



GTIN Allocation Team

Minneapolis, June 2006

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The global language of business

www.gs1.org



Work Group – GTIN Allocation

Summary Today's of Presentation:

1. Introduction to HUG GTIN Allocation Work Team
2. Demonstration of GTIN Allocation Rules Website (www.gs1.org/gtinrules)
3. GTIN Allocation Rules – Basic Top Level Principles for Healthcare
4. Complex Issues – open questions
5. Next Steps – your input



1) Work Group – GTIN Allocation

Co-Chairs

Mark Walchak- Pfizer

Mark Hoyle- Tyco Healthcare

Members

David Buckley - GS1

Leen Danhieux - GS1

Ulrike Kreysa - GS1

Sue Schmid - GS1

Tom Werthwine – J&J

Heribert Wirges - Phoenix

Volker Zeinar – Braun

Jill Buss - 3M

Colleen Dooley- Sobey

Pat Morrison - Lawtons

Peter Tomicki- Baxter

Jim Wilmott – Smiths Medical

Nigel Wood - GS1



Charter

- Simple and easy to use worldwide standard for GTIN Allocation in Healthcare
 - Developed using published GS1 GTIN Allocation Booklet
- Easy navigation based upon
 - General Rules and Over-the-Counter (OTC)
 - Specific rules Prescription (Rx)
 - Specific rules Medical Devices
- Schedule
 - Today (Minneapolis) finalise concept and table of content
 - September 2006 – Provide HUG with final draft



Table of Contents – Top Level

1. Scope and Background
2. Introduction to Global Trade Item Number in Healthcare
 - 2.1. Definition of a GTIN
 - 2.2. Healthcare Items (definitions)
3. Allocating the Numbers
4. Regulators
5. GTIN Allocation Scenarios
 - 5.1. Over the Counter (OTC)
 - 5.2. Prescription (Rx)
 - 5.3. Medical Devices
6. Glossary



TofC: 1. Scope and Background

Main Statements:

- voluntary guideline
- developed by the Healthcare User Group www.gs1.org/hug
- aiming at consistent world-wide use of GTIN
- provides details on GTIN Allocation within Healthcare



TofC: 2. Introduction to Global Trade Item Number in Healthcare

Main Statements:

- Overview of GTIN
- While all GS1 standards are voluntary, the rules are intended to drive consistent implementation in the Global Healthcare Community.
- NOTE: *National, federal or local regulations may apply and take precedence. For example, some healthcare regulators may dictate a new GTIN for a given change*
- Definitions of:
 - Over The Counter (OTC)
 - Prescription (Rx)
 - Medical devices



TofC: 3. Allocating the Numbers

Main Topics Covered:

- General rule
- Responsibility
- Guidelines for Allocating Global Trade Item Numbers
 - Best Practice in Healthcare is not to reallocate any GTIN that has previously be used on a product which has become obsolete.
- Packaging Levels
- Data Requirements in Healthcare
 - GTIN and Batch and Expiry Date
 - GTIN and Serial Number
- Acquisitions and Mergers
- Data alignment



TofC: 4. Regulators

Main Statements:

- When in doubt, obey the law
- For a summary information, by country regulator, see:
http://www.gs1.org/hug/work_teams/standards_implementation/

(HUG Page of Standards Implementation / Regulatory Affairs)

5.1 Over the Counter Rules:

New Language - New language on a package sold in one Market/Country- NEW GTIN



Plus many more (see draft document)



TofC: 6. Glossary of Terms?

GLOSSARY Open question:

- Reference the 'existing' GS1 Glossary?
- Reference a wider 'HUG' Glossary (which would have to be developed)?
- Include here a short summary of the key terms used in this document?



Team meetings & Working Drafts

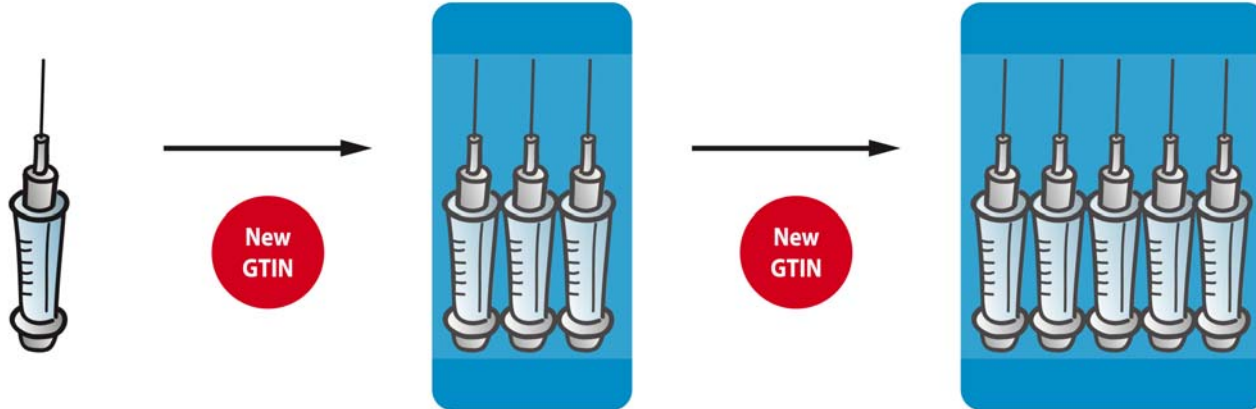
- 23 February 2006 Kick-Off Telecom
- 10 March 2006 – Telecom
- 27 March 2006 - ROME HUG meeting (formal review)
- 19 May 2006 – Telecom
- **tbd June 2006 – Next Telecom**

http://www.gs1.org/hug/work_teams/gtin_allocation/

Version	Date	Responsible	Changes
Version 0.2	14 March 2006	David Buckley	Summary of work team results
Version 0.3	15 March 2006	Ulrike Kreysa	Comments of Leen Danhieux
Version 0.4	10 May 2006	David Buckley	Comments following Rome HUG Meeting
Version 1.0	10 June 2006	David Buckley	DRAFT For Minneapolis HUG meeting (update from 19 May 2006 team call and image updates)

Packaging Levels

Each packaging level needs a different GTIN



Example Syringe: Different GTIN for single, pack of three, pack of five

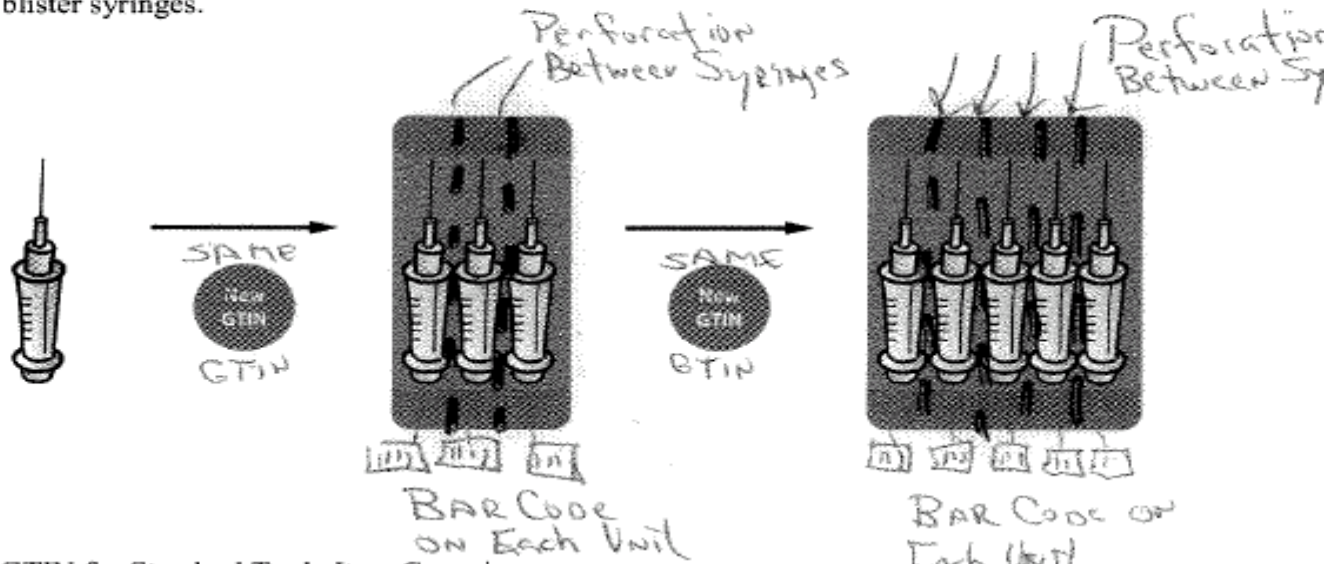
.. But still a lot of work to do?

DIFFERENT QUANTITIES / Perforated Blister/GTIN on Each Blister Cell

Type of Change to Trade Item

Grouping of the same item containing different quantities

Example: A single item- loose syringe, a multi-pack of 3 blister syringes, and also a 5 blister syringes.



GTIN for Standard Trade Item Grouping
(Picture of case with New GTIN bug)

Rationale

GTIN for a single unit should be the same if it is for a single pack or a multi pack.

Consequence if Rule Not Applied

The GTIN identifies all aspects of the standard trade item grouping for ordering, stocking or billing systems. The GTIN for a single unit should not



2) www.gs1.org/gtinrules

- Modern technology (database)
- Simplified/quicker maintenance
 - Simplified translation
- Detailed hit reports:
 - At scenario level
- Ability to link to Associated Rules
 - *discussion?*
- Search Feature
- Integrated into GS1 Website look and feel

*Have a look new:
GTIN Site*



Areas of Concerns and Resolution

- Country Specific?
 - Make reference to Standards Implementation and Regularly Affairs Group
 - Countries not using Systems coding not compatible with GTIN
- Multiple bar codes on the package
 - one GTIN and another country required (example Germany, Austria, Italy)
- Assigning GTINs to lowest level
 - Unit of use
 - Multiple bar codes on the same package (UPC and Data Matrix)
- The Bar Coding of Expiry Dates which are not day related
 - (e.g., Expiration in March 2009 (which is not 1 March 2009 nor 15 March 2009 nor 31 March 2009)).

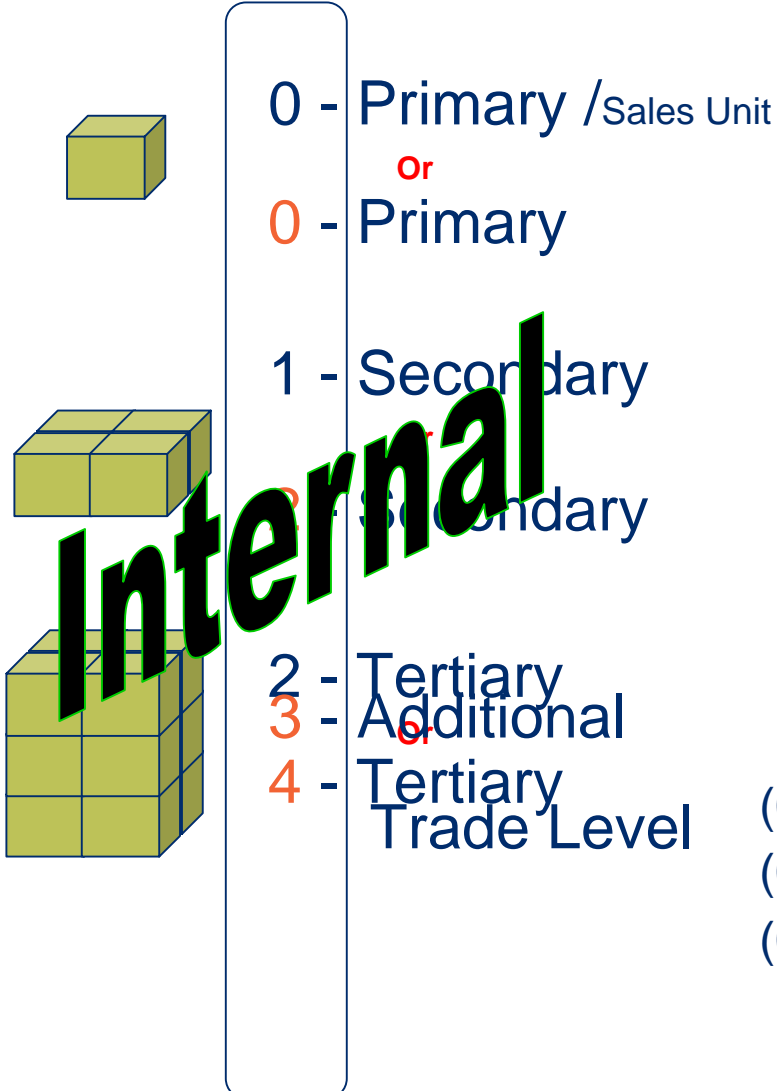


3) GTIN Allocation for Healthcare

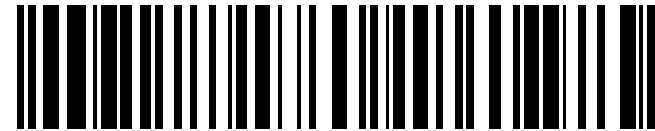
- GTIN Allocation Rules – Basic Top Level Principles
 - e.g. Package Level Indicators
 - Internal or External Affect
- GTIN Allocation Rules – Basic to Complex Devices / Kits
 - Application
 - When is a Package not a Package?
- GTIN Allocation Rule Concepts
 - What Signifies a Change?
 - Commercial Variance, Price of Trade Item?
and / or
 - Regulation alignment.....
 - Form, Fit or Function, Configuration Management Principles?



Top Level Principles



The GTIN, GS1-128



(01)00123456123450



Application Identifier AI(01)

Element Correlation

- (01)00xxxxxx55555z
 - (01)20xxxxxx55555z
 - (01)40xxxxxx55555z
 - (01)10xxxxxx66666z
 - (01)20xxxxxx77777z
- External**



Top Level Principles

CE



CE-0318



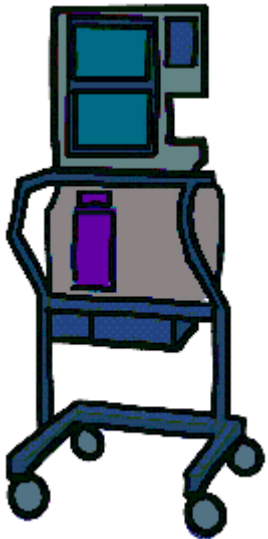
New
GTIN



4) Complex Devices

Three Component Parts

Ventilator



- 1. GUI
 - 2. Primary Unit
 - 3. Battery
- } Independent Serial Numbers }
- } Master Serial Number AI(21)

New GTIN ?

Configuration

- 1. Language
- 2. Country of Use
- 3. Firmware Revision
- 4. Software Options
- 5. Hardware Revision

Commercial

- ✓
- ✓
- ✗
- ✓
- ✗

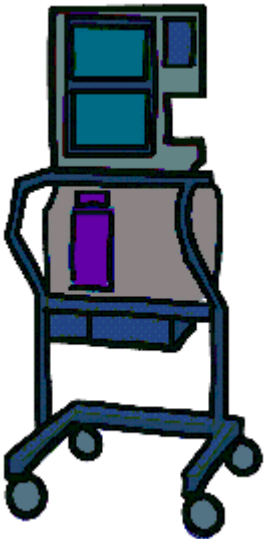
Form, Fit or Function

- ✓
- ✓
- ✓
- ✓ Additional Option GTIN's
- ✓

What are the Boundaries and Degree of Change before GTIN Modification is Necessary? Define!



Configuration



- Software Options
 1. Installable Options (CD Rom / Modem / Internet Download)
 2. Activated Options (Authorisation Code)

If an Option is Purchased or Transacted FOC the Option Must Have a GTIN Assignment, Manufacturers Configuration Management Databases Will Track the Build State Over the Lifetime of the Device by Association to it's Serial Number.



Kits – GTIN Allocation

Combinations of Independent Trade Items Each Having a Separate GTIN

Suction Catheter / Sterile Saline & Exam Gloves



Swabs, Gauze sponge, Forceps, Scissors etc.



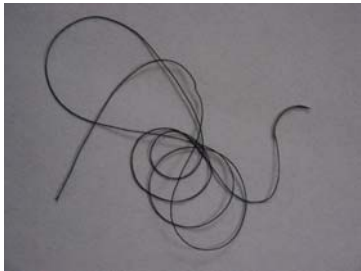


When is a Package not a Packaging Level ?

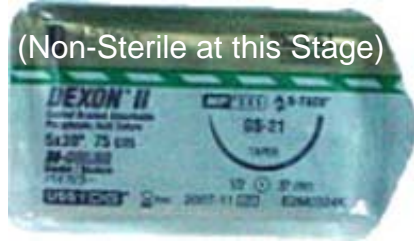
When Two Levels are Used to Form the Sterile Barrier

Sealing Inner Through Outer (SITO)

Absorbable Suture



Inner Foil
(Non-Sterile at this Stage)



Outer Gas Permeable Pouch



Finished Sterile Single Unit of Use Pack



Secondary



Multiples of x36

Tertiary



Multiples of 36 x 200

Does both Inner & Outer require a GTIN with different Packaging Level assigned?



5) Within Scope or Out? Next Steps

Items Transacted Inside the Healthcare Portfolio but not individually Regarded as OTC, Rx or MD.

- Medical Device Service Kit
- Spare Parts
- Manuals
- IFU's (paper)
- IFU's on CD
- etc.

Define Our Rules!

Workshop Tomorrow, Clear Objectives: Open Participation Encouraged - **Thank You**





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