The Past: 1990’s
- Supply Efficiencies
- Pallet Through Retail Packages

The Present: 2000-2005
- Prevention of Dispensing Errors
- Unit Dose and Unit of Use Packages

The Future: 2005 Forward
- Counterfeit Deterrence
- Pallet/Case/Retail Packages

GS1 GLOBAL Healthcare User Group
- Mission
- Vision
- Focus Areas
The Past:
Supply Chain Efficiencies
The Past: 1990’s

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Early 1990’s

Retail Packs –

• Wholesalers’ Need for Increased Levels of Automation in their Warehousing and Distribution Facilities
• Initial Focus on Retail Packages
• National Drug Code in Barcode Format (UPC)
  • Manufacturer/Labeler, Product, and Package Size
• Code Utilized by Wholesalers, Pharmacists and FDA
• All Retail Packages by 1992

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The Past: 1990’s

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1993 - 1996
Shipping Containers – Healthcare Distribution Management Association (HDMA)
Voluntary Standards for Barcodes

- NDC, Case Quantity, Lot Number, and Expiration Date
- Two Adjacent Panels

Dilantin®
(Extended Phenytoin Sodium Capsules, USP)

100 mg

60 Cartons x 100 Capsules

60 Carions x 100 Capsules
The Present:

Patient Safety

Dispensing Error Prevention

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Patient Safety – Unit Dose and Unit of Use Packages

- March 2004: Final Rule Published
  - NDC on Unit Dose or Unit of Use Container Labels
  - Lot and Expiration Date Optional
  - Linear Symbology
  - UCC.EAN or HIBCC Standards
  - Two Year Implementation
The Present: 2000-2005

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Pfizer Position:

• Meet or Exceed Regulatory Requirements
• Meet Customer Needs Where Feasible
  • Utilize all Three Data Elements
    • NDC, Lot Number and Expiration Date

On Line Platen Printing

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The Present: 2000-2005
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Importance of Data Standards: Structures vs. Carriers

Data Structures -
• Global Trade Item Number
  • Enables us to use existing NDC (or JAN/EAN)
  • Identifies Package Level
    • Mitigates the Need to Change Code for Unit Dose Level
• Application Identifiers for Format
  • 01 for Global Trade Identification Number (GTIN)
  • 10 for Lot Number
  • 17 for Expiration Date
    • Addresses Individual Site Needs on Dating Formats
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The Present: 2000-2005

Importance of Data Standards:
Structures vs. Carriers

Data Carriers -
• Barcodes - Linear vs. Two Dimensional
  • 2D Codes
    • More Information, Less Space
    • Improved Readability over Linear Codes
  • Laser Scanner vs. Imaging Scanner
    • Price Differential is Declining
• FDA Requires Linear for NDC
  • OK with 2D for Lot and Expiration Date
• Market will Drive in the End
  • Those Hospitals Wanting the Variable Info, Will Invest in the Technologies
  • Those Drug Manufacturers Wanting Improved Relations, Will evaluate how to accomplish

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The Future: 2005 Forward

Patient Safety

Secure Supply Chain
The Future: 2005 Forward

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Lots of Discussion About Data Elements Needed

• Product Codes - NDC/EAN/JAN
  • Prevention of Dispensing Errors
  • Inventory Management (via GTIN)
• Lot Number
  • Traceability and Recalls
• Expiration Date
  • Dispensing of Expired Medicine
  • Pharmacy Stock Rotation / Pharmacy Returns
• Serialization of Retail Packages
  • Authentication
  • Anti Counterfeiting via Track and Trace
  • Anti Diversion
    • Italian Bolino Initiative Ready for Implementation
    • Portugal, Belgium and South Africa Reviewing

All Four Data Elements are Related!

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The Future: 2005 Forward

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Relationship of Data Elements

**Highest Level**
- JAN/EAN/NDC
- Product Identification

**Linked Codes**

**Unlinked Codes**
- Lot Specific Information
- Lot Number and Expiration Date

**Lowest Level**
- Unique Retail Package Identification
- Mass Serialization

Product Code and Serial Numbers are “Pointers” to more information

- **Product Name:**
  - Latest Available Full Prescribing Information
  - UCC/EAN Standards Allow Linkage to Lot Specific Info
- **Serial Number:**
  - Lot Specific Info
    - Recall Information
    - Product Tracking and Authentication
    - Can Live on Its Own (EPC)

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The Future: 2005 Forward

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What has Delayed Mass Serialization?

- Pallet and Cases Possible Today via EAN.UCC Barcode Standards
- Attempts at Package Level Stalled
  - Technology
    - Barcodes Require Line of Site
    - Contradicts Term “Mass”
  - Standards
    - Proprietary Solutions => High Cost

What will Enable Mass Serialization?

- Electronic Product Code
- Radio Frequency Identification and/or 2D Barcodes
Global Healthcare User Group (HUG)

Mission:

Lead the healthcare industry to the effective utilization and development of global standards with the primary focus on automatic identification to improve patient safety.

Vision:

Become the single source for regulatory agencies and trade organizations (manufacturer, wholesaler, hospital and pharmacy) to seek input and direction for global standards in the healthcare industry.
Focus Areas

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Prevention of Medical Errors

• Encoding of the unit dose or unit of use package to enable automated verification to ensure right dose, for the right patient at the right time
• Encoding of the unit of use package to enable automated verification to ensure the right device for the right patient.

Product Authentication

• Utilizing a GS1 data structure, enable authentication of individual packages, cases or pallets
Focus Areas (continued)

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Tracking and Tracing

- Utilizing a GS1 data structure, work with supply chain trading partners to enable an electronic pedigree[1] for individual packages such that in the event of a counterfeiting incident, tracing of the suspect product can occur.

Increase Total Supply Chain Efficiency

- Through greater visibility, accuracy and velocity.

[1] Traceability by law to prevent counterfeiting
Communication Strategy – To Date

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✔ With charter members, ensure mission, vision etc are approved by member companies
✔ Develop a press release announcing the formation of the HUG describing mission, vision and initial focus areas
✔ Distribute to:
  ✔ HUG Members
    ✔ Encourage distribution to press through their channels with their individual company comments.
  ✔ GS1 Members via GS1 Affiliates
  ✔ Major health regulatory authorities
  ✔ Trade organizations (manufacturer, wholesaler, pharmacy, hospital)
✔ Post to GS1 HUG Web Site
  ➢ Let’s Take a Quick Tour

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Communication Strategy – Next Steps

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✔ Develop electronic newsletter to:
  • Raise awareness of HUG activities
    • Emerging Standards, Practices and Positions
    • Sub-team Progress
  • GS1 will maintain a distribution list for newsletter
  • GS1 will distribute as appropriate
  • Solicit members as needed
  • Solicit sub-group members as needed