Members

Co-Chairman
• Mark Walchak- Pfizer
• Mark Hoyle- Tyco

Members
• David Buckley- GS1
• Nigel Wood-GS1
• Leen Danhieux-GS1
• H. Wirges- Phoenix
• Sue Schmid-GS1
• Colleen Dooley- Sobey
• Jim Wilmott- Smith Medical
• Peter Tomicki- Baxter
• J Buss- 3M
• Volker Zeinar- Braun
Guideline Document
Worldwide Standard
  • Built on GS1 GTIN rules
  • OTC, Pharma, and Medical Devices

Country Specific?
  • Regulatory
  • Would require a living document??
Introduction to GTIN in Healthcare

Definition

- OTC
- Rx
- Medical Device

Allocation of GTIN

Regulators

GTIN Examples/Guidelines

- OTC
- Pharma
- Medical Devices
DIFFERENT QUANTITIES

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
Different GTIN necessary to distinguish between the different pack sizes.

Consequence if Rule Not Applied
The GTIN identifies all aspects of the standard trade item grouping for ordering, stocking or billing systems. Using the same GTIN for the standard trade item grouping containing different quantities invalidates these systems.

Notes:
- In this situation the blister does not have perforations separating each individual unit in the multi unit. (See ……)
- The GTIN on the individual syringes remains the same in all packs
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

Notes:
- In this situation the blister has perforations separating each individual unit in the multi unit. So the individual blister units will all have the same GTIN
- The GTIN on the individual syringes would be the same as the individual perforated blisters
• New Language - New language on a package sold in one Market/Country - NEW GTIN REQUIRED
• Additional Language on the packaging sold in several markets - SAME GTIN
• Language group cluster substitution - ex an item in English, Spanish and Portuguese that will now appear in English, French and Italian - NEW GTIN
• **GTIN Standard Trade Item Grouping** - NEW GTIN Minor changes which are not relevant to trading partners or consumers (example - neither the consumer nor the ordering, billing, prescribing, stocking, dispensing information is impacted - SAME GTIN
• Minor artwork changes - example - change to reflect a new Marketing “look” - SAME GTIN
• Changes to weight, count volume - NEW GTIN
• Changes in dosage - NEW GTIN
• Changes in usage - NEW GTIN
• Changes in packaging materials - example - glass to plastic package - SAME GTIN
• Change in weight of declared units - examples - 100 to 125 tablets - NEW GTIN
• Change to a new form - example Aspirin tablet to Aspirin gel cap - NEW GTIN
• Change that affects the trade item name or brand - example Joe’s Aspirin to Paul’s Aspirin - NEW GTIN
• New/additional pallet layouts to the co-exist permanently with the original layout - example aspirin is sold standard pallet loads but Market pressure requires additional pallet configurations to be made - NEW GTIN
Groupings of same item containing different quantities- ex. one syringe pack, 3 pack and 5 pack- NEW GTIN

- NOTE: GTIN for each individual syringe will remain the same
- GTIN Standard Trade Item Grouping- NEW GTIN

Unit of Use packaging

- One each five pack blister (no perforations) in a carton- THE ONE GTIN PRINTED ON THE CARTON AND THE BLISTER WOULD BE THE SAME
- Two of more five pack blisters (no perforations) in a carton- THE ONE GTIN PRINTED ON THE CARTON AND THE BLISTER WOULD BE different
KITS:
- Surgical Stapler and staples
- ECG Electrodes single or set
- Generator and electrodes
- Stutures, multiple types per kit for fixed surgical procedure
- Breathing kits
- Vascular access systems
- Nebulisation kit
- Introduction kit for transurethral catheter
Medical Device

Mark Hoyle
Areas of Concerns and Resolution

- Number of GTINs for Medical Devices
  - Software
    - Upgraded Versions
  - Voltage
  - Country
  - Language
    - Ex. UK and US
- Countries not Using Systems coding systems not compatible with GTIN- Two codes on the package one GTIN and another country required.
  - i.e. Germany, Austria, Italy
  - UPC and Data Matrix
- Assigning GTINs to lowest level
  - Unit of use
- Best practice in health care is never to reuse GTINs.
• General Review of Process
• Review definitions of OTC, Rx and Medical Devices
• Review listing OTC, Rx and Medical Device Situations to make sure all options are covered.
  • Group 1 OTC/Rx
  • Group 2 Medical Devices
Contact Details

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

Mark Hoyle-Tyco

E Mark.Hoyle@tyco.com
1. Scope and Background
2. Introduction to Global Trade Item Number in Healthcare
   2.1. Definition of a GTIN
   2.2. Healthcare Items (definitions)
      2.2.1. Over The Counter (OTC)
      2.2.2. Prescription (Rx)
      2.2.3. Medical devices (classification I, II, III plus their subset and the 4 subject levels- non-invasive, invasive, active, special rules
3. Allocating the Numbers
3.1. General rule
3.2. Responsibility
3.2.1. Branded and Non-Branded items
3.3. Guidelines for Allocating Global Trade Item Numbers
3.3.1. Pre-defined characteristics
3.3.2. Lead time in re-using a GTIN
3.3.3. Prepriced merchandise
3.3.4. Trade item changes
<table>
<thead>
<tr>
<th>Assigning GTIN to Groupings</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.4. What are groupings (hierarchies)</td>
</tr>
<tr>
<td>3.4.1. Unit of Use Package (i.e., individual blister)</td>
</tr>
<tr>
<td>3.4.2. Shipper or Case</td>
</tr>
<tr>
<td>3.4.3. Pallet</td>
</tr>
<tr>
<td>3.4.4. GTIN</td>
</tr>
<tr>
<td>3.4.5. Expiry Date</td>
</tr>
<tr>
<td>3.4.6. Batch</td>
</tr>
<tr>
<td>3.4.7. Serial Number</td>
</tr>
<tr>
<td>3.5. Acquisitions and Mergers</td>
</tr>
<tr>
<td>3.5.1. Partial Purchase</td>
</tr>
<tr>
<td>3.5.2. Split or Spin-Off</td>
</tr>
<tr>
<td>3.6. Data alignment</td>
</tr>
<tr>
<td>3.6.1. Data Alignment Best Practice</td>
</tr>
</tbody>
</table>
4. Regulators

4.1. Changes not requiring new GTIN

4.1.1. Over the counter

4.1.2. RX

4.1.3. Medical Devices

4.2. When a new GTIN is required

4.2.1. Over the counter

4.2.2. RX

4.2.3. Medical Devices