By number - the global standards behind barcodes and serialization

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

November 2019
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
Are you using GS1 standards today?

- Yes
- We are planning to do so in the near future
- No
About GS1 VIETNAM
## GS1 Vietnam Main Services

<table>
<thead>
<tr>
<th>Barcodes</th>
<th>Traceability</th>
<th>LEI</th>
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<tbody>
<tr>
<td>GS1 VIETNAM IS THE ONLY OFFICIAL AUTHORITY IN VIETNAM PROVIDING AND MANAGING PRODUCT BARCODES FOR MORE THAN 40,000 ENTERPRISES WITH OVER 1,000,000 PRODUCTS</td>
<td>FROM 19/01/2019, PRIME MINISTER APPROVE THE DECISION 100 CALLED “APPROVAL OF THE DEPLOYMENT, THE APPLICATION AND MANAGEMENT OF TRACEABILITY SYSTEM”</td>
<td>THE LEI IS A REFERENCE DATA TOOL TO STANDARDIZE HOW A COUNTERPARTY IS IDENTIFIED ON FINANCIAL TRANSACTIONS.</td>
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About Healthcare Product Regulations In Vietnam
Regarding the Circular 32 issued by Ministry of Healthy, at article 23 (14), all the barcode, QR code and DataMatrix is acceptable.

All three types of barcodes are accepted for medical devices in Vietnam, but **GS1 only recommends to use DataMatrix to be accepted globally.**
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, operational and supply chain efficiencies.
Our vision

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...
Global standards in healthcare
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, 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...**

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GTIN Terminology & structure...

- **I** = Indicator or “Zero Filler”
- **P** = Item reference
- **C** = Check digit

**Assigned by GS1 Global Office**

**Assigned by GS1 Vietnam**

**Assigned by Brand Owner**

**GS1 Country Code for Vietnam**

**C** = GS1 Company Code

**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...

Primary Package

Secondary Package

Tertiary Package (Case)

Tertiary Package (Pallet as a Trade Item)

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.
Identification of pharmaceuticals

- Green: country accepts GS1 Standards
- Orange: country requires national ID #
- Pink: no input available
In Healthcare we need often more than the GTIN...

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).
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.
Position – 2D Imager/Camera scanners...

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

*Including Europe
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
Results

Reliable and safe supply of drugs to patients

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

More than

45 million daily transactions through ITS

Response time is 0.02 seconds per transaction

More than $1 billion in annual savings

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.
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

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*
USA – 2015, 2017, 2023
Drug Supply Chain Security Act (DSCSA)

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)

Protect the product  Protect the patient
Some other countries implementing GS1 standards for pharma traceability

- Argentina
- Australia
- Bahrain
- Brazil
- Chinese Taipei
- Colombia
- Egypt
- Ethiopia
- India
- Indonesia
- Iran
- Japan
- Jordan
- Kazakhstan
- Lebanon
- Malaysia
- Oman
- Pakistan
- Qatar
- Russia
- Saudi Arabia
- South Africa
- South Korea
- Turkey
- UAE
WHO VPPAG recommendations

• 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.

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
Interagency Supply Chain Group (ISG)
Adoption of global GS1 standards

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 2019 - new guideline for global health commodities, requesting all components of the GS1 system: 
**Identify, Capture and Share**

Call to Action for the “Africa Strategy for Pharmaceutical Traceability”

Signed by...

- 25 African regulatory authorities
- 6 health financing and donor organisations
GAVI announcement: vaccine manufacturer GS1 compliance

- Starting 1st October 2019, for vaccine tenders backed by Gavi financing and issued by UNICEF, GS1 barcoding on the secondary packaging will be a requirement by latest 31st December 2021.

https://www.unicef.org/supply/index_103734.html
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 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
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)

It is important to remember that...

Safer, more efficient care starts with a simple scan