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
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
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
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
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
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)
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/

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<tr>
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<td>14 March 2006</td>
<td>David Buckley</td>
<td>Summary of work team results</td>
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<td>Version 1.0</td>
<td>10 June 2006</td>
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<td>DRAFT For Minneapolis HUG meeting (update from 19 May 2006 team call and image updates)</td>
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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

- Check Digit
- Unique Identifier
- Manufacturer ID
- Separator Digit (GS1-USA)
- Packaging Level Indicator
- Application Identifier AI(01)

Element Correlation

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

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4) Complex Devices

Three Component Parts

1. GUI
2. Primary Unit
3. Battery

Configuration

1. Language ✓ ✓
2. Country of Use ✓ ✓
3. Firmware Revision ✗ ✓
4. Software Options ✓ ✓ Additional Option GTIN’s
5. Hardware Revision ✗ ✓

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
Contact Details

Mark Walchak-Pfizer
Senior Manager-Global Packaging
T + 1 908 901 7230
E Mark.Walchak@pfizer.com

Mark Hoyle-Tyco Healthcare
Manager, European Packaging
T + 44 (0) 1329 224016
E Mark.Hoyle@emea.tycohealthcare.com

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