Objective: The Case for Global Standards: Creating the Business Case for Global Data Standards in the Healthcare Supply and Regulatory Chain

Global Target Audience: Manufacturers, Distributors, Hospitals, Pharmacies, Regulatory Agencies, Trade Groups, Certification Bodies

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

Implementation: Partnering with outside help, research and detail findings around the key areas as shown in the next few slides. Adjust the content as research findings demand.
Document Section Overview:

1. Seizing the Opportunity
2. Value Proposition of Global Standards: What Will You Gain?
3. Mapping the Process Benefits
4. Global Standards in Healthcare will result in these Benefits
5. Implementation of Global Standards: How to Get There From Here
6. Why Going Global Is the Right Approach
7. Taking the Next Steps Toward Global Standards
1. Seizing the Opportunity:
   - Building the Case for Global Data Standards
   - Timing of this Healthcare User Group and synergies
   - How GS1 standards fit this model

2. Value Proposition of Global Data Standards: What Will You Gain?
   - **Regulatory Agencies:**
     - One method for Global access to data about products
     - Each agency could customize their requirements within the system, not rely on data on the package
   - **Healthcare Providers (Hospitals, Point of Care):**
     - Verify that product as scanned meets the 5 Patient Rights (Patient, Drug, Dose, Route, Time)

- **Manufacturers:**
  - One method to code packages, with a unified data format
  - Insure all groups are synchronized: Pharma, Medical Device, and Consumer OTC

- **Distributor:**
  - Allow easier track & trace, anti-counterfeiting, pedigree, billing, and lot control

- **Retailer Pharmacies:**
  - Be able to verify the pedigree, anti-counterfeiting, and lot trace

- **Certification Bodies:**
  - Basis for Global evaluation and best practices

- **Reimbursement (Insurance, Government Programs):**
  - Data for reimbursements accessible within database, not limited to constraints of what is on the package
  - More accurate data transmission and puts one piece of electronic medical records in place

- **IT providers:**
  - Consistent standards allowing applications to be generic and global
  - Long term cost reduction for IT industry and customers

- **Trade Groups:**
  - Access to industry and standards bodies to align technologies globally
3. Mapping the Process Benefits:

- More accurate item creation and maintenance
- Anti-Counterfeiting for all interested parties
- Order management – Track & Trace
- Product Diversion
- Regulatory compliance
- Corporate IT and reporting
- Healthcare Provider data availability
- Benefits to the Consumer – 5 Rights (Patient, Drug, Dose, Route, Time)
- Reimbursement
- Reduction of Medical Errors
4. Global Data Standards in Healthcare will result in:

- Improved in-stocks
- Accurate item information
- Lower cost-to-serve
- Flow-through logistics
- Fewer returned and expired products
- Global sourcing
- Lower invoice disputes
- Easier Anti-counterfeit identification
- Track & Trace
- Faster reimbursement
5. Implementation of Global Data Standards: Getting There From Here:

- Implementation Steps:
  - Linkage & alignment with GS1 and EPC Global
  - Description of interoperability of Bar Codes - RFID
  - Data Format agreement
  - Healthcare feedback
  - Global Regulatory feedback
  - Certification Body feedback
  - Trade Organization alignment
- Case Studies
6. Why Going Global Is the Right Approach:

- Cross-border trading
- Multiregional coverage of manufacturers and retailers
- Increased collaboration of Manufacturers, Distributors, Retailers, Healthcare Providers, Regulatory Agencies, Certification Bodies, Trade Organizations
- E-business developments
7. Taking the Next Steps Toward Global Standards – HUG Teams:

- Communication and Coordination Work Team – Rich Hollander, Pfizer
- Membership – Volker Zeinar, B. Braun
- Regulatory Affairs – Jackie Elkin, Medtronic
- Standards Development – Peter Tomicki, Baxter
- Standards Implementation – Tom Werthwine, J&J
- Business Case – Ed Dzwil, J&J (This document)
Next Steps:

• Comments/Feedback from Sept. HUG Meeting
• Listen to comments and input during these 3 days
• Adjust Business Case as required
• Find Partner for Business Case Development
• Continue development of Business Case
• Delivery of Business Case – 2006
• Questions?
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