Healthcare System in Japan
—UCC/EAN-128 System—

GS1-Japan

Sep. 14, 2005

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Summary

◆ A Brief Profile of GS1-JAPAN

◆ History of Healthcare project

◆ Healthcare Market

◆ UCC/EAN-128 Healthcare System

◆ Hospital Information System

◆ Pilot Project in the Medical & Pharmaceutical industry with RFID
A Brief Profile of GS1-Japan

Project and Work items of GS1-Japan

Administration of Distribution Codes
• EAN /UCC System
• GLN
• Other Distribution Codes
• Seminar Activity
• Information Service

Product Catalogue & POS system
• JICFS / IF-DB
• POS Database Service
• Research on Actual Situation of
  • Information- oriented Distribution
• Development of Standards
• JEDICOS
• Development of XML-EDI Standard
• 2-Dimensional Symbols /RSS
• EDI for Fresh Produce Transactions
• ECR Scorecard
• Healthcare(UCC / EAN-128/RSS/EPC)
• RFID System

Research & Development
• Project to Promote, Develop, and Verify
  Supply Chain Management
• Development of Information System for
  Shopping Districts
• IC Card System Connected With a Virtual Mall
• Electronic Money System
• Research and analysis of XML-EDI
• Open Business Network (OBN)

Other Business
• International Cooperation
• 2002 RMOMM in Tokyo
• Overseas Study Mission
• Distribution Information System Study Group
• IT-Oriented Wholesale Industry Study Group
• GCI Japan

EPCglobal Japan
History of Healthcare project in JAPAN

■ 1999
○ The JFMDA & GS1 Japan (DCC-Japan) formulated “The Guideline of Standardizing Product Codes and UCC/EAN-128 Bar Codes for Medical /Surgical Materials in Global Supply Chain”.

■ 2000
○ The JFMDA & GS1-Japan published “Operation Manual for Standardizing of Product Codes and UCC/EAN-128 Bar Codes for Medical /Surgical Materials in Global Supply Chain”.

■ 2001
○ Japan Government published “e-Japan Strategy”, “E-Japan 2002 Programs” enclosed the innovation of The Japan healthcare systems.

■ 2001
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○ Empirical test on UCC/EAN-128 labels have been carried out between Sept. 2001 and Feb. 2002 by hospitals, dealers, and medical material/equipment manufactures.

■ 2002
○ Some large-scale national hospitals introduce systems based on the UCC/EAN-128 label.
○ The JFMDA & GS1-Japan revised “Operation Manual for Standardizing of Product Codes and UCC/EAN-128 Bar Codes for Medical /Surgical Materials in Global Supply Chain”.

■ 2003
○ The JFPMA & GS1-Japan carried out studies of RSS & Composite for Pharmaceutical.
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○ and The Committee of Standardizing Product Codes for Pharmaceutical. (Cooperate with the Ministry of Health)

■ 2004
○ Pilot Project in the Medical and Pharmaceutical Products Industry with RFID System.

The Japan Federation of Pharmaceutical Manufacturers’ Associations
The Japan Federation of Medical Device Associations
## Healthcare Market in Japan

### No. of Traders in Japan (2003)

#### Medical device

<table>
<thead>
<tr>
<th>Category</th>
<th>Domestic production</th>
<th>Importer</th>
<th>Export</th>
</tr>
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<tbody>
<tr>
<td>Domestic production</td>
<td>15,000</td>
<td>880</td>
<td>420</td>
</tr>
<tr>
<td>Importer</td>
<td>880</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Export</td>
<td>420</td>
<td></td>
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</table>

#### Pharmaceutical

<table>
<thead>
<tr>
<th>Category</th>
<th>Domestic production</th>
<th>Importer</th>
<th>Export</th>
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</thead>
<tbody>
<tr>
<td>Domestic production</td>
<td>48,000</td>
<td>1,700</td>
<td>100</td>
</tr>
<tr>
<td>Importer</td>
<td>1,700</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Export</td>
<td>100</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

100 million (Y)
**No. of Medical Institutions & Facilities in Japan**

<table>
<thead>
<tr>
<th>Category</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Institution (Hospital)</td>
<td>350</td>
</tr>
<tr>
<td>Public Institution</td>
<td>1,500</td>
</tr>
<tr>
<td>Private Medical Corporation</td>
<td>5,900</td>
</tr>
<tr>
<td>Family-owned Hospital</td>
<td>1,000</td>
</tr>
<tr>
<td>Others</td>
<td>250</td>
</tr>
</tbody>
</table>

Total No.  \( \equiv 9,000 \)
Market Size of Medical materials

100 million (Y)

- Total shipments
- Domestic production
- Import amount
- Export amount

Year

- 1989年
- 1990年
- 1991年
- 1992年
- 1993年
- 1994年
- 1995年
- 1996年
- 1997年
- 1998年
- 1999年
- 2000年
- 2001年
Trend of Medical Devices Export & Import in Japan

(Unit 0.1 Billion Yen)
Characteristic Features of medical/surgical items

1. Internationally-traded, 36%~40% of the items are imports from the north America and Europe

2. Wide variety, low volume production

3. Government approvals required

4. Short life-cycle
Standard barcode for medical/surgical material industry

Basic Items

① Product code (GTIN) (A1) = 01
② Expiry date/Usage term (A1) = 17
③ Quantity (Total amount contained in the case) (A1) = 30
④ Lot/Batch number (A1) = 10
   or Serial number (A1) = 21
Anticipated benefits brought to manufacturer and importer

- Service improvement for medical institutions and wholesalers
- Accuracy improvement for stocktaking and shipment, and inventory management
- Elimination of internal labeling operations
- Efficient management of expiry date and usage term
- Implementation of item tracking system
Anticipated benefits brought to wholesaler and retailer

- Simplification and accuracy improvement of order placing, order receiving, stocktaking and shipment, and inventory management
- Efficient management of expiry date and usage term
- Reduction of distribution costs
- Reduction of delivery lead times
Anticipated benefits brought to medical institution

- Cost reduction through a simplification and accuracy improvement of order placing, order receiving, stocktaking and shipment, and inventory management
- Elimination of individual code systems and in-hospital marking
- Efficient management of expiry date
- Prevention of insurance billing omissions
- Implementation of item tracking system
System overview

Standard merchandise code

Standardize barcode

VAN

Exchange data with standardized merchandise code

Mainly ordering

Data exchange between Maker and Dealer

GS1 Japan

Register Maker code (JAN Code)

MEDIS-DC

Database

1. Information about distribution
2. Receipt, electronic record, safety information

Maker

Dealer

Medical Organization
Individual package shows package indicator 0.

With JAN code

- Product name: ◎◎◎…◎◎
- M. Code: 4512345678906
- Exp. date: 2005.04
- Lot NO: 01234567

Character information
Clearly label "JAN Code"

Character information
Clearly label "UCC/EAN-128"

Standard

- Product name: ◎◎◎…◎◎
- M. Code: 4512345678906
- Exp. date: 2005.04
- Lot NO: 01234567
Actual application to medical/surgical material distribution
Example of barcode imprinting for medical/surgical material

Outer package

Inner package

Individual package

(01) Product code (GTIN)
(17) Expiry date
(30) Quantity
(10) Lot/Batch number
Actual application of wristband type of barcode labels for the patient, used in medical institution
National Center for Child Health and Development

- Location:
  2-10-1, Okura, Setagaya-ku, Tokyo, 157-8535, Japan
- Area: 75,469 m²
- Surface: 9,748 m²
- Building: 12F+B2F
- (height: 59.9m)
Activities of NCCHD

- Outpatients: 900/day
- Operation: 3000/year
- Delivery: 1000/year

- 500 beds (10 for ICU, 12 for NICU)
- 9 operation rooms
- 6 LDR (Labor, Delivery, Recovery) rooms
The objectives of medical information system

Safety First!

- Patients’ amenity and safety
- Efficiency for hospital management
- Support for medical staffs
- Co-operation with other hospitals
Key words of medical information system

- Electronic Medical Records (E.M.R.)
- Amenity (patient services)
- S.P.D. (Supply, Processing, Distribution)
- Bedside terminal with Bar-code reader
- Database for child health and development
Electronic Medical Records
Development Concept

Patient information is collected in one database.

A medical record, ordering and nursing support are unified.

Database realizes unification and processing realizes distribution
Bedside terminal (PC)

- 12 inch TFT
- Touch panel
- Bar-code reader
- 4 USBs
Medical staffs can input clinical data directly by touch panel.
Bar-code system
Confirmation system of medical orders by bar-code

<table>
<thead>
<tr>
<th>Right case</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Wrong case</th>
</tr>
</thead>
</table>
E.M.R. system is connected to S.P.D. system and Account system by Bar-code

1 input order has 3 outputs in each systems
Integrated Medical Information System

- Internet
- Medical Information services
- Electronic health Insurance account
- Electronic medical records
- Data-warehouse
- Supply, processing, Distribution system
- Sub-systems
  - Bed-side terminal
  - Patients services
  - Research Institute
Results of 2004 Pilot Project in the Medical and Pharmaceutical Products Industry

- Sales records must be maintained including organism-derived formulation's names (according to the Pharmaceutical Affairs Law revised in 2003).
- It is necessary to efficiently manage huge amounts of vials.
- Traceability and safety must be pursued.

- Attach RFID automatically to small, fragile products with large curvature (labeler).
- Mount antennas with a high identification rate in order to attach RFID to curved surfaces.

Issues to be validated

Implementers: The Federation of Pharmaceutical Manufacturers’ Associations
Cosponsors: Toppan Printing, SAP Japan, etc.
Period: January – February 2005
Place: Toppan Packaging Services (Saitama), Toho Pharmaceutical (Tokyo), Alfresa (Tokyo), etc.

Consistent traceability from manufacturers to hospitals

Organism-derived drug’s vial

Develop RFID that may be bent and attached to small vials and still functions

Cooperate with the Ministry of Health, Labour and Welfare

Usage unit
Sales unit
Packaging unit
Pallet/cargo

Medical institutions
Medical institutions
Wholesalers
Wholesalers
Results of 2004 Pilot Project in the Medical and Pharmaceutical Products Industry

Experiment Items and Results

I. Basic performance test

- Reading range characteristics were identified when a RFID was wrapped and attached to cylinder-shaped vials. It was discovered that the reading rate at a 90-degree angle was poor. However, this problem may be overcome when readings are performed from multiple directions or when items are rotated during reading.
- As for pharmaceuticals with liquid content, a RFID in the 13.56 MHz and UHF bands was superior to those in the 2.4 GHz.

II. Development of labelers

- The technology to insert RFID into labels was developed.
- Equipment to automatically affix RFID-attached labels was developed. The labels were attached to vials (diameter of 10 mm) without problems.

III. Validation experiment on a supply chain

- The inspection time was shortened by about 91% compared to the current visual or barcode methods.
- Man-hours were reduced during receiving, shipping and shipment inspections at manufacturers/wholesalers' warehouses (48% at manufacturers and 23% at wholesalers).

Future issues

- Improve batch reading accuracy for multiple items.
  — Improve operational factors including the timing of reading and transfer speed.
- Implement traceability
  — Individual units are not controlled at the beginning of the supply chain. It is, however, necessary to manage each unit's expiration date and usage history on site at medical institutions. In order to implement traceability, a RFID must be attached to each unit at the time of production.
Pilot Projects on RFID in FY 2005

In FY2005, Ministry of Economy, Trade & Industry decided to fund the 8 projects on RFID System.

<table>
<thead>
<tr>
<th>Category</th>
<th>Industry</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industrial restructuring</td>
<td>1. Home Electrical Appliances and Electronic Products</td>
<td>Using RFID on electronic parts in terms of recycling.</td>
</tr>
<tr>
<td></td>
<td>2. Pharmaceutical Products</td>
<td>This year, it includes distribution to pharmacy of medical agency in addition to last year experiment (from manufacture to drug store).</td>
</tr>
<tr>
<td></td>
<td>3. Supply Chain of Japan Self Defense Forces</td>
<td>RFID will be used for efficient logistics in Self Defense Forces. It is aimed to collaborate with DOD system in the future.</td>
</tr>
<tr>
<td>Development of new industry</td>
<td>4. Self-control Robots</td>
<td>Self-control robots using RFID for spatial awareness and recognition human and things</td>
</tr>
</tbody>
</table>
# Pilot Projects on RFID in FY 2005

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<td>Inter-industry coalition</td>
<td>5. Books, CD/DVD</td>
<td>The targets are item level tagging (direct attachment), CRM in the book store, and theft detection in supply chain</td>
</tr>
<tr>
<td></td>
<td>6. Retail (supermarket,</td>
<td>The target is CRM in each retail store, using smart shopping-cart, kiosk, cell-phone etc. (Japanese Future Store)</td>
</tr>
<tr>
<td></td>
<td>department store, convenience</td>
<td></td>
</tr>
<tr>
<td></td>
<td>store)</td>
<td></td>
</tr>
<tr>
<td>International cooperation</td>
<td>7. Automotive Parts</td>
<td>This project will use RFID for parts and RTI for efficient supply-chain of the automotive parts industry in ASEAN</td>
</tr>
<tr>
<td></td>
<td>8. Office Equipment</td>
<td>Between Japan, China and South Korea, in the office equipment industry, for the purpose of efficient distribution, RFID will be attached to parts and pallet.</td>
</tr>
</tbody>
</table>
Thank you for listening!!
Thank you
for your kind attention !!

Please contact me if you have any questions.

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