Identification and marking of vaccines

DCVMN Workshop

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GS1 standards framework...

**Identify**

*Globally unique identification keys*
Companies, Products, Locations, Patients, Providers, Assets, Logistics, Documents, Services, Shipments, Consignments

**Capture**

*Automatic data capture*
Barcodes and EPC-enabled RFID

**Share**

*Exchange of patient care & business critical information*
Master Data, Transactional Data, Traceability & Event Data and Digital Content

...the AIDC “bits”...
Part of the traceability “building blocks”...

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

2. Data capture
   - Bar codes
   - EPC/RFID

3. Links management
   - Physical
   - Information flow

4. Data communication
   - Share data
   - Retrieve data

...the AIDC “bits”...
AIDC for Healthcare - the Vision...

**EVERY** item has **ONE** set of key identification data carried in **ONE** data carrier able to be scanned by **EVERYONE** at every key process step...
Identify
**Scope – ID at all packaging levels...**

*Note 1:* There is no globally standardized definition of “tertiary package”...

*Note 2:* Images shown are for illustration only, refer to local regulations and/or the latest version of the GS1 General Specifications for more detail.
Foundation of the GS1 System...

...the GS1 Identification Keys

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

GS1 Identification Key: 12345678901234

GTIN 12345678901234
Product name
Product type
Variation
Functional name
Net Content
Net Content UOM
Prosthesis Rebate Code
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.
Anatomy of a GTIN, an example

GTIN-14 example
GTIN terminology & structure...

GTIN-13 encoded as a 14-digit number within a GS1 DataMatrix

GTIN-14 encoded within a GS1 DataMatrix

...both are valid uses, are unique GTINs and are valid barcode symbols for use dependent upon how a brand owner wishes to identify their products & groupings.

The same applies for encoding a GTIN in GS1-128!!
GS1 Healthcare GTIN Allocation Rules...

New Version

Available Mid-June

GTIN assignment in Healthcare

Available online at:

Work group is launched to review and update

Translated in many other languages

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Brand owners (the 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
  - Example - Change GTIN when pack of 20 becomes pack of 25
- Add language, same GTIN
- Change language, new GTIN
- Country of manufacturing changes... GTIN does not need to change when manufactured to the same specifications
- **Never re-allocate a GTIN to another product!**
GTIN Hierarchy – Pharmaceuticals...

Example of Typical Pharmaceutical Hierarchy Levels

<table>
<thead>
<tr>
<th>Single Unit</th>
<th>Each</th>
<th>Case or Shipper</th>
<th>Pallet</th>
</tr>
</thead>
<tbody>
<tr>
<td>GTIN A</td>
<td>GTIN B</td>
<td>GTIN C</td>
<td>GTIN D</td>
</tr>
</tbody>
</table>
GTIN allocation fundamentals

1-pack, multiple identifiers including 3 GTINs
9088882431984 / PZN-2006490 / 5012712003083 / 7046260081383

An example of an INCORRECT method...
Determine which additional information is required in the barcode
In addition to the GS1 “Keys” a GS1 Application Identifier (AI) is an element string that carries dynamic or “production identification” data that... in conjunction with the GS1 ID “Key”... provides more granular information about the items identified at the point of data acquisition (scanning).
The GS1 Gen Specs include 100+ “AI’s” for various use cases & sectors

..however relying on Master Data as well as limiting & staging the Application Identifiers commonly used in Healthcare helps:

• ...to reduce implementation complexity
• ...maximise use of existing systems
• ...potentially minimize cost implications

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>GTIN (Global Trade Item Number) – 14 digit numeric</td>
</tr>
<tr>
<td>10</td>
<td>Batch / Lot – up to 20 characters, alphanumeric</td>
</tr>
<tr>
<td>17</td>
<td>Expiry Date – 6 digit numeric, YYMMDD format</td>
</tr>
<tr>
<td>21</td>
<td>Serial Number – up to 20 characters, alphanumeric</td>
</tr>
</tbody>
</table>

**Note 1** – Other than certain efficiency recommendations within the GS1 General Specifications, the order of AI’s is *not significant and should not be mandated*.

**Note 2** – GTIN and serial number makes a product truly unique – serial numbers can be repeated with other GTIN’s. Randomisation is today state of the art although not part of GS1 Gen Specs.
### Scanning & Processing GS1 Data Structures

**ENCODED (In) – User dependent:**

`<FNC1>01108576740020171714112010NYFUL01<GS>21192837`

**DECODED (Out) – Scanner dependent:**

```
]d201108576740020171714112010NYFUL01<GS>21192837
```

**PROCESSING:**

<table>
<thead>
<tr>
<th>GTIN:</th>
<th>BATCH/LOT:</th>
</tr>
</thead>
<tbody>
<tr>
<td>0110857674002017</td>
<td>21192837</td>
</tr>
<tr>
<td>10857674002017</td>
<td>21192837</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EXPIRATION:</th>
<th>SERIAL:</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 Nov 2014</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Select a GS1 barcode format
Healthcare – Data / Data Carrier needs...

- Expiry Date, Lot, and/or Serial Number
- Small space
- Direct part marking
- Additional data & variable data at high production rates
- Non-retail channels

And more...
Healthcare - Specific marking needs...

Barcode on the Label/Package

Barcode on a LABEL on the item or on the item PACKAGING

Direct Marked Parts barcode directly ON the item
GS1 Data Carriers...
...mainly used in healthcare...

NOTE: In Healthcare GS1 QR Code is not endorsed for Trade Item related marking.
A need to capture the GTIN & more...

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).
Data Carriers – 2D/Matrix scanning...

**Linear Scanners:**
- Laser line or linear imager based
- Massive, long-term installed base
- Scans 1D / Linear and some 2D Stacked symbols

**Area Image Scanners:**
- Camera based
- Growing installed base in all sectors
- Scans 1D/Linear, 2D/Stacked & 2D/Matrix symbols

Camera-based bar code scanners… needed in Healthcare AND are GS1 Healthcare Leadership Team recommended!!

GS1-128

GS1 DataMatrix
Use of smartphones for scanning is increasing as their performance... and that of any associated apps... also increases...

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.
GS1 DataMatrix versus GS1 QR Code...
Use of GS1 2D Matrix Data Carriers in Healthcare

Purpose
The purpose of this paper is to provide guidance on the use of 2D Matrix barcode symbols in the healthcare industry. It is done through discussion of the similarities and differences between GS1 DataMatrix and GS1 QR Code, and their implications for healthcare supply chain, and the GS1 Healthcare preference for the use of GS1 DataMatrix for GS1 Keys typically found on these items (GTIN, GRIA, GIAT and SSCC, when applicable).

Executive Summary
The members of GS1 Healthcare continue to support the use of GS1 DataMatrix as the only enabled 2D Matrix data carrier for encoding GS1 Keys on healthcare trade items and logistics labels. For use cases or processes that require a single data carrier selection for all Keys, to improve consistency and to optimize training and additional expenditure, the recommendation is the use of GS1 DataMatrix for all GS1 Keys within these implementations.

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>✓</td>
<td>✗</td>
</tr>
<tr>
<td>• GTIN</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>• GRIA</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>• GIAT</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>• SSCC</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>b) Other Identification use cases</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• GLN</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>• GDTI</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>• GSRT</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>• ...etc.</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

*Note: This paper discusses the use of GS1 DataMatrix 2D and does not alter the present policy on use of linear 1D data carriers with GS1 keys.
Make sure you have HRI
What is HRI?

**Human Readable Interpretation**

- HRI show a human **exactly what’s in a barcode**

- It’s there in case the barcode does not read

- Some HRI rules are **specific to Healthcare** and these have been recently updated

Whether a GS1 AIDC Data Carrier encodes a GS1 Identification Key, GS1 Key Attributes, or a combination of both, the HRI should be placed below the barcode and grouped together wherever physically possible while maintaining the HRI legibility and minimum barcode height.
HRI... in the GS1 General Specifications...

GS1 has always had HRI Rules and Recommendations...

- HRI is noted individually in many other sections of the Gen Specs.

The “basic guidance” within is clear...

- The GS1 System requires printing both the GS1 AIDC data carrier and the HRI that represents all the information encoded within that GS1 AIDC data carrier.
- HRI shall appear except in rare circumstances for specific applications where there are extreme space constraints
- ...rules are intended for global use. Exceptions may occur only when local regulatory or legal requirements mandate otherwise
HRI... in the GS1 General Specifications...

...as are the base format recommendations...

Figure 4.14.1-1. Preferred HRI Format Examples

Scan for online product information or go to: http://www.gs1.org/demo/09504000059101

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The Healthcare HRI rules enable label designers to minimise space requirements by merging HRI and non-HRI text. This enables the manufacturer to display product safety information such as the lot and expiry date, without the need to display it both as HRI and in a standard label structure.

The above figure illustrates one application of this approach, combining data labels (e.g. GTIN, SN, and batch/lot) with application identifier labels [(01), (21), (10)]
Ensure your barcodes work!
Barcode quality... key points...

- Colour
  - Print contrast
- Barcode width
  - Magnification
- Barcode height
  - Truncation
- Quiet Zones
- Print quality
- Location

Barcode quality... where it begins...

- Each manufacturer should make sure that GTINs are correctly allocated and recorded for all their products.

- Staff responsible for artwork should be made aware of the minimum requirements for barcode quality and work with their packaging printers.

- Packaging printers need to know about barcode verification and how to use verifiers properly.

- Specialised solution providers can help, they can be found via your local GS1 member organisation
Summary and more information
Use the Ten Steps to Implementation

- Step 1: Get a GS1 Company Prefix
- Step 2: Assign GTINs to your products
- Step 3: Select a bar code printing method
- Step 4: Select a "Primary" scanning environment
- Step 5: Select a bar code symbology
- Step 6: Pick a bar code size
- Step 7: Format the bar code text
- Step 8: Pick a bar code colour
- Step 9: Pick the bar code placement
- Step 10: Ensure you have a bar code quality plan

https://www.gs1.org/standards/barcodes/10-steps-to-barcode-your-product/english
Where to find more information?

Find information & support at GS1 Global Healthcare on the web...

Healthcare

As a patient you are entitled to the best care. The use of our standards in healthcare increases patient safety, drives supply chain efficiencies and improves the traceability of medicines.

Check out: http://www.gs1.org/healthcare

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The Global Language of Business
It is important to remember that...

Safer, more efficient care starts with a simple scan
Thank you for your time and attention!