



Agenda

Healthcare

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

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The Past: Supply Chain Efficiencies

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The Past: 1990's

Healthcare

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

1993 - 1996

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

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



60 Cartons x 100 Capsules

Dilantin®
(Extended Phenytoin
Sodium Capsules, USP)
100 mg

Store at controlled room temperature,
15°- 30°C (59°- 86°F).

Protect from light and moisture.

Distributed by



Parke-Davis

Division of Pfizer Inc, NY, NY 10017

89-5965-00-3

NDC 0071-0362-40



(01) 5 03 0071 0362 40 1

7603

QTY: 60 EXP: EXPIRE LOT: LOTNUM



(22) 8 60 3 YYMMDD LOTNUM 1

NDC 00 / 1-0362-40



(01) 5 03 0071 0362 40 1

7603

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The Present:

Patient Safety

Dispensing Error Prevention

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The Present: 2000-2005

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

Healthcare

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



Hospital Unit Dose Blister
Reduced Space Symbology with
Composite Code

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The Present: 2000-2005

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





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





The Future: 2005 Forward

Patient Safety

Secure Supply Chain

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The Future: 2005 Forward

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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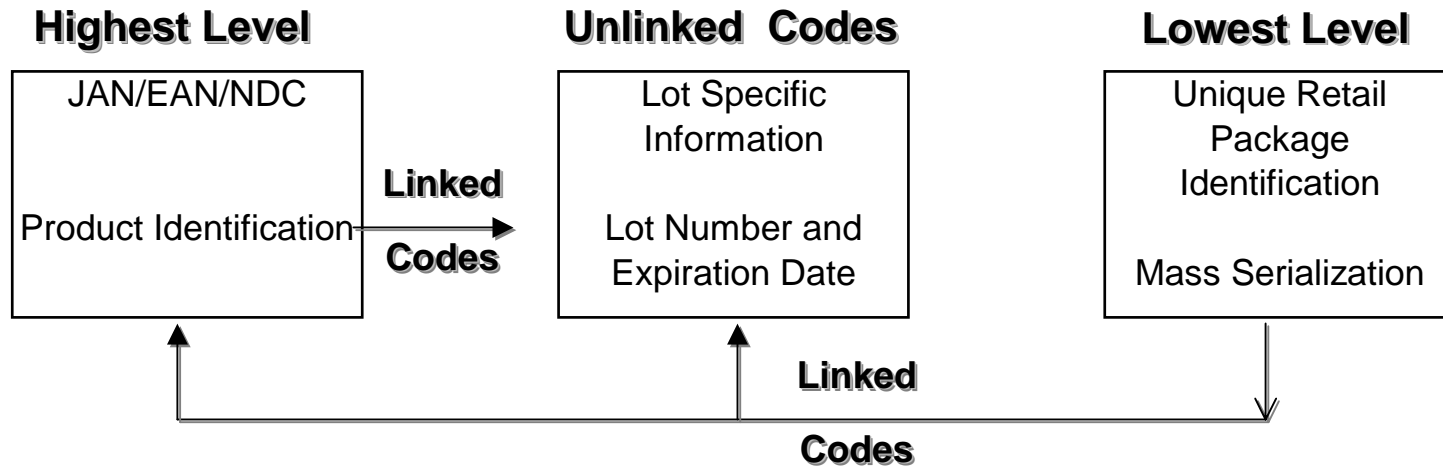




The Future: 2005 Forward

Healthcare

Relationship of Data Elements



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

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

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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.

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Focus Areas

Healthcare

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

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Focus Areas (continued)

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

- ✓ 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

- ✓ 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

