By number - the global standards behind barcodes and serialization

GS1 - Safer, more efficient care starts with a simple scan

Ulrike Kreysa, SVP Healthcare and Geraldine Lissalde Bonnet, Director Public Policy, GS1 Global Office, Brussels/Belgium
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Why do we need global standards?
Lack of standards in Healthcare is dangerous, inefficient and creates additional costs!

- Multiple bar codes on one package – which one to scan?
- Different types of bar codes – inconsistency; incompatibility
- No bar code – need to bar code; re-package; re-label
GS1 – a global standards organisation

- More than one million companies worldwide use GS1 standards
- 150 countries
- 25 industries served across 150 countries
- 6 billion barcodes scanned more than 6 billion times per day globally
- 112 Member Organisations around the world
Poll: Are you using GS1 standards today?

- Yes
- We are planning to do so in the near future
- No
Voluntary, Global Healthcare User Group

GS1 Healthcare is a neutral and open community bringing together all related healthcare stakeholders to lead the successful development and implementation of global GS1 standards enhancing patient safety, operation and supply chain efficiencies.
GS1 Healthcare envisions a future in which the healthcare sector achieves harmonised implementation of global standards in business and clinical processes enabling interoperability, optimal quality and efficiency of healthcare delivery to benefit patients.

- Patient safety
- Supply chain security & efficiency
- Traceability
- Product data
Working with global organisations...

Joint Initiative Council

World Health Organization
World Customs Organization
International Hospital Federation
International Council for Commonality in Blood Banking Automation
International Society for Quality in Healthcare
European Federation of Pharmaceutical Industries and Associations
European Medical Devices Industry Association

Clinical Data Interchange Standards Consortium
Integrating the Healthcare Enterprise
Digital Imaging and Communications in Medicine
Personal Connected Health Alliance

Health Level 7 International
Health Terminology SDO
HL7 International
SNOMED
ISO TC215
CEN Health Informatics
CDISC
GS1
IHE Integrating the Healthcare Enterprise
DICOM

The Global Language of Business
The healthcare supply chain needs global standards

- Medication errors result in additional treatments, disabilities and even loss of life
- Counterfeiting is an increasing global threat
- Traceability from manufacturer to patient is problematic
- Product recalls can be difficult to manage, in particular for healthcare providers
- Manual interventions in the healthcare supply chain decrease its efficiency and accuracy
Why regulation? A main driver - counterfeiting

According to Interpol more than **one million people** die each year from counterfeit drugs!

An estimated 1 in 10 medical products in low- and middle-income countries is substandard or falsified. They affect every region of the world.

WHO Fact Sheet on Substandard and Falsified Medical Products, 31 January 2018
Combating counterfeiting

The introduction of a unique identification for drugs or medical devices, where appropriate, will enable authentication and traceability systems.

This will make it much more difficult for counterfeiters to intrude into the Healthcare supply chain.

GS1 standards play a major role!
GS1: global system of standards
GTIN – Global Trade Item Number...

Used on 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.

The base for unique item identification... GTIN is an umbrella term for all GS1 "trade item" identification numbers. A Global Trade Item Number may use the GTIN-8, GTIN-12, GTIN-13, or GTIN-14 numbering structure.
**GTIN Terminology & structure...**

<table>
<thead>
<tr>
<th>GTIN - 8</th>
<th>GTIN - 12</th>
<th>GTIN - 13</th>
<th>GTIN - 14</th>
</tr>
</thead>
<tbody>
<tr>
<td>$N_1$</td>
<td>$N_2$</td>
<td>$N_3$</td>
<td>$N_4$</td>
</tr>
<tr>
<td>$N_5$</td>
<td>$N_6$</td>
<td>$N_7$</td>
<td>$N_8$</td>
</tr>
<tr>
<td>$C_8$</td>
<td>$C_{12}$</td>
<td>$C_{13}$</td>
<td>$C_{14}$</td>
</tr>
</tbody>
</table>

- 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.
GTIN Terminology & structure...

- **I = Indicator or “Zero Filler”**
- **P = Item reference**
- **C = Check digit**
- **C = GS1 Company Code**
- **GS1 Country Code for China**
- **Assigned by GS1 Global Office**
- **Assigned by GS1 China**
- **Assigned by Brand Owner**
- **Calculated**

GS1 Company Prefix
Healthcare primary packaging - The first level of packaging for the product marked with an AIDC data carrier either on the packaging or on a label affixed to the packaging. For non-sterile packaging, the first level of packaging can be the packaging in direct contact with the product. For sterile packaging, the first level of packaging can be any combination of the sterile packaging system, may consist of a single item or group of items for a single therapy such as a kit. For packaging configurations that include a retail consumer trade item, primary packaging is a packaging level below the retail consumer trade item.

Healthcare secondary packaging - A level of packaging marked with an AIDC carrier that may contain one or more primary packages or a group of primary packages containing a single item.

Notes:
[1] The above are GS1 General Specifications definitions.
[2] "Primary packaging" is usually also the "unit of use".
[3] As shown here "Tertiary" refers to "Trade Items only" and not "Logistic Units". (See the GS1 General Specifications for more detail.)
Ideally - ID and data carriers at all levels...

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.
Harmonisation around the identification of pharmaceuticals

- Green: country accepts GTIN
- Orange: no regulation in place
In Healthcare we need often more than the GTIN...

<table>
<thead>
<tr>
<th>GS1-128 Barcode</th>
<th>A GS1 Application Identifier (AI) is an element string that carries dynamic or “production identification” data that... in conjunction with the GS1 “Key”... they provide more granular information about the items identified at the point of data acquisition (scanning).</th>
</tr>
</thead>
<tbody>
<tr>
<td>(01)19506000117843(17)141120(10)NYFUL01(21)192837</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>GS1 DataMatrix Barcode</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(01)19506000117843</td>
<td></td>
</tr>
<tr>
<td>(17)141120</td>
<td></td>
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<tr>
<td>(10)NYFUL01</td>
<td></td>
</tr>
<tr>
<td>(21)192837</td>
<td></td>
</tr>
</tbody>
</table>

**GTIN-14**

**Expiry Date**

**Batch Number**

**Serial Number**
The globally harmonised approach: a serialised secondary pack...

Assignment of GTIN, serial number, lot/batch number and expiry date is the responsibility of the manufacturer
Why standardise on as few as possible...

• The barcode grows larger when too much information is included...
• With local variances costs increase beyond those already necessary for changing packaging lines...
• Increased complexity for manufacturers in managing “multi-market” or special packaging...
• When local rules are not aligned with rest of the world, it becomes an additional burden for any exporting and well as importing manufacturer...
Poll: Is your company already affected by serialisation/implementing it?

- Yes
- Just starting
- No
Position – 2D Imager/Camera scanners...

Preparing members, solutions providers and end users for the future...

Get your copy at:
http://www.gs1.org/docs/healthcare/GS1_HUG_ps_Camera_Based_Scanners.pdf
Pharma – World* – an ever growing number of coding & serialisation requirements

*Including Europe
Serialisation of pharmaceuticals

- Bahrain

countries developing requirement or requiring serial number
GS1 DataMatrix on pharmaceuticals

country developing requirements or requiring DataMatrix and/or using DataMatrix in pilots

The Global Language of Business

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Challenge
To ensure and guarantee the reliable supply of legitimate drugs to patients in Turkey. Like most countries, this supply was put at risk by illegal activities that could seriously impact public health and safety.

Approach
Turkey developed a Pharmaceutical Track and Trace System and built a centralised repository to monitor drug movement throughout the supply chain. With this central management system in place, the ITS can track and trace a drug from the point of manufacture to the point of dispense by leveraging GS1 identification keys, attributes and barcodes.

Healthcare
Turkish Pharmaceutical Track and Trace System (ITS)
ITS was the first successful application of a "Pharmaceutical Track and Trace System" in the world and is designed to track the location of every drug unit to ensure the reliable supply of drugs to patients.

Results
- Reliable and safe supply of drugs to patients
- Enhanced ability to combat illicit drug sales, barcode scams and theft
- More than $1 billion in annual savings
- More than 45 million daily transactions through ITS
- Response time is 0.02 seconds per transaction
- Sophisticated and efficient recall management

Enhanced ability to combat illicit drug sales, barcode scams and theft

Sophisticated and efficient recall management
Many achievements and benefits

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

Source: Presentation of Turkish MoH
The Unique Identifier in the Delegated Regulation (EU) 2016/161 in force NOW

The move towards harmonisation and GS1 standards in Europe

*Italy has until 2025 to comply*
A full traceability system in 2023

- Identification on saleable units and homogeneous cases
- Data elements: NTIN, Expiry date, lot/batch number, serial number
- Data carrier: 2D DataMatrix
- **Serialisation (SNI) Nov. 2017** (will not be enforced for one year)

- The US FDA points to EPCIS as one of possible way for exchange of traceability data in their draft guidance, industry alignment
- GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability (R1.2)
- New guideline for grandfathering published

**Protect the product** ➔ **Protect the patient**
Latin America

**Argentina**
- Secondary pack.: GTIN + Exp. date + Batch # + Serial #
- GS1 128, GS1 DataMatrix, RFID
- ANMAT Portal
- Implementation since 2011

**Brazil**
- Pilot finalized end of April 2019
- Implementation starting in May 2020

**Colombia**
- Draft on data standardization in 2018
- National code for medicinal products (IUM) instead of GTIN

**Chile, Mexico, Panama, Peru** under discussion
### Bahrain
- **Secondary pack.**: GTIN+Exp.+Batch#+Serial# GS1 DataMatrix
- **GCC attributes in BrandSync**: end April 2018
- **Master data reporting**: end July 2018
- **Serialisation**: 31 Dec. 2019

### Egypt
- **Secondary pack.**: GTIN+Exp.+Batch#+Serial# GS1 DataMatrix
- **Tertiary pack.**: SSCC GS1 128, GS1 DataMatrix
- **Serialisation**: end of 2018
- **Reporting on MoH portal**: June 2019
- **Possible use of EPCIS**

### Iran
- **Secondary pack.**: GTIN+UID+Exp.+Batch# GS1 DataMatrix
- **Deadline**: 1 Jan. 2015
- **Use of EPCIS**

### Jordan
- **Secondary pack.**: GTIN+Exp.+Batch#+Serial# 1D to 2D: end June 2018
- **Barcoding**: end 2019
- **Serialisation**: 1 Jan. 2020

### Lebanon
- **Secondary pack.**: GTIN+Exp.+Batch# GS1 DataMatrix
- **Barcoding - imported**: end 2019
- **Barcoding – local**: end 2022
- **Reporting to MoH**: end 2022

### Ethiopia
- **Roadmap towards TT in 9 years based on GS1**
- **Currently Phase 1**: “Strengthening environment”
Oman
Secondary pack.: GTIN+Exp.+Batch# + Serial#
GS1 DataMatrix
GCC attributes in BrandSync: 30 days before shipping
Serialisation: 1 March 2019
Also **tender requirements**

Qatar – TENDER (HMC)
Secondary pack.: GTIN+Exp.+Batch#
Tertiary pack.: SSCC
GS1 128, GS1 DataMatrix
Deadline: 1 Jan. 2018

Saudi Arabia
Secondary pack.: GTIN+Exp.+Batch# + Serial#
GS1 DataMatrix
Barcoding: March 2015
Serialisation: March 2017
Registration & reporting: 7 Jan. 2019
Aggregation: 1 Oct. 2019

South Africa
Secondary pack.: GTIN+Exp.+Batch# + Serial#
GS1 DataMatrix
Serialisation: June 2022 (tbc)
Release final regulation

United Arab Emirates – Dubai HA
Secondary pack.: GTIN+Exp.+Batch#
GS1 DataMatrix
Master data: GTIN, DDC, DHA item ode, DHA item description
Deadline: 1 Jan. 2017
Also **tender requirements**

GCC
Secondary pack.: GTIN+Exp.+Batch# + Serial#
GS1 DataMatrix
Aggregation recommended
GCC attributes in BrandSync (17 M. – not for Saudi)
Asia Pacific - 1/2

**Australia**
Serialisation+DataMatrix on blood prdt.: 1 Jan. 2018
Medicines labelling: GTIN+DataMatrix: 1 Sept. 2020
TGA running public consultations

**China**
eCode on hold since Feb. 2016
Drug traceability system guide: 2018, distributed model
Implementation in 2022
Pilot with stakeholders
Vaccines: Pilot and first regulation expected soon

**Chinese Taipei**
Secondary pack.: GTIN+Exp.+Batch#+Serial#
GS1 DataMatrix
Identification: Jan. 2018
Serialisation: Jan. 2019
Registration for reporting: Jan. 2020
? Release final requirements

**India**
For export:
Serialisation since 2013
Reporting & Aggregation: 1 July 2019
? Primary pack as of 1 April 2020 with QR
For domestic market:
? timeframe
? SMS on primary pack

**Indonesia**
Secondary pack.: GTIN+Exp.+Batch#+Serial#
GS1 DataMatrix or QR code
Deadline: ID by 2023, authentication by 2023
Aggregation not mandatory

**Japan**
Secondary pack.: GTIN+Exp.+Batch# or Serial#
GS1 DataBar
Deadline: March 2021
Asia Pacific – 2/2

**Kazakhstan**
- Pilot announced
- 2020/2012: voluntary labelling
- 2023/2024: mandatory labelling

**Malaysia**
- In discussions on track & trace

**Pakistan**
- Aligned with GS1 standards and 4 data elements

**Russia**
- Secondary: DataMatrix, GTIN+Serial# +Exp.+Lot# +crypto (AI(91) AI(92))
- Tertiary: GS1 128, SSCC or sGTIN
- Aggregation required
- Reporting: Labelling Information System (LIS)
  - ? 1 Oct 2019: 12 Nosologies
  - ? 1 Jan 2020: Full track and trace

**South Korea**
- Secondary: GTIN+Serial# +Exp.+Lot#
- DataMatrix (for narcotics: RFID)
- All products serialised by end 2015
- Aggregation voluntary by 2016
- Reporting by 1 July 2016

Also,
- Ukraine, Kyrgyz Republic, Mongolia, Sri Lanka, Vietnam
WHO VPPAG recommendations

• 2019 Generic Preferred Product Profile for Vaccines (PSPQ2) recommends barcodes on all packaging levels used by manufacturers, with the exception of primary packaging

• GS1 standards and associated specifications are being used to encode the Global Trade Item Number (GTIN), lot number, and expiry date

• http://www.who.int/iris/bitstream/10665/148168/1/WHO_IVB_14.10_eng.pdf
The vaccines supply chain

Often the supply chain is broken
- Vaccines are expired or not stored correctly
- Vaccines are not available when needed
- Inventory management is not optimal
- Traceability is not achievable
- Responsibility towards donors not fulfilled
Supporting documents

- VPPAG Bar Code Implementation Technical Guideline
- Barcode implementation considerations document
- Pilots, experiences, learnings
Several pilots have been going on

- Tanzania
- Gambia
- Nicaragua
- Pakistan

All with very good results!
The ISG: Bill and Melinda Gates Foundation, DFID, Global Affairs Canada, the Global Drug Facility, KfW, the Global Fund, Gavi, NORAD, UNDP, UNFPA, UNICEF, USAID, World Bank, WFP and WHO published a position paper in August 2017 on the adoption of GS1 standards committing to the process of transitioning to include established, global data standards as part of their procurement requirements and support country uptake of these standards.
Alignment on global standards

Published end of March - new guideline for global health commodities, requesting all components of the GS1 system: Identify, Capture and Share

The need for global standards

Healthcare is **local**
- Healthcare providers are local
- Regulations are local

Healthcare is **global**
- Healthcare supply chains often cross borders

Country-by-country solutions are not sufficient nor effective
A global harmonised approach and implementation is needed
New McKinsey & Company report quantifies supply chain issues in Healthcare

New McKinsey report “Strength in unity: The promise of global standards in healthcare”

Highlights the cost savings and patient safety benefits of adopting a single global supply chain standard in healthcare

Available at:
http://www.gs1.org/healthcare/mckinsey

Source:
http://www.mckinsey.com
Huge cost savings and patient safety benefits when adopting a single global standard in healthcare

“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 millions 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” from the implementation of global standards

“Adopting a single set of global standards will cost significantly less than two” (between 10-25% less cost to stakeholders)

36th GS1 Healthcare Conference

New Delhi, India • 5-7 November 2019

- Traceability, unique medical device identification (UDI) and global regulatory developments
- Implementation success stories from manufacturers, wholesalers and hospitals – experiences and benefits
- How to improve patient safety and quality of care
- Hospital implementation awards
- And much more...
Safer, more efficient care starts with a simple scan.
Contact Details

Ulrike Kreysa
E Ulrike.Kreysa@gs1.org
Geraldine Lissalde-Bonnet
E Geraldine.Lissalde@gs1.org

GS1 Global Office, Brussels
W www.gs1.org/healthcare