 keystrokes	1 keystroke (input) error in 350 Thousand (350,000)

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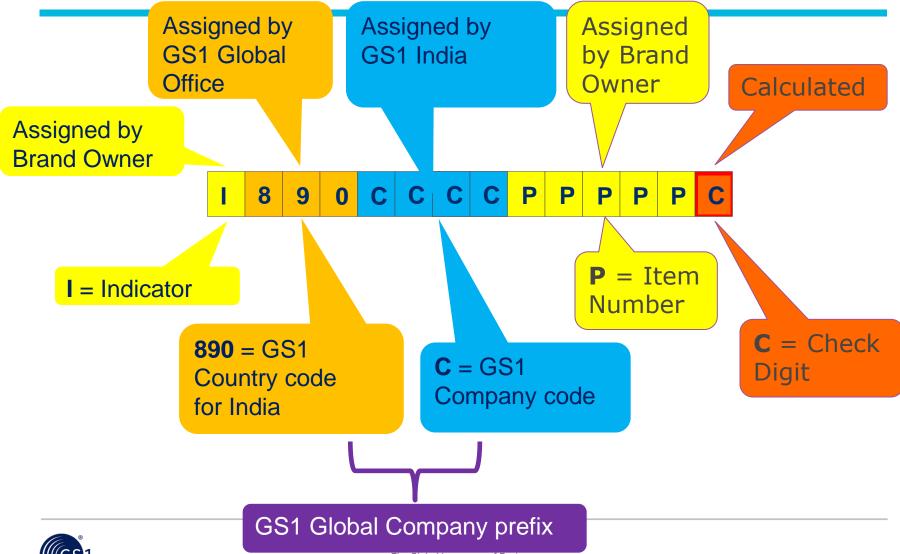
…used on any item upon which there is a need to retrieve pre-defined information and that may be priced, or ordered, or invoiced at any point in any supply chain.

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

Assigned by GS1 Global Office

Assigned by GS1 India

Assigned by Brand Owner

Calculated

Assigned by Brand Owner

I **8** **9** **0** **C** **C** **C** **C** **P** **P** **P** **P** **P** **C**

I = Indicator

890 = GS1 Country code for India

C = GS1 Company code

P = Item Number

C = Check Digit

GS1 Global Company prefix

GS1

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:

01	GTIN (Global Trade Item Number)
10	Batch / Lot
17	Expiry Date
21	Serial Number
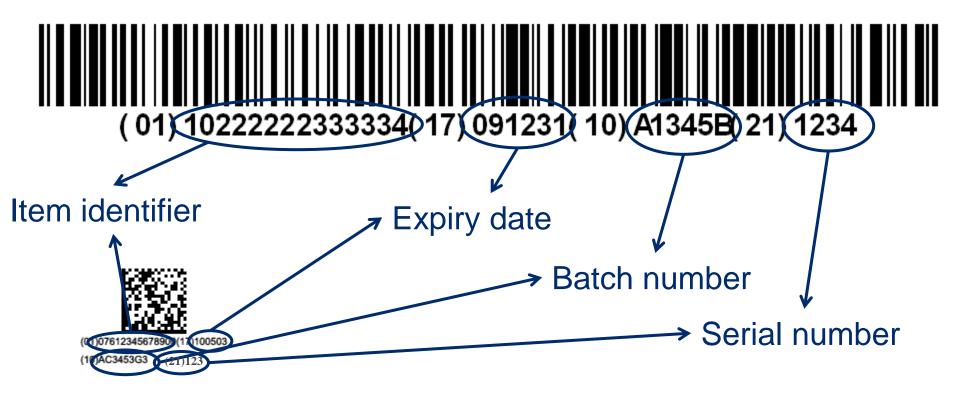
Note – Other than certain efficiency recommendations within the GS1 General Specifications, the order of AI's is *not significant and should not be mandated*.

The need to capture the product item ID and more information…

Linear GS1-128 barcode

(01) 10222222333334 (17) 091231 (10) A1345B (21) 1234

Item identifier

Expiry date

Batch number

Serial number

(01)07612345678900 (17)100503
(10)AC3453G3 (21)123

2D GS1 DataMatrix barcode

Scanning & AIs in action...

(01)10857674002017
(17)141120
(10)NYFUL01
(21)192837

01108576740020171714112010NYFUL0121192837 **?**

0110857674002017   **17**141120   **10**NYFUL01   **21**192837

10857674002017   20 Nov 2014   NYFUL01   192837

ERP Entries

GTIN:

SERIAL:

EXPIRATION:

BATCH/LOT:

GS1
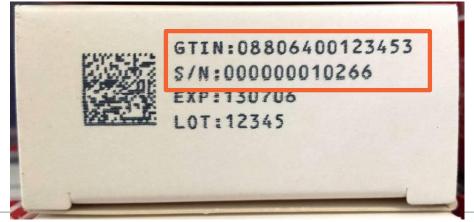
Serialisation

- **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


```
GTIN:08806400123453
S/N:000000010266
EXP:130706
LOT:12345
```
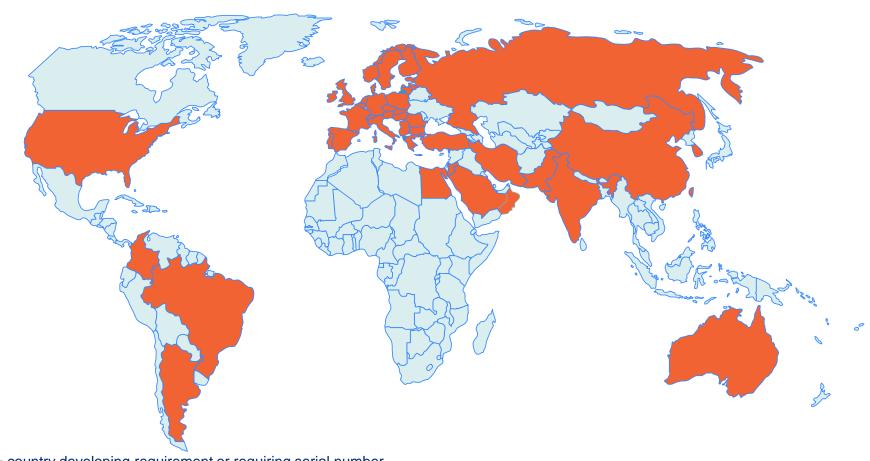
Serialisation of pharmaceuticals

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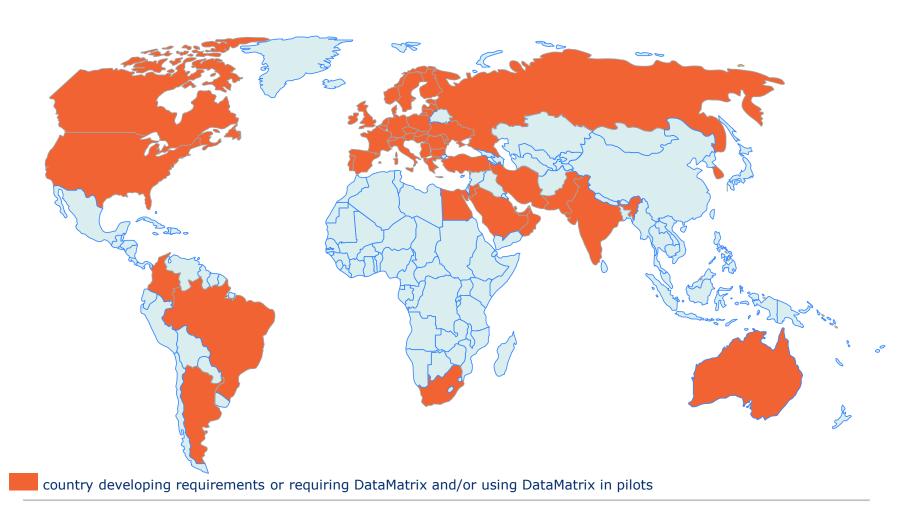
GS1 DataMatrix on pharmaceuticals

country developing requirements or requiring DataMatrix and/or using DataMatrix in pilots
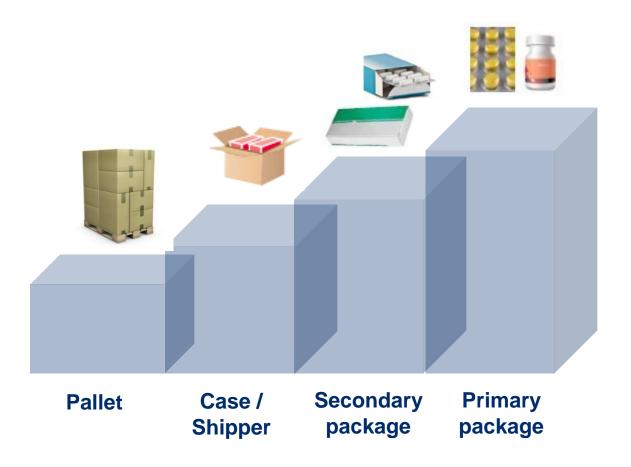
Different packaging levels require different GTIN's

Pallet   **Case / Shipper**   **Secondary package**   **Primary package**
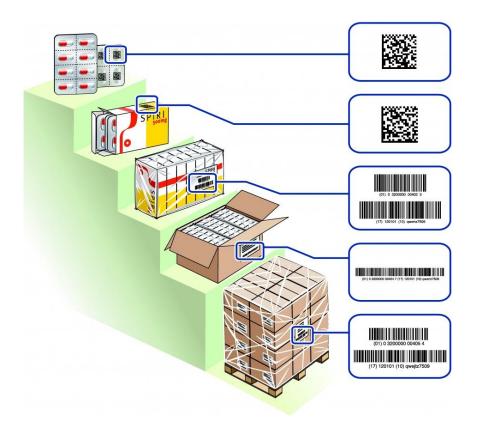
Ideally - identifiers and barcodes at all packaging levels
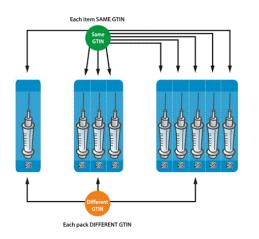
NOTE: Data carriers shown are for illustration purposes only!

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 bar code scanners are needed in HC !!
Can read linear and 2D bar codes

GS1 **Healthcare**   **Position Statement**

**GS1 Healthcare recommends investing in
Camera-Based bar code scanners to address
specific needs for Automatic Identification in Healthcare**

Because of the increased capabilities of camera-based bar code scanners, GS1 Healthcare (GS1 global Healthcare user group) strongly recommends to invest in such scanners when introducing bar code scanners or when replacing existing laser bar code scanners. This will facilitate the future adoption of global standards for automatic identification in the Healthcare supply chain.

Global standards for automatic identification provide the opportunity to make the Healthcare supply chain more efficient and accurate, and thus safer. It will also help enable the patient to receive the five patient rights: *the right patient gets the right product at the right time, in the right dose, and using the right route.*

GS1 Healthcare promotes the adoption and implementation of the GS1 System of standards to automatically identify patients, products, caregivers, and locations. It is the most widely used system worldwide, with more than 5 billion transactions per day based on GS1 standards. The system is built on a scheme of identification keys (such as the GTIN, Global Trade Item Number) and attributes (such as the expiry date), which remains the same independent of the data carrier. Identification can be based on GS1 BarCodes (such as the GS1-128 bar code symbology) and on GS1 EPCglobal (using an RFID tag).

Compared to product coding in for example, a grocery retailer environment, pharmaceuticals and medical devices coding has very specific requirements, including:
- a large amount of data (product ID, batch/lot number, expiry date, date of manufacture, serial number, ...) to be stored on a small space
- variable information (such as unique identification number at unit dose level) to be marked at high production rates
- direct part marking (e.g. surgical instruments and implants)
- unscannable bar codes do not only impact supply chain efficiency, but more importantly, patient safety

The above requirements may not always be achieved with the 'traditional' linear bar codes, but a solution is available:

GS1 DataMatrix

(01)35019315001974(17)120300(10)1234567

The two examples contain identical data

Or mobile phones?

Original Paper

Feasibility and Limitations of Vaccine Two-Dimensional Barcoding Using Mobile Devices

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Abstract

Background: Two-dimensional (2D) barcoding has the potential to enhance documentation of vaccine encounters at the point of care. However, this is currently limited to environments equipped with dedicated barcode scanners and compatible record systems. Mobile devices may present a cost-effective alternative to leverage 2D vaccine vial barcodes and improve vaccine product-specific information residing in digital health records.

Objective: Mobile devices have the potential to capture product-specific information from 2D vaccine vial barcodes. We sought to examine the feasibility, performance, and potential limitations of scanning 2D barcodes on vaccine vials using 4 different mobile phones.

Methods: A unique barcode scanning app was developed for Android and iOS operating systems. The impact of 4 variables on the scan success rate, data accuracy, and time to scan were examined: barcode size, curvature, fading, and ambient lighting conditions. Two experimenters performed 4 trials 10 times each, amounting to a total of 2160 barcode scan attempts.

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 time was observed across devices in all trials performed.

Conclusions: 2D vaccine barcoding is possible using mobile devices and is successful under the majority of conditions examined. Manufacturers utilizing 2D barcodes should take into consideration the impact of factors that limit scan success rates. Future studies should evaluate the effect of mobile barcoding on workflow and vaccine administrator acceptance.

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Journal of Medical Internet Research, vol.18, 2016
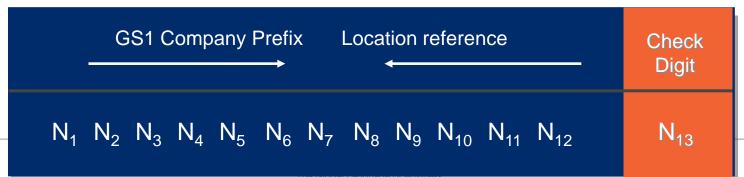
Locations

Global Location Number (GLN)

- The GLN can be used to identify physical locations and legal entities

- GLNs 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:

GS1 Company Prefix → Location reference ←												Check Digit
N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8	N_9	N_{10}	N_{11}	N_{12}	N_{13}

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

SSCC – Serial Shipping Container Code

- The SSCC is assigned for the life time of the **transport item** using Application Identifier (00)
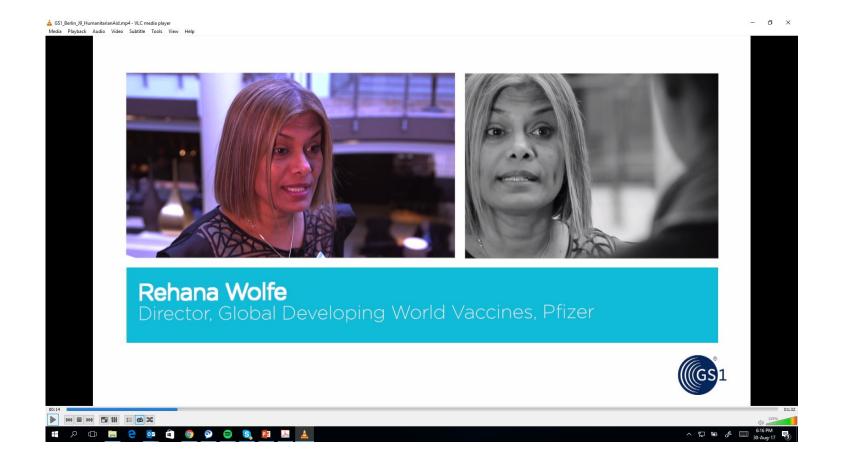
- The SSCC is constructed as:

Extension Digit	GS1 Company Prefix → ← Serial reference	Check Digit
N_1	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} N_{15} N_{16} N_{17}	N_{18}

The SSCC is a crucial number for traceability, it uniquely identifies each distributed logistic unit and its content

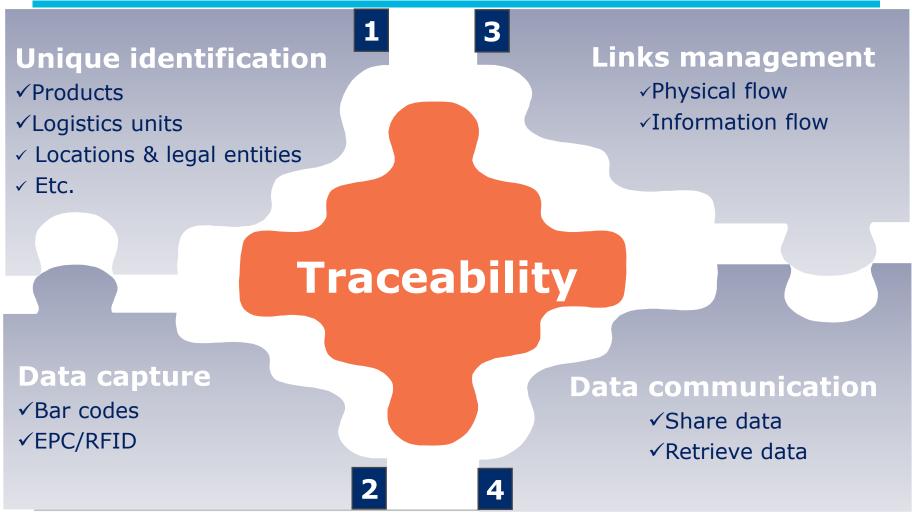# Standards in Access and humanitarian aid in the developing world

Regulatory requirements and global developments
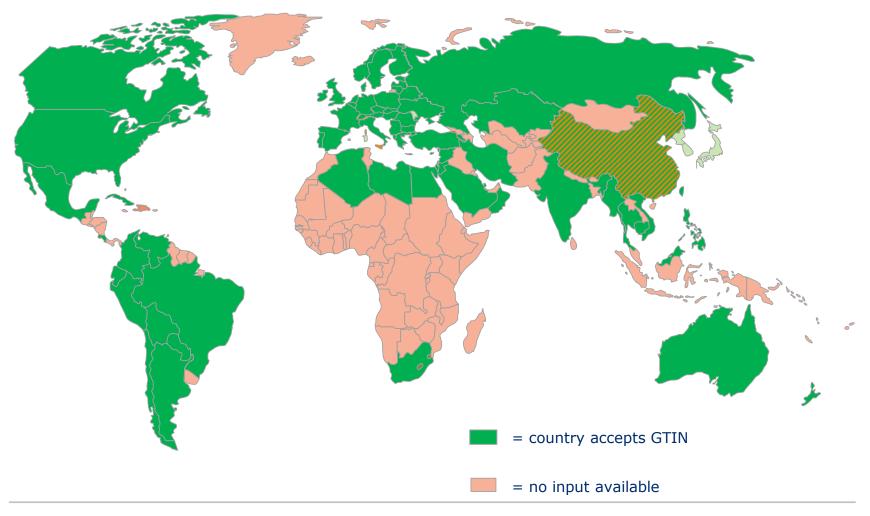
Barcodes as first step for traceability

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

3 — Links management
- ✓Physical flow
- ✓Information flow

Traceability

2 — Data capture
- ✓Bar codes
- ✓EPC/RFID

4 — Data communication
- ✓Share data
- ✓Retrieve data

Harmonisation around the identification of pharmaceuticals

■ = country accepts GTIN

■ = no input available

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

European Commission

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).

Product code	Serial number	Batch number	Expiry date

(01)09876543210982(21)12345AZRQF1234567890(10)A1C2E3G4I5(17)180531

Illustrative example – not binding

European Federation of Pharmaceutical Industries and Associations (EFPIA)

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.

http://www.gs1.org/sites/default/files/docs/healthcare/gs1_healthcare_reference_book_2015-2016.pdf

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
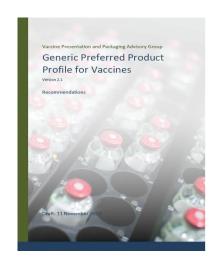
WHO and USAID/UNFPA

- 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

  http://www.who.int/iris/bitstream/10665/148168/1/WHO_IVB_14.10_eng.pdf

- 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
  http://summit2017.familyplanning2020.org/commitment.html

Vaccine Presentation and Packaging Advisory Group
Generic Preferred Product Profile for Vaccines
Version 2.1
Recommendations

Draft: 11 November 2013

Identification Guidelines for Reproductive Health Products
Reproductive Health Global Traceability Advisory Group

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

"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."

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

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!

The Waiting Room

Contact Details

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