The basics of identification and barcoding for traceability
GS1 AIDC Standards in Healthcare

African GS1 Healthcare Conference 2018
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Your Panelists

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GS1

The Global Language of Business

GS1 AIDC Standards in Healthcare
The basics

Chuck Biss - Senior Director, AIDC Healthcare - GS1 Global Office

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

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
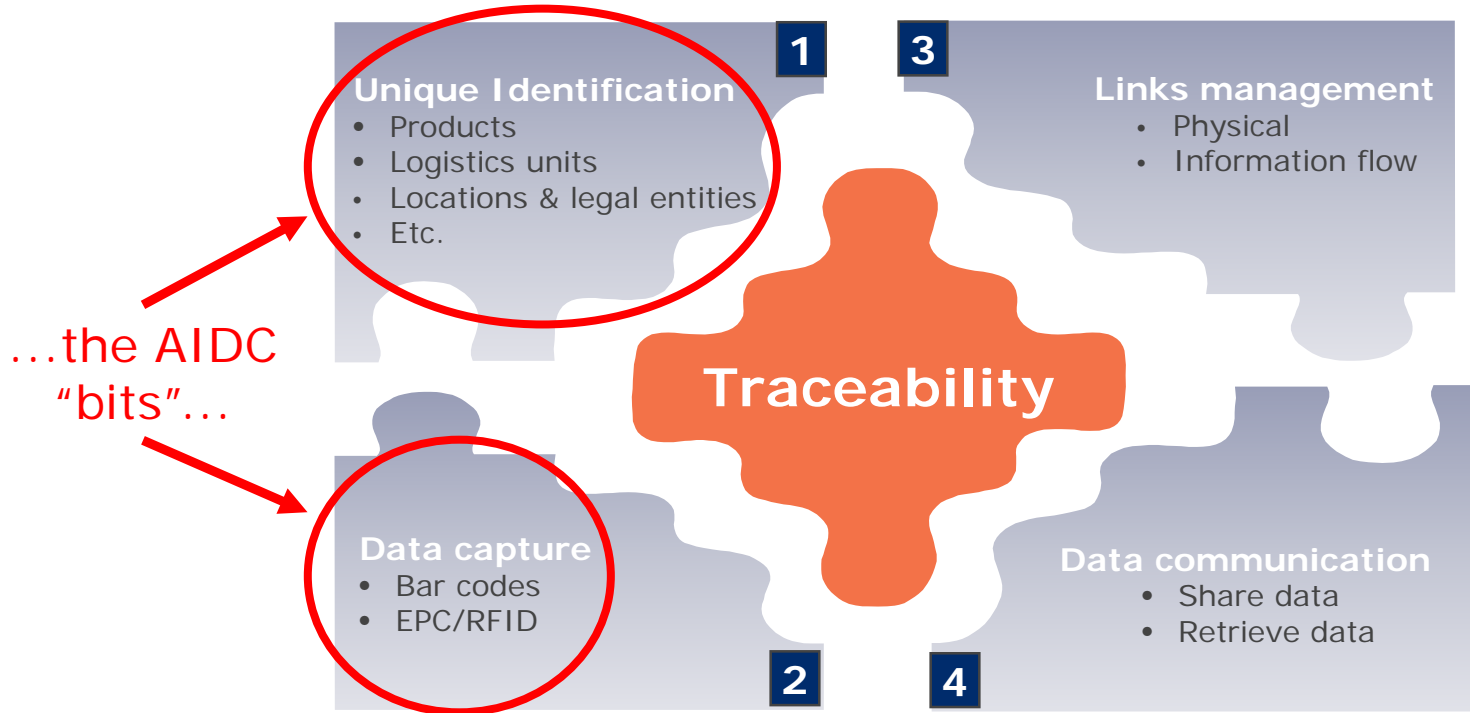
…the AIDC "bits"…

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

Part of the traceability "building blocks"…

…the AIDC "bits"…

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

3 Links management
- Physical
- Information flow

Traceability

2 Data capture
- Bar codes
- EPC/RFID

4 Data communication
- Share data
- Retrieve data

GS1 AIDC in Healthcare

Identification "Keys"

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

Product name
Abcdef
Sdfqdfqs
Qdfqsdf
Qdfqdfqf
qfqsdfqsf

GS1 Identification Keys…

Item identifier = **GTIN**
Global Trade Item Number

Logistics unit identifier = **SSCC**
Serial Shipping Container Code

Location identifier = **GLN**
Global Location Number

Service relation identifier = **GSRN**
Global Service Relation Number

- Unique
- Non-significant
- International
- Secure
- Foundational

…and there are more …

GS1 AIDC in Healthcare

Identification "Keys" - GTIN (Global Trade Item Number)

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.

9 506000 117843

(01)09506000117843

(01)09506000117843

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...

	GS1 Application Identifier	Global Trade Item Number (GTIN)												
		GS1-8 Prefix or GS1 Company Prefix $\longrightarrow$							$\longleftarrow$ Item reference					Check digit
(GTIN-8)	0 1	0	0	0	0	0	0	N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8
(GTIN-12)	0 1	0	0	N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8	N_9	N_{10}	N_{11}	N_{12}
(GTIN-13)	0 1	0	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}
(GTIN-14)	0 1	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}

The GTIN-14 Data Structure is used for grouping of items. The Indicator Digit (the "N_1") has a value of 1 to 8 and allows for the identification of eight packaging levels. The 9 has a special application for Variable Measure. The Indicators have no inherent meaning. These digits do not have to be used in sequential order, and some may not be used at all. The holder of the Company Prefix determines their use. By definition... if it has 14-digits and starts with a "0" it is not a GTIN-14... it is a GTIN-8, -12, or -13 in a 14-digit format with a "Filler" digit "0"

Anatomy of a GTIN... an example

Assigned by GS1 Global Office

Assigned by GS1 Denmark

Assigned by Brand Owner

Assigned by Brand Owner

Calculated

I 5 7 0 C C C C P P P P P C

I = Indicator or "Zero Filler"

GS1 Country Code for Denmark

C = GS1 Company Code

P = Item reference

C = Check digit

GS1 Global Company Prefix

NOTE: GTIN-14 example

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© GS1 2017
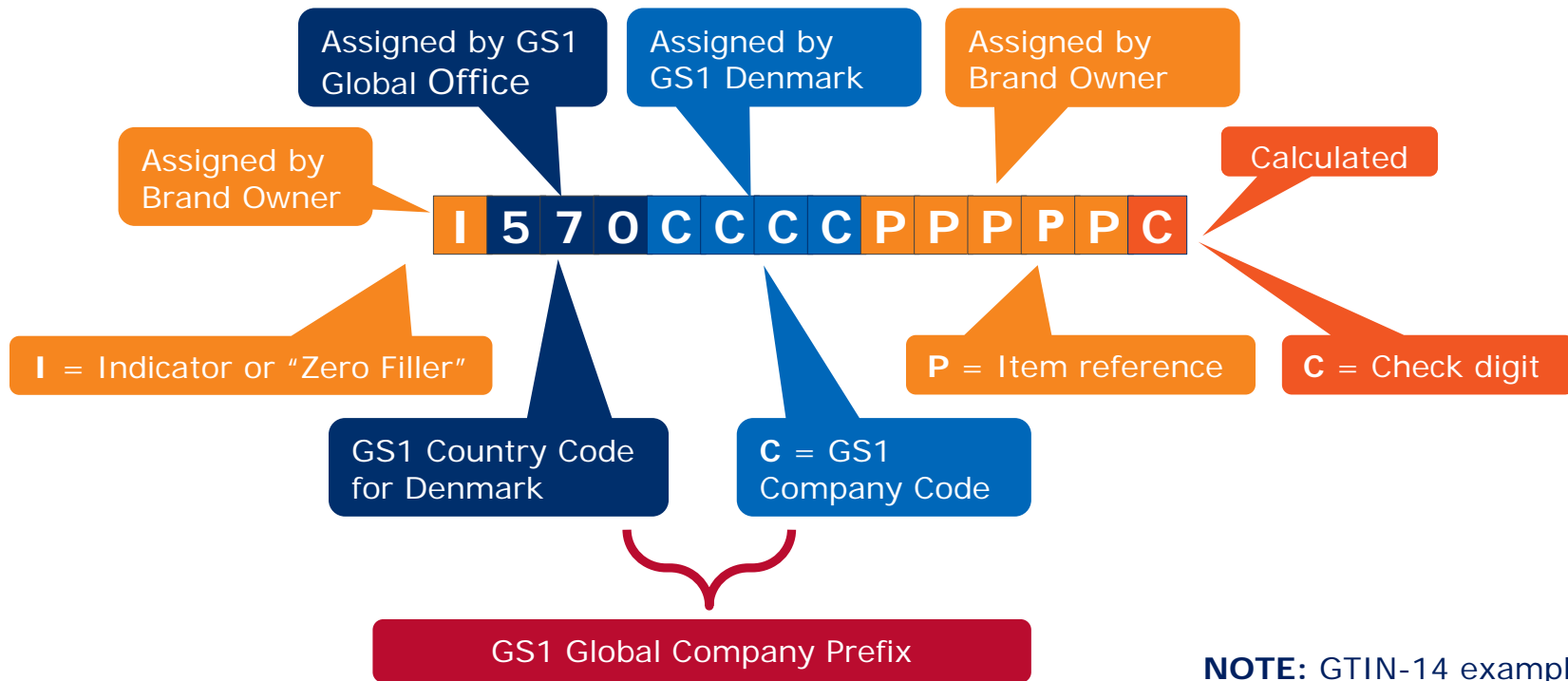
GTIN allocation rules in brief...

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 !**
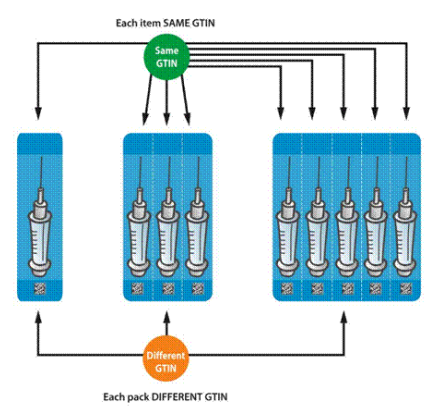
GTIN allocation a "1 to 1" relationship...
1 Product to 1 GTIN / 1 GTIN to 1 product

8961234560116   X

8961234560208   ✓

9312367800016   X

X

✓

X
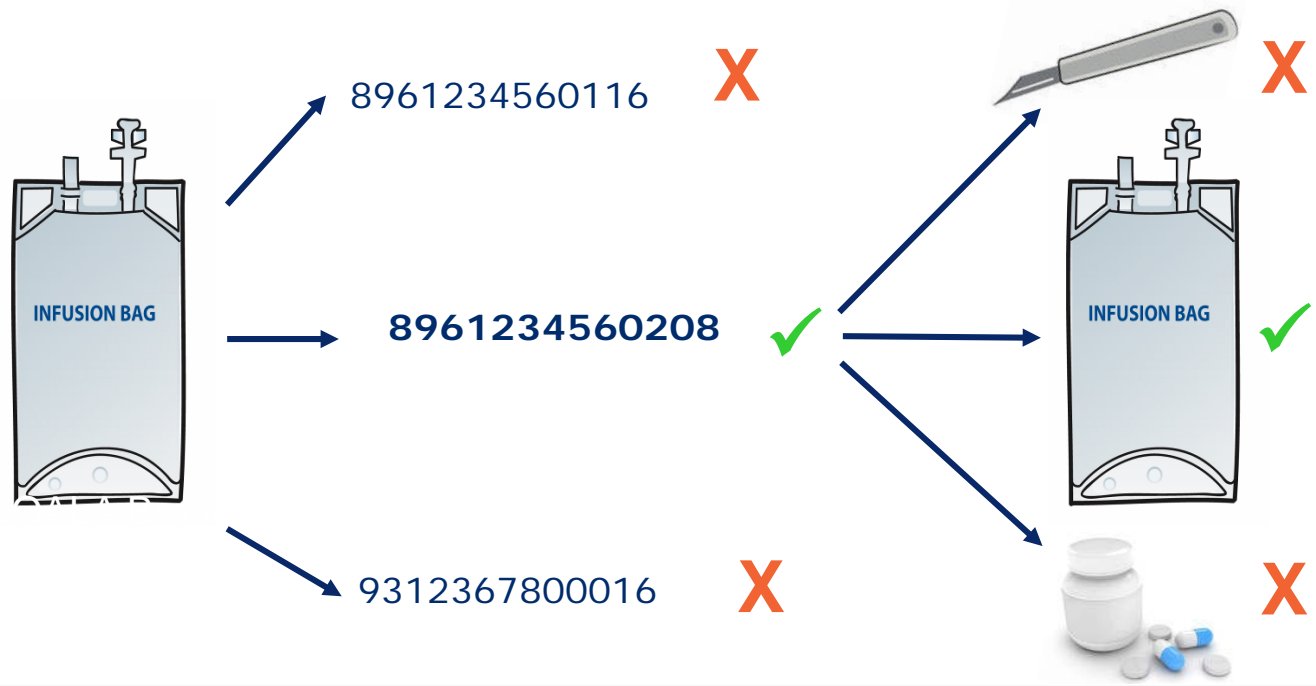
GTIN allocation in a hierarchy...

Example of Typical Pharmaceutical Hierarchy Levels

Single Unit	Each	Case or Shipper	Pallet
GTIN A	GTIN B	GTIN C	GTIN D
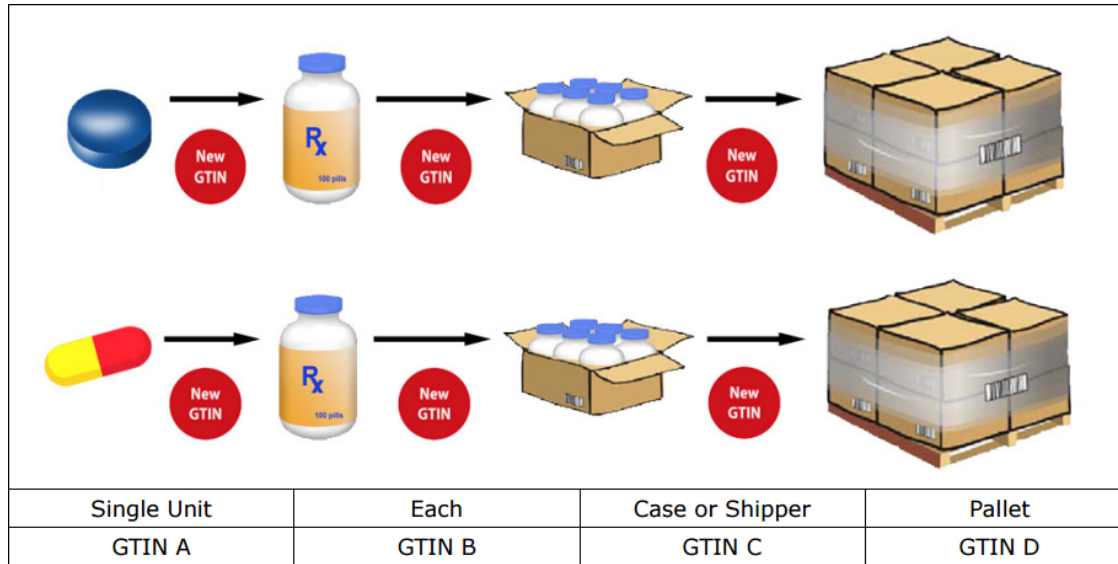
NOTE: Depending upon the particular "Single Unit" the "GTIN A" in this example could be an assigned but "unmarked" GTIN.

Packaging levels... definitions & roles...

Primary packaging

Secondary packaging

Secondary or Tertiary

Tertiary
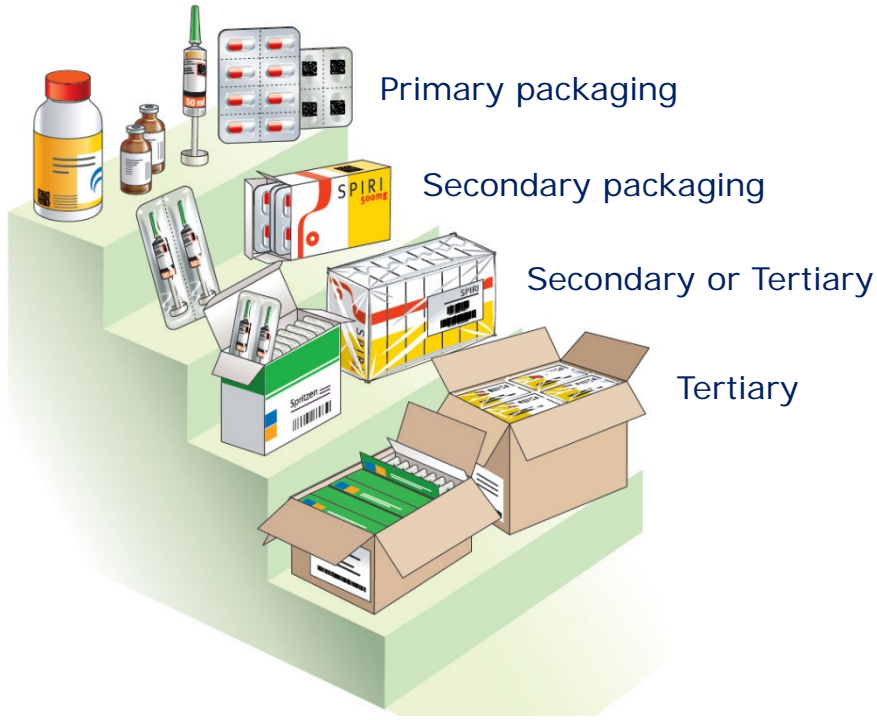
<u>Healthcare primary packaging</u> - The first level of packaging for the product marked with an AIDC data carrier either on the packaging or on a label affixed to the packaging. For non-sterile packaging, the first level of packaging can be the packaging in direct contact with the product. For sterile 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.

<u>Healthcare secondary packaging</u> - 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.)

Packaging level examples…

Primary

Tertiary
Case / Shipper

Secondary

Tertiary
Pallet
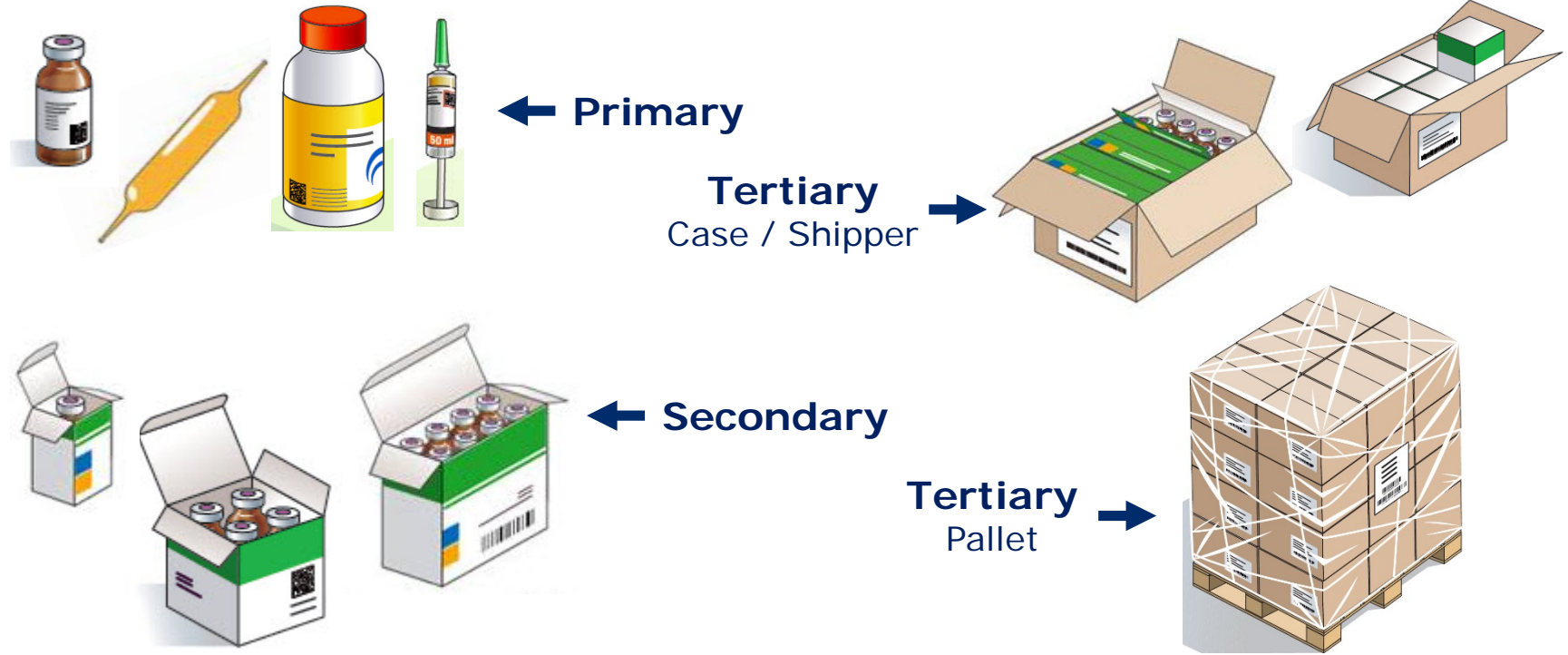
Reuse of a healthcare GTIN…

8961234560208

8961234560208

Not allowed in healthcare

Healthcare re-use of GTINs is not allowed at all
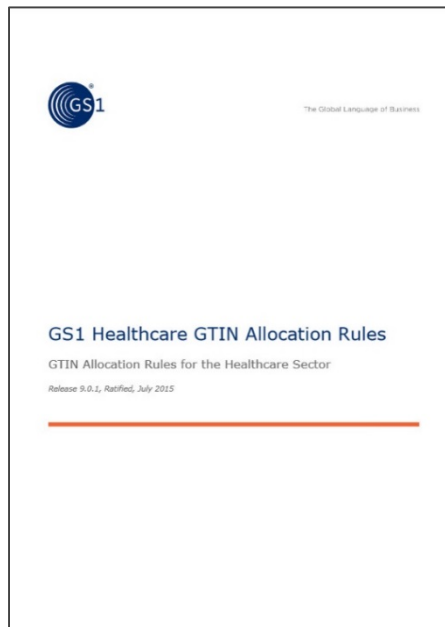
GS1 Healthcare GTIN Allocation Rules...

GTIN assignment in Healthcare

- A guide to GS1 ID Key assignment... the GS1 GTIN Allocation Rules presented in Healthcare related terms with Healthcare specific examples – Available online at: http://www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf
- Translated in many other languages

GS1 Healthcare GTIN Allocation Rules

GTIN Allocation Rules for the Healthcare Sector

Release 9.0.1, Ratified, July 2015

The Global Language of Business

GS1 — The Global Language of Business

GS1 AIDC in Healthcare

Application Identifiers

A need to capture the GTIN & more…

GS1-128 Barcode
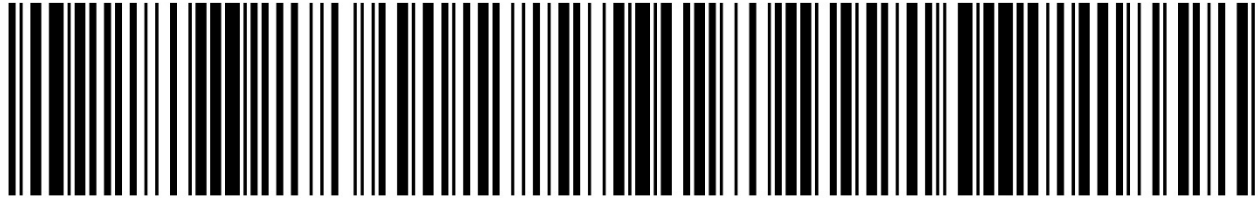
(01)19506000117843(17)141120(10)NYFUL01(21)192837

GTIN-14

(01)19506000117843
(17)141120
(10)NYFUL01
(21)192837

GS1 DataMatrix Barcode

Expiry Date

Batch Number

Serial Number

A GS1 Application Identifier (AI) is an element string that carriers 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).

GS1 Application Identifiers (AIs)…

The GS1 Gen Specs include <u>100+ "AI's"</u> for various use cases & sectors

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

- **…to reduce implementation complexity**
- **…maximize use of existing systems**
- **…potentially minimize cost implications**

01	GTIN (Global Trade Item Number) – 14 digit numeric
10	Batch / Lot – up to 20 characters, alphanumeric
17	Expiry Date – 6 digit numeric, YYMMDD format
21	Serial Number – up to 20 characters, alphanumeric

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

Why standardize on as few as possible...

- The barcode grows larger when too much data is included...
- With local variances costs increase beyond those already necessary for changing packaging lines...
- Increased complexity for manufacturers in managing "mult-market" or special packaging...
- When local rules are not globally aligned, it becomes an additional burden for any **exporting** and well as **importing** manufacturer...
- ...and when looking at serialization...

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Item identification: **Serialization**

GTIN plus Serial Number (a.k.a. **Serialized GTIN** or **SGTIN**) is a context-dependent feature of the GTIN that is used to identify a specific instance of a product or service identified by a GTIN. It is the "concatenation" of Application Identifiers AI(**01**), GTIN, and AI(**21**), Serial Number:

e.g. **01**09312345000000**21**01B2C3

AI(21) "Serial Number" is alphanumeric and 20 characters maximum

Though the addition of a serial number to the encoded data for a Secondary package in the pharmaceutical sector is becoming more common it is at present a "future goal" for the Primary package level.

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Identification "Keys" — SSCC (Serial Shipping Container Code)

Serial Shipping Container Code (SSCC)

18 digits

SSCC 393123450000000013

(00) 393123450000000013

SSCC Application Identifier (00)

- The SSCC identifies logistics units. This key is comprised of an extension digit, the GS1 Company Prefix, serial reference, and check digit.

- Provides a link between the physical logistic unit and information about that logistic unit communicated between trading partners using Electronic Data Interchange (EDI).

- The SSCC is assigned for the life of the logistic unit and is a mandatory element of the GS1 Logistic Label.

GS1 Application Identifier	SSCC (Serial Shipping Container Code)		
	Extension digit	GS1 Company Prefix ⟶ Serial reference ⟵	Check digit
0 0	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}

So… do I use GTIN and/or SSCC…

First Question – Is it a "Trade Item" or "Logistic Unit"?

- **Trade items:** Any item (product or service) upon which there is a need to retrieve pre-defined information and that may be priced **or** ordered **or** invoiced at any point in the supply chain
  - ➢ Identify and mark with a <u>GTIN / GTIN+</u>

- **Logistic units:** An item of any composition established for transport **and/or** storage which needs to be managed though the supply chain
  - ➢ Identify and mark <u>with at least</u> an <u>SSCC</u>
  - ➢ IF also a Trade Item it can <u>also have</u> GTIN / GTIN+

So... do I use GTIN and/or SSCC...

Case / Shipper
Logistic Unit

Mark w/ SSCC at minimum

IF the Case / Shipper is also a Trade Item it can also be marked with GTIN+

Ship to End Use Customer

→

Case / Shipper
Trade Item

Mark w/ GTIN+

Combine Cases on Pallet →

Mark Pallet w/ SSCC at minimum

IF the Pallet is also a Trade Item it can be also be marked with GTIN+

Break Pallet

If sold

Leave w/ GTIN+

If re-shipped

Mark w/ SSCC
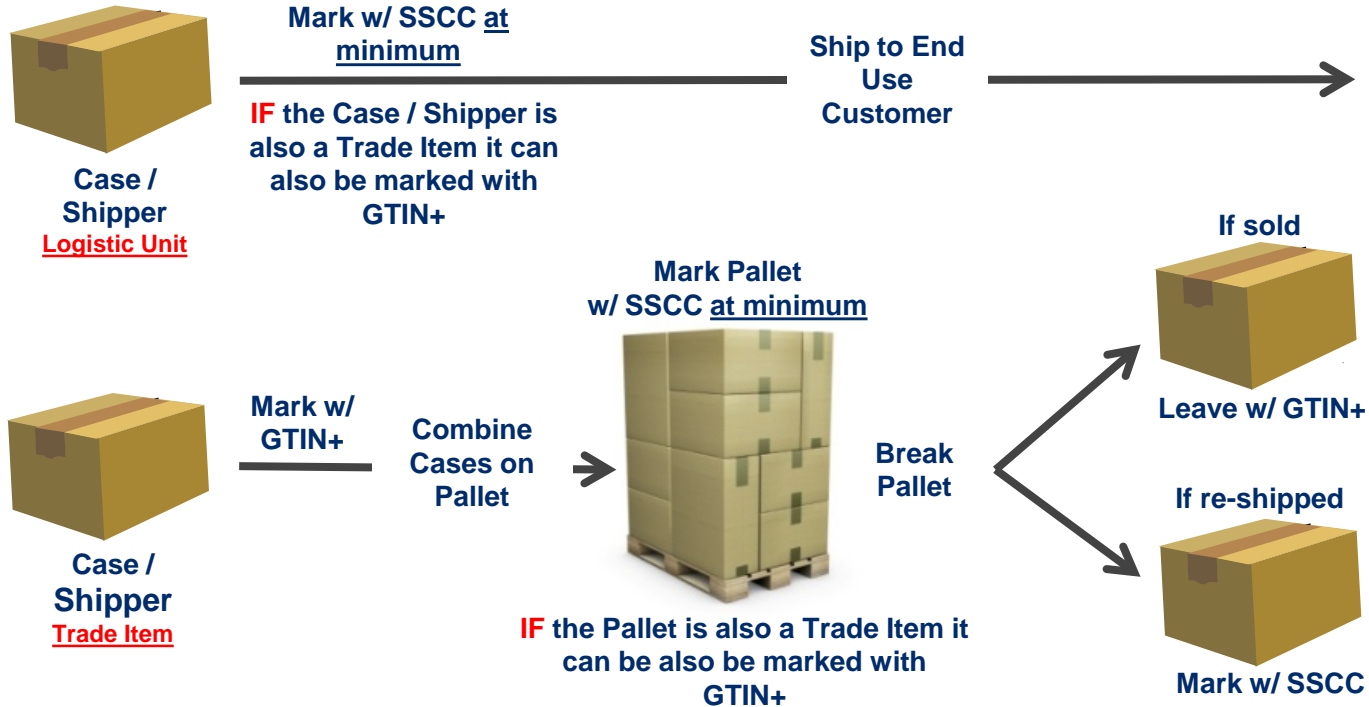
GS1 AIDC in Healthcare

Identification "Keys" - GLN (Global Location Number)

What is a GLN?

The **Global Location Number** is designed to improve the efficiency of communication with trading partners and add value to the trading partners involved, as well as to consumers.

GLNs can be used to identify a:

- Legal entity
- Function
- Physical location
- Digital location

GS1 Application Identifier	GS1 Company Prefix →							← Location reference				Check digit
4 1 4	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}

Global Location Number

Example: GLN Use GS1 Application Identifiers

- AI (410): Ship to - Deliver to GLN
- AI (411): Bill to - Invoice to GLN
- AI (412): Purchase from GLN
- AI (413): Ship for - Deliver for - Forward to GLN
- AI (414): GLN of a physical location
- AI (415): GLN of Number of the Invoicing Party

(414) 0614141000012

GS1-128 Symbol encoding a GLN using AI (414) Identification of a Physical Location

GS1 AIDC in Healthcare

Data carriers

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GS1 AIDC Data Carriers...

GS1's ISO compliant machine-readable **Data Carriers** for use with the product (via packaging, label or DPM... Direct Part Marking) containing the Product ID – 1D / Linear & 2D / Matrix bar code symbols, RFID.
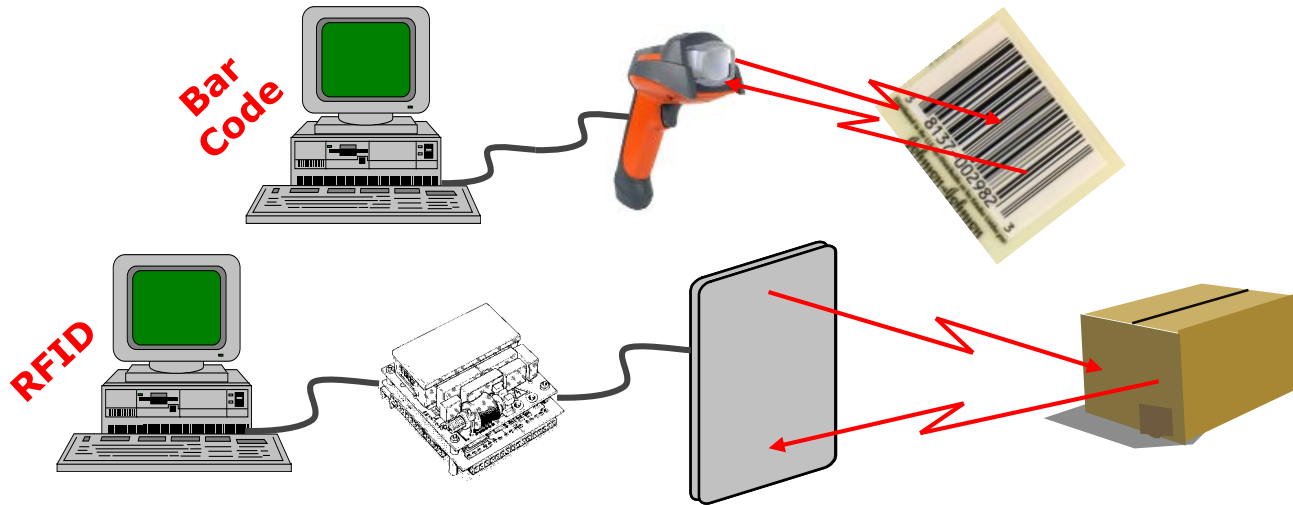
NOTE: Though "any" approved machine-readable Data Carrier is applicable... GS1 Healthcare members have agreed to focus at this time on the use of bar code technology before considering other data carriers...

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…

GS1 Data Carriers...
...chosen to support item serialization...

EAN/UPC

GS1 DataBar

5 012345 678900

(01)00012345678905(21)12345678

(01)00012345678905

GS1-128

(00) 0 0123456 123456789 6

GS1 DataMatrix

(01)00012345678905

GS1 Composite Component

(00) 0 0123456 123456789 6
(02) 5 0123456 78901 7 (37) 000289 (02) 5 0123456 11111 5 (37) 000045

GS1 QR Code

ITF-14

00012345678905

NOTE: In Healthcare GS1 QR Code is not endorsed for Trade Item related marking.

"Mechanics" of reading barcodes…
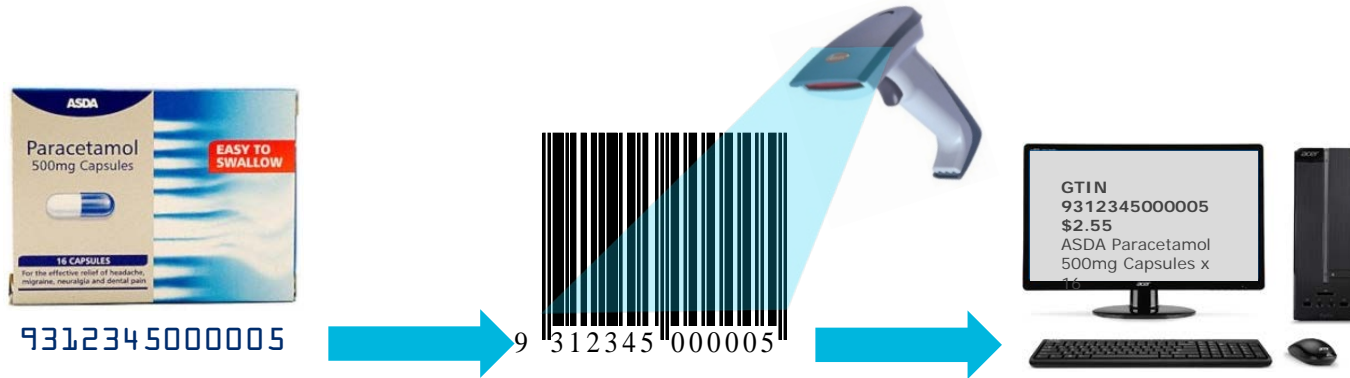
- A barcode is a "data carrier" that has the GS1 ID number encoded within as a **key** to the **information** about a product

- The GS1 data carrier is a **graphical representation** of the GS1 ID key used to **automatically capture** data and access information and data through a database in a computer system

- NOTE THAT camera-based bar code scanners are needed in Healthcare for 2D Data Carriers such as GS1 DataMatrix AND are a GS1 Healthcare Leadership Team recommendation!!

"Mechanics" of reading barcodes…

(01)10857674002017
(17)141120
(10)NYFUL01
(21)192837
(713)A1B2C3D4E5F6G

ENCODED (In) – User dependent:

<FNC1>**01**108576740020174**17**141120**10**NYFUL01<GS>**21**192837

DECODED (Out) – Scanner dependent:

]d20110857674002017171411201NYFUL01<GS>21192837

PROCESSING:

0110857674002017171411201NYFUL0121192837   **??**

0110857674002017	**17**141120	**10**NYFUL01	**21**192837
10857674002017	20 Nov 2014	NYFUL01	192837

ERP Entries

GTIN:

EXPIRATION:

BATCH/LOT:

SERIAL:

GS1

Mobile phones…

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 barcode were the slowest to scan, although only by 0.5 seconds on average. Barcodes with up to 50% fading had a 100% success rat but success rate deteriorated beyond 60% fading. Curved barcodes took longer to scan compared with flat, but success ra deterioration was only observed at a vial diameter of 10 mm. Light conditions did not affect success rate or scan time betwee 500 lux and 20 lux. Conditions below 20 lux impeded the device's ability to scan successfully. Variability in scan time wa observed across devices in all trials performed.

Journal of Medical Internet Research, vol.18,2016

GS1 AIDC in Healthcare

GS1 DataMatrix

Healthcare - Data carriers...

(01) 0 0012345 67890 5

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

| GS1-128	GS1 DataMatrix	EPC/RFID
Preferred option if:	**Preferred option** if:	**Additional option**
✓ Package allows (size)	✓ Larger amounts of data in a small space	✓ Non-line of sight
✓ Moderate amount of data	✓ Variable information at high production rates	✓ Large amount of data
	✓ Direct Part Marking	

GS1 DataMatrix support...

GS1
DataMatrix

(01) 00012345678905

As we see more AIDC marking on small Pharmaceutical and Medical Device products (and/or on their packaging) we will see more GS1 DataMatrix due to its ability to efficiently and securely carry more data in smaller areas, and also due to its promotion for use by the GS1 Healthcare global members.
Becoming familiar with the available support materials is advised...
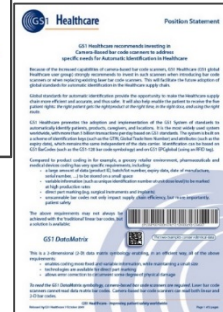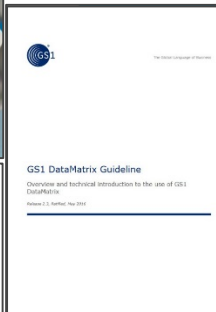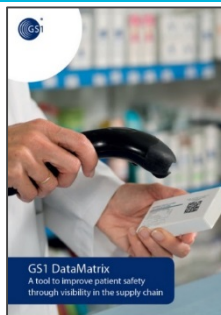
CHECK OUT: http://www.gs1.org/healthcare/library
http://www.gs1.org/docs/barcodes/GS1_DataMatrix_Introduction_and_technical_overview.pdf

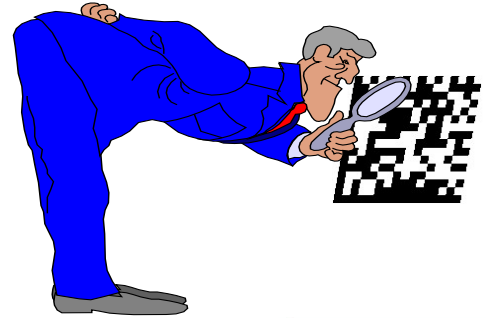# GS1 AIDC in Healthcare

Barcode symbol quality - Verification

Barcode symbol quality – Verification...

- Need an understanding that...
  - ...barcode scan failure causes delays and possible errors in the supply chain
  - ...you need to know what to verify... print and data
  - ...scanners are not quality verifiers
  - ...all need to follow GS1 & ISO/IEC standards

Symbol decode:
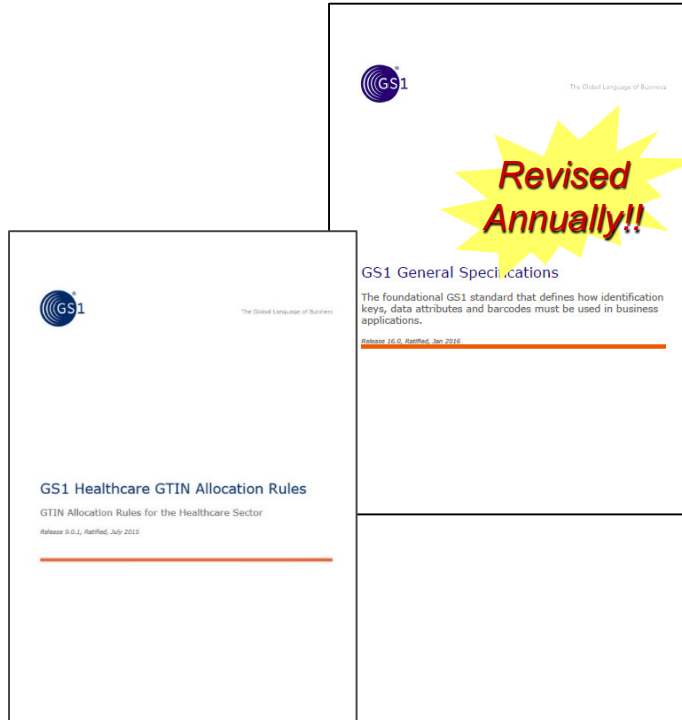
GS1 DataMatrix - (FNC1 & AIs)

]d2 0110857674002017171411201 0KMB11205201[GS]21CEB630078700

A	B	C	D	F
4	3	2	1	0
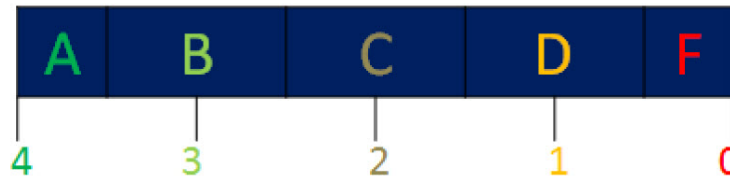
Minimum quality specification
1.5/06/660
1.5/08/660

So... where can I find more information ?

GS1 General Specifications – the ONE global standard for AIDC in Healthcare

- The core standards document of the "GS1 System"... describes how GS1 keys & data carriers should be used - Available online at: http://www.gs1.org/docs/barcodes/GS1_General_Specifications.pdf

GS1 Healthcare GTIN Allocation Rules – GTIN assignment in Healthcare

- A guide to GS1 ID Key assignment... the GS1 GTIN Allocation Rules presented in Healthcare related terms with Healthcare specific examples – Available online at: http://www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf

Many countries have already adopted GS1 Standards... and we anticipate many more!

Revised Annually!!

GS1

The Global Language of Business

GS1 General Specifications

The foundational GS1 standard that defines how identification keys, data attributes and barcodes must be used in business applications.

Release 16.0, Ratified, Jan 2016

GS1

The Global Language of Business

GS1 Healthcare GTIN Allocation Rules

GTIN Allocation Rules for the Healthcare Sector

Release 9.0.1, Ratified, July 2015

So... where can I find more information ?

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

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

The Global Language of Business

The basics of identification and barcoding for traceability
Manufacturer's Perspective

Pascal Aulagnet - Senior Manager Business Technology - Pfizer

The basics of identification and barcoding for traceability

Pfizer Global Serialization Program

African GS1 Healthcare Conference – Ethiopia

Pascal Aulagnet, Senior Manager Business Technology, **Pfizer Inc**

9th of May 2018 – Addis Ababa

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agenda

- Introduction

- GS1 Standards and focus on Identification and Barcoding

- Lesson Learned from European Falsified Medicines Directive Implementation

Introduction – Pascal Aulagnet

- Member of GS1 Healthcare Leadership team

- 18 years experience in Healthcare (As consultant and Pfizer)

- 11 years experience with traceability, track& trace and logistic

GS1 Standards Application

GS1 DataMatrix as Data Carrier

❖ High-density and smallest size barcode

❖ Small footprint fits on most package sizes

Key Data Elements / Application Identifiers:

1. GTIN (01)
2. Serial Number (21)
3. Expiry Date (17)
4. Lot Number (10)

❖ Unique identification of a unit

❖ Regulated by most worldwide mandates

GTIN (01) 00300694210304
SN (21) 100009876543
EXP (17) YYMMDD
LOT (10) L102034

Illustrations show variability of options based on packaging site capabilities and component size restrictions

GTIN and Serial Number may be placed in different location than Expiry and Lot

GTIN and Serial Number may be placed in different location than Expiry and Lot

Label for square bottle with standard serialization

Area for text and/or code

Pfizer
Product® (generic name) tablets
100 mg*
00 Tablets

0000000

(01) 08699532000010
(21) 21109210000031927
(17) 110921
(10) 7b3873116D

Area for text and/or code

IDENTIFY

CAPTURE

SHARE

Interoperability

1. GS1 GDSN for master data
2. EDI for transaction data

❖ Common language between partners

❖ Master data is DNA for Serialization

Printing format of the 2D DataMatrix

- ✓ The European Delegated Regulation states that International Standards can be used for the 2D barcode format

- ✓ International standards allow for the 2D barcodes to be produced in several different formats e.g. square and rectangular

- ✓ International Standards also allow the 2D barcodes to be produced in a positive version (black on white) or a negative version (white on black*)

- ✓ Different technologies produce either a positive or negative image and this will vary across MAHs

- ✓ Scanning equipment must be able to read all these variations according to International Standards

   other dark colours may also be used as long as there is a high contrast

Square, Rectangular, White & Black 2D barcodes must be accommodated

Encoded data order

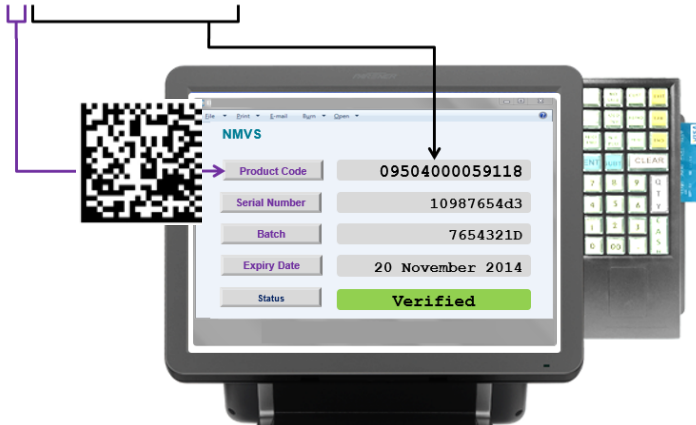]d2**01**09504000059118**17**14110**01**07654321D**<GS>21**10987654d3

Product Code	09504000059118
Serial Number	10987654d3
Batch	7654321D
Expiry Date	20 November 2014
Status	Verified

Green = Encoding type used e.g. GS1
Purple = Application Identifiers
Blue = Group Separators

✓ GS1 standards define how data in the 2D barcode should be encoded

✓ Scanning and IT systems do not identify the content e.g. Product Code, based on its position in the encoded data. They use the Application Identifiers which "signpost" the data e.g.
01 = product code, 17 = Expiry date, etc

✓ Mandating a specific order to encode the data serves no purpose as fields such as batch and serial number vary in length

✓ Failing to encode data using these standards will lead to scanning systems not being able to read the codes

No specific order should be mandated

Usage of Application Identifier

PC (01)   09504000059118
SN(21)   10987654d3
Exp   11.2014
Lot(10)   7654321D
PVP   €10,50

NN (710)   10389358

PC   09504000059118
SN   10987654d3
Exp   11.2014
Lot   7654321D
PVP   €10,50

NN   10389358

- ✓ Application Identifiers are encoded in the 2D barcode to signpost the data for the IT and scanning systems

- ✓ International Standards and good practice recommend they also appear on the human readable text to help if the barcode fails to scan, perhaps due to damage.

- ✓ Space and technical constraints can mean that these Application Identifiers can not always be included (which is also considered and allowed by International Standards)

- ✓ It should therefore be left to the MAH to determine whether to include the Application Identifiers following International Standards

Application Identifiers in the human readable text should be at the discretion of the MAH, in accordance with International Standards

Transition Period for implementation
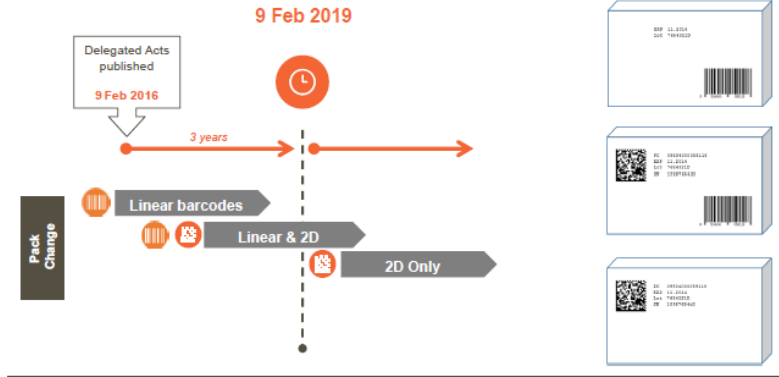
✓ When a legislation to introduce 2D Barcoding entry into force, stakeholders are only obliged as of this date to be capable to read the 2D DataMatrix code, existing linear barcodes need to be kept and cannot be removed before this date. And even after that date two scenarios must be foreseen:

✓ 1. For some of their products, MAHs may want to remove the linear barcodes after the implementation date in order to remove unnecessary information and to free up space.

✓ 2. For other products, the DataMatrix and the linear barcode will need to co-exist to ensure continued supply of shared packs and also taking into account any individual members of the pharmaceutical sector that might not have implemented the capability of DataMatrix read in time.

Transition period should be allowed to let at the discretion of the Marketing Authorization Holder

Human Readable Information

✓ Complying with a specific order and layout for the data elements is not achievable due to physical, technical and other regulated requirements.

✓ We also can not comply with a specific order where the data is split over several faces of the pack, which is allowed by the DR, art 7(3)

✓ The order of these data elements does not impact on patient safety or usability of the product as long as the information is clearly laid out and legible.

✓ It may not always be possible to locate the headers for the human readable data elements beside the elements themselves but instead follow current common practice of locating these near to the data elements.

The layout of the elements should not follow a specific order and header location should follow current common practice

thank you!

Contact Information

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GS1

The Basics of Identification and Barcoding for Traceability Manufacturer's Perspective

Ulf Suerig - Head Global Business Processes - Abbott

ULF SUERIG, ABBOTT ESTABLISHED PHARMACEUTICALS
GLOBAL SUPPLY CHAIN

The Basics of Identification and Barcoding for Traceability

GETTING PEOPLE BACK TO DOING THINGS THEY LOVE

Nutrition

Diagnostics

Medical devices

Medicines

TACKLING CHALLENGING HEALTH NEEDS AROUND THE WORLD

Demand for healthcare rising in growing economies

People living longer

Innovation in personalized medicine

Prevalence of chronic conditions

People taking a more active role in healthcare decisions to live their fullest lives

65%

OF SALES OUTSIDE THE U.S.

58%

OF SALES IN DEVELOPED MARKETS

42%

OF SALES IN EMERGING MARKETS

5/9/2018

Emerging Markets

Abbott is the only global company whose pharma business is 100% focused on emerging markets.

What does

Serialization & Traceability

implementation mean to us?

New regulations are changing the information, symbols and data sharing requirements at the saleable unit

Dynamic Coding

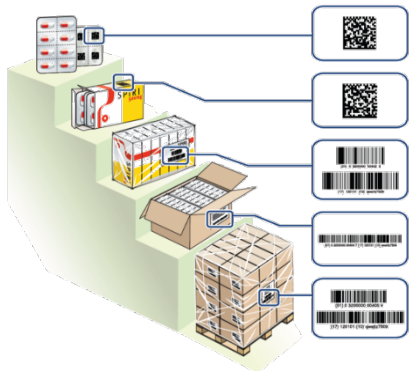Human readable lot and expiry

GS1 DataMatrix
with GTIN, lot, expiry

Serialization
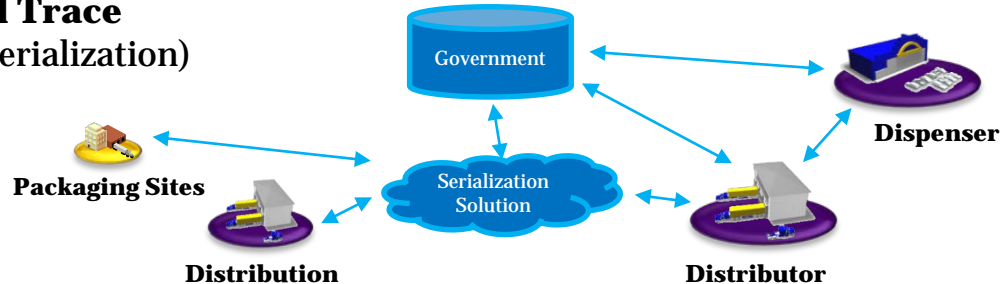
GS1 DataMatrix with
GTIN, lot, expiry, SN

China – Code 128
with Chinese Product & Serial Number

Track and Trace
(includes Serialization)

Government

Dispenser

Packaging Sites

Serialization
Solution

Distribution

Distributor

Serialization & Traceability is equal to Complexity and Big Data

- The implementation of Serialization and Traceability will transform the supply of medicines

- The complexity will increase and therefore it is wise to invest in the design of the regulation

  - What are the objectives?

  - What kind of stakeholders are effected by the implementation?

  - What are the benefits of using global standards?

  - What are realistic timelines to implement Identification, Data Capture and Sharing Data?
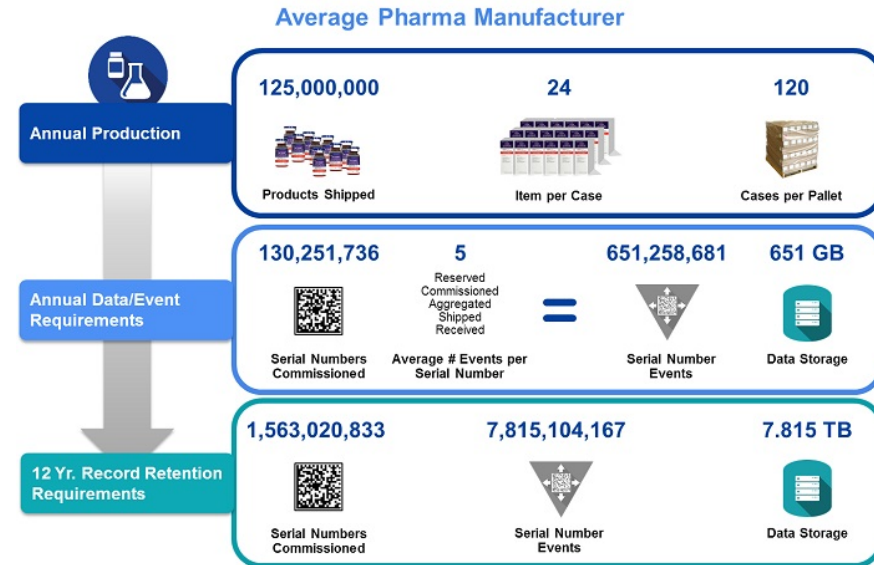
Data Integrity

- Understanding global standards is key to correctly design the technical specifications
- Based on this the right information can be exchanged between the different business partners
  - Manufacturers
  - Distributors
  - Pharmacies
  - Government agencies (for reporting)
- Build expertise on data and barcoding standards

vs.

Data Security

- **Serialization & Traceability will provide high quality medicines via a secure supply chain to patients**

- **Data Security is essential for the data exchange and the reporting – this is valid for**
    - Authentication
    - Authorization
    - Encryption
    - Data Exchange and Data Sources

Data Modeling & Reporting

- It is important to differentiate static and variable data and the different master data sources

- The model should be scalable and the end state (w/ or w/o track & trace) should be determined on a very early stage

- Design the data model for big data

- The reporting can have an extraordinary impact on the supply chain performance, depending on the level of reporting required – and esp. on small business partners

Simplicity is the ultimate Sophistication.

Leonardo da Vinci

Challenges for the implementation of different coding systems

- **Equipment is not able to print all codes**

  Longer lead times and efforts (verification and testing) driving up the cost

- **Additional information are difficult to print**

  Size limitation to read a 2D code are existing as well as the number per lines printable by one print head

- **Upstream complications for external manufacturers**

  Same efforts for internal manufacturing needs to be implemented where sourcing is externalized

- **Centralized distribution of serial numbers**

  The more we have non-standardized codes and centrally maintained serial numbers the higher the risk is for failures or data breaches

Global Standards are a Key Success Factor for Serialization and Traceability
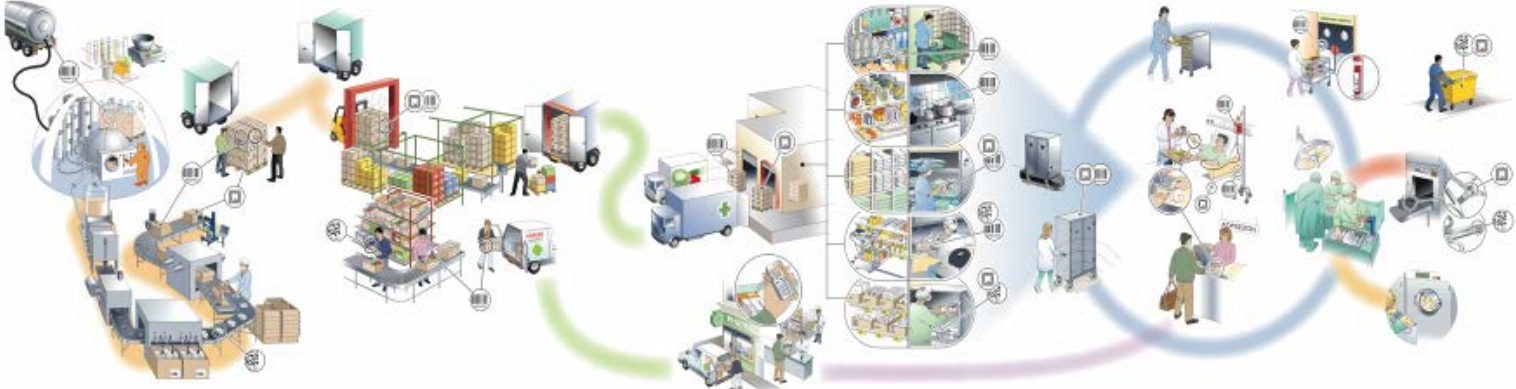
Audience Q&A time...

…and THIS WEEK do not miss…

...the "Q&A with the Experts" panels related to Standards & AIDC in Healthcare:

Thursday – 10 May

- 14:00 to 15:00 hrs

   Understanding the difference between standardisation and technology - Chuck Biss, Senior Director AIDC Healthcare / Peter Alvarez, Senior Director, Identification and Data Strategy, Healthcare / Craig Alan Repec, Senior Manager, Supply Chain Visibility, EPCIS & RFID, all GS1 Global Office and Cyndi Poetker, Director of Enterprise Standards and Traceability, Abbott

- 15:00 to 16:00 hrs

   Identification and bar coding - Chuck Biss, Senior Director AIDC Healthcare, GS1 Global Office and Ulf Suerig, Head Global Business Processes, Abbott

Networking Dinner on Wednesday, 19:30

Yod Abyssinia

Bole Medhaniyalem Area,

Addis Ababa,

Ethiopia

Bus departure: **meet in the main lobby** at 19:00 pm

Bus return: beginning at 21:30 and will run on a loop with a last shuttle leaving at 22:30.

Dress code: business casual.

PLEASE WEAR YOUR EVENT BADGE ☺

COFFEE BREAK

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Contact information…

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