A Look at the World

Plenary Session
8 April 2011
Global Overview
GS1 Healthcare
Public Policy WT Charter

Grant Courtney, GSK (Co-Chair)
Jackie Elkin, Medtronic (Co-Chair)
Public Policy Charter

• Provide **strategic leadership in the conduct and interaction** with global public policy makers / government authorities to influence the movement towards harmonization of product identification requirements in alignment with GS1 Global Standards.

• Provide a **forum for open exchange of information** between members including discussion concerning actions and trends of global public policy as it relates to healthcare product Identification.

• **Monitor the global landscape** of laws, regulations, directives, etc., around the topics of healthcare product identification, data synchronization and traceability and determine priorities for GS1 to engage in and act upon.

• Establish a framework and **repository of global regulations and directives** related to Healthcare Product identification as a reference for membership.
Current WT activities

• Continuously high participation
• Split on Pharma and MD works well with both co-chairs
• Information flow very good
• Concentration on GHTF and EU Directive
• In the next weeks:
  • India – pharma and MD
  • Responses to ANVISA, FDA and GHTF
  • Turkey – vaccines
  • Denmark
  • Netherlands
  • Brasil
• PP DB training sessions - input further improving
GS1 Healthcare
Public Policy Database

GS1 Healthcare Conference
8 April 2011, Washington D.C.
Emilie Danel, GS1
What is the Public Policy Database?

• Comprehensive global repository of country regulations and guidelines, stakeholder agreements or user requests for healthcare product identification, product catalogues and traceability. http://healthcare.gs1.org/pp/

• Only for global GS1 Healthcare members and GS1 Member Organisations ➔ login required

• Information comes from staff of the worldwide network of 108 GS1 Member Organisations (MOs) and members of the global GS1 Healthcare community.
Online Demo

- http://healthcare.gs1.org/pp/
Dossiers & visitors

• 116 dossiers
• 83 countries represented in the Database
• More than 100 members registered
• Between 100 and 200 visits per month from 48 countries

• Database promoted at Healthcare conferences (Geneva, Singapore, Washington)
• Link from the Global Healthcare website
Updated information & Data Quality

• GS1 Member organisations and GS1 Healthcare users can directly update the information on dossiers very easily.

• Information will always be verified before publication

• Data quality is crucial for the reliability and usefulness of the database

• Don’t hesitate to update information yourself!
New features

• New features in the Beta version:
  - Google tool to search for specific terms in the database (in development)
  - New section « Stakeholders impacted »
Thank you!

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Brazil
• CMED Resolution No. 2/2011 - The Interministerial Council for Drug Regulation instructed ANVISA to conduct a new study on the technology solutions for the implementation of the Brazilian Traceability System for Medicines and revise all legal instructions accordingly.

ANVISA Normative Instruction 1/2011: revokes the IN 11/2010 which had defined the use of the Seal, supplier as Casa da Moeda and timeline.
ANVISA Ordinance 225/2011 - Establishes a Working Group to evaluate technology solutions for the traceability from production to consumption of drugs. The WG needs to conclude the studies in 60 days after the nomination of all participants. The participants are:

I - representative from the ANVISA’s Presidency;
II - representative from the ANVISA’s Drug Department;
III - representative from the ANVISA’s Inspection Department;
IV - representative from the ANVISA’s IT Department;
V - representative from the ANVISA’s Legal Department;
VI - representative from the Ministry of Health;
VII - representative from the Ministry of Justice;
VIII - representative from the Ministry of Industry and International Trade.

This group will have 60 days to give a response.

The law which mandates the serialization is still in force, only the technological alternatives will be reviewed (mint carton seals vs. printed 2d code).
# Healthcare in Canada

<table>
<thead>
<tr>
<th>Population</th>
<th>34,000,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare system</td>
<td></td>
</tr>
<tr>
<td>• Public Healthcare System</td>
<td></td>
</tr>
<tr>
<td>• Federal Funded, provincially administered</td>
<td></td>
</tr>
<tr>
<td>• Some specialty care and pharmacy not covered by public system</td>
<td></td>
</tr>
<tr>
<td>• Employs the most people in the country</td>
<td></td>
</tr>
<tr>
<td>Healthcare Expenditure per Capita</td>
<td>$5,000</td>
</tr>
<tr>
<td>Healthcare expenditure % of GDP</td>
<td>11%</td>
</tr>
</tbody>
</table>
Healthcare Efficiencies – A Top Priority In Canada

• Canadians are passionate about their healthcare system and expect the highest standards

• Canada’s governments have educated Canadians about the urgent need to find efficiencies and system improvements to bend the cost curve.

• Focus on Patient Safety and Supply Chain Efficiency

• Healthcare is cross sector
  • Pharmaceuticals
  • Medical Devices
  • Food Service
  • Retail
ISMP Canada and Canadian Patient Safety Institute Team Up with GS1 Canada to Advance Patient Safety in Canada

Two of Canada’s patient safety organizations – Institute for Safe Medication Practices Canada (ISMP Canada) and Canadian Patient Safety Institute (CPSI) are collaborating with GS1 Canada, a global supply chain standards organization, to advance automated identification (e.g., bar coding) of pharmaceutical products in Canada. To this end, the three organizations are working collaboratively to advance the Canadian Pharmaceutical Bar Coding Project.
<table>
<thead>
<tr>
<th>Pharmacy Retailers</th>
<th>Wholesalers/GPOs</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Familiprix (270 Pharmacies)</td>
<td>AmerisourceBurgen Canada</td>
</tr>
<tr>
<td>*Katz Group – Rexall (1,800)</td>
<td>Canadian Pharmaceutical Distribution Network</td>
</tr>
<tr>
<td>*Le Group Jean Coutu (378)</td>
<td>Gamma Wholesale</td>
</tr>
<tr>
<td>*Loblaws (500)</td>
<td>HealthPRO</td>
</tr>
<tr>
<td>*Metro (186)</td>
<td>*Kohl and Frisch</td>
</tr>
<tr>
<td></td>
<td>Services multiple pharmacy chains , including Walmart Canada</td>
</tr>
<tr>
<td>Overwaitea</td>
<td>*McKesson Canada</td>
</tr>
<tr>
<td></td>
<td>6,300 retail pharmacies / 1,350 institutional pharmacies</td>
</tr>
<tr>
<td>Pharmachoice</td>
<td>*Medbuy</td>
</tr>
<tr>
<td>PharmaSave</td>
<td>UniPharm</td>
</tr>
<tr>
<td>*Shoppers Drug Mart (1,180)</td>
<td></td>
</tr>
<tr>
<td>*Sobeys Pharmacy Group (200)</td>
<td></td>
</tr>
</tbody>
</table>

* denotes compliance notices issued to their vendor community.
Automatic Identification of Vaccine Project (AIVP)
Public Health Agency of Canada (PHAC) published Canadian Consensus Statement on Proposed Standards for Bar Codes on Vaccine Products August 2010.

- Two dimensional (2D) bar codes on the primary package which include the Global Trade Identification Number (GTIN) and the lot number. *

- 2D or linear (also known as 1D) bar codes on the secondary package that include GTIN and the lot number. *

- All vaccine products will be loaded into GS1 Canada’s ECCnet Registry to support the population of the Vaccine Industry Database (VIDS)

*Including the expiry date in the bar code is optional as it can be determined through the lot number. Lot number and expiry date will continue to appear in human readable form on the primary/secondary packaging as per Canadian labelling requirements.
To speed the adoption of a common system of supply chain standards in healthcare institutions in order to **improve patient safety, cost efficiency and staff productivity** and, ultimately, ensure all healthcare trading partners are able to fully operate in an increasingly e-driven global supply chain reality.
Implementation Roadmap

Milestone

A  Mar. '09  Carenet Standards Implementation Roadmap Announced
B  July '09  Canadian Healthcare Product ID Standards Announced
C  Dec. '09  EDI Guidelines Completed (832, 850, 997, 855, 856, 810)
D  Mar. '10  Canadian Product Description Guidelines Finalized

E  April '10  Canadian Global Location Number Registry Launch
F  Q3 2011  Canadian Healthcare Product Registry Launch
G  Dec. '10  Carenet/North American GLN Sunrise Date
H  Dec. '12  Carenet/North American GTIN Sunrise Date

Carenet Healthcare Community Groups

2009

Product ID and Location ID

- Product ID (GTIN)
- Location ID (GLN)

Global Trade Item Number (GTIN) Implementation
GLN Implementation

2010

- Product Description Standardization
- Develop GLN Registry

Product Description Standardization
GLN Data Synchronization

2011

- Develop Canadian Healthcare Product Registry
- Standardize EDI Transactions

Healthcare Product Data Synchronization
Implementation of EDI Transactions

2012

2013

2014

Supply Chain Standards Project – Phase 1
Sector Implementation – Phase 2

Carenet Standards Implementation Roadmap
December 2009
Canadian Healthcare Supply Chain Standards Project – Phase I

1. Healthcare Industry Outreach and Communications Program
   - Engage community and set governance structure
   - 6 Customized Healthcare Implementation Guidelines for the Transaction Sets
   - 3 Healthcare Specific Education Modules Developed

2. Advancing Electronic Commerce (EDI) in Healthcare
   - Standardize Six Transaction Sets - Specific to Healthcare
     - 810 Invoice
     - 832 Price Catalogue
     - 850 Purchase Order
     - 855 Purchase Order Acknowledgement
     - 856 Ship Notice/Manifest
     - 997 Functional Acknowledgement

3. Global Supply Chain Standards in Healthcare
   - Implementation Roadmap for Product and Location Numbers (GTIN/GLN)
   - Development of Medical Product Registry and GLN Registry
   - Define Canadian Attribute Requirements
   - Represent Canadian Requirements in Global Standards Development Process

Complete
Project Phase II - Implementation

EDI Standards Advancement and Implementation

• Implementation of 3 pilot projects including:
  • Integration of standardized EDI transaction set attributes
  • Global product identifiers (GTIN and GLN)

• Provide one-on-one support and “how to” enable EDI implementation

• Develop up to four new EDI transaction sets

• Leverage the Industry group created in Phase I to manage ongoing maintenance of Phase I transaction sets
Project Phase II - Implementation

Healthcare Industry Outreach, Engagement and Education Program

- Establish Industry Stakeholders Committee to drive Implementation Plan
- Establish Solution Providers Committee to drive integration of standards, processes and registries into systems
- Education support including education modules, support materials
- Media Relations Implementation Strategy
- Implementation Support Material

Data Synchronization, Product /Location Standards Implementation

- Launch Canadian Healthcare Product Registry and Interim GLN Registry
- Establish committee for trading partner data synchronization
- Launch standards implementation in acute care facilities
- Provide data synchronization implementation support
Canadian Healthcare Product Registry GDSN Enabled

Manufacturers

Source Product Information

Pharmaceutical

Food Service

Grocery

Consumer Goods

Medical/Surgical*

Data Loading Solutions

Data Integrity/Data Validation/Normalization

Data Integrity/Data Cleansing

Hospitals/Retail Pharmacy

GPOs

Shared Services Organizations/Distributors

GS1 Canada Data Pool

Global Data Synchronization Network

*Available July 2011
Through OntarioBuys, the Ontario Ministry of Finance is providing one-time funding for all acute care facilities in Ontario to receive a 2011 GS1 Company Prefix License and GS1 GLN
Traceability of pharma products must be done with:

- A 2D barcode printed on the secondary package
- Exchange of data to secure the deliveries

- **Regulation starting January 2011**: all medicines sold in pharmacies must have a GS1 DataMatrix on the retail pack level, GTIN (3400 prefix+AMM), lot number and expiry date

- The regulation also requests an electronic dispatch advice to help tracing of products
  - This means to identify logistic units with SSCC (requested by wholesalers) and GS1 EANCOM DESADV (dispatch advice message)
Pharma regulation : feedback

Approximately 30% of medicines with a DataMatrix

• It’s not mandatory for retail pharmacies to use it - the regulation addresses “pharmaceutical company” only
• Retail pharmacies are not all equipped with 2D scanners
• They need to read the price label (linear barcode) for invoice and reimbursement
• They don’t want to scan two barcodes for each package
• Some Datamatrix are not “scannable”
  • Example: 01 followed by a wrong GTIN, Expiry date badly formatted, Quality of printing, etc…
How GS1 could help?

• We try to understand where is the problem …
• We hired a consultant, pharmacist, helping us to get in touch with all the pharmacists stakeholders
  • Regulatory agency for medicines
  • Syndicates (association of pharmacists)
  • Wholesalers
  • Pharmacies
  • …
• An audit beginning of may in a pharmacy to evaluate how many Datamatrix are not scannable and why
  • Call the suppliers and explain how to improve their Datamatrix
  • Training, brochure …
Netherlands
Hans Lunenborg
GS1 Netherlands
GS1 The Netherlands

Ready to implement!
Overview Dutch Market

- 16,500,000 people
- Average Healthcare expenses € 5000 p/y
- 100 Hospitals, incl 8 University Hospitals
- 1950 public pharmacies
• Focus on:

  – Patient safety improvement

  – Supply Chain Efficiency improvement
GS1 Healthcare Taskforce

Uniform GS1-codes throughout the Healthcare Supply Chain
Increase of patient safety
Increase of efficiency

- Focus group Datasy_nonchronisation
- Focus group Automatic Identification and Datacapture (AIDC)
- Focus group Traceability
- Focus group EDI
- Steering committee ZorgDAS G-Standaard Logic
December 2012

Both primary and secondary packaging level are marked with a GS1 DataMatrix (containing GTIN, batch/lot or serialnumber and expirydate)
Where are we now?

GS1 Barcodes on secondary packaging

Surgical Implants
- GS1: 68%
- GS1/HIBC: 32%

Pharmaceuticals
- GS1: 76%
- GS1/HIBC: 24%
How do we support this goal?

• G-Standaard Logic
• Traceability projects
  – Surgical implants
  – Blood products
  – Bed-side scanning
  – Patient ID in hospitals
• Healthcare Solution Provider Program
  – Direct Part Marking on surgical instruments
  – Scanpanel
• Lobby at Dutch government
• Cooperation with EHR
What is G-Standaard Logic?

- Dutch Healthcare Trade Item Datapool with a single point of entry for both care and logistic information

- Accessible for:
  - Suppliers (pharmaceutical and medical device)
  - Suppliers providing products to Food-retail and healthcare
  - Care providers (pharmacy, hospital etc)

- Official cooperation between Dutch Pharmacists Association (called Z-Index) and GS1 Netherlands
G-Standaard Logic

- Care information
- Logistic information

G-Standaard + GS1 DAS = 1SYNC-datapool (GDSN)

G-STANDAARD LOGIC

gs1
Nederland

G-Standaard Logic

Z-Index

samen werkt
G-Standaard Logic

EDI ASSPRI for information on assortment and prices

Supplier

Care and logistic information

G-STANDAARD LOGIC

GLN-registry

Hospital / -Pharmacy

Wholesaler

Public Pharmacy
Who will connect?

Farmaceutical suppliers
• GSK, Bayer, Pfizer, AstraZeneca, Abbott, Novartis Pharma, Roche, Teva, Sandoz, Beiersdorf, Nutricia, Duchefa

Medical device suppliers
• Biomet, Medeco

Wholesalers
• Mediq (OPG), Brocacef (Phoenix), Alliance Boots
_status implementation G-Standaard Logic

April 2011
• Testsession with pilot parties

June 2011
• Live with G-Standaard Logic
• Workshops for suppliers

June –End 2011
• Visits and connect suppliers
• Implementation of the ASSPRI-message & GLN-registry
Traceability in Hospitals:

- 6 Use cases have been defined with hospitals and suppliers

Key findings:

- Involve Solution providers to capture and use information in hospital systems
- Use 1 international standard
- Use 1 data carrier, i.e. GS1 Datamatrix, containing article/batch/serial number and expiry date
Next steps:
• Deliver business case to create GS1 exposure through (social) media
• Caregivers will spread their findings through sector organisations
• GS1 will support and guide suppliers and caregivers
• Workinggroup members will tell the sector how to apply the standards
AIDC: from ‘guide’ to ‘implementation’:

- Testing on top 20 suppliers sterile implants barcode quality (report)
- Scanpanel

Next:

- test and publish hospital readiness
- feedback on AIDC2 working groups output
- steps on getting started for hospitals/ pharmacies and suppliers
Tools

• Advice on (bar)codes for products and parties
  • Online barcode tool: product marking grid (soon available on website)
  • ‘Scanpanel’: test barcodes
• GLN Registry
• Implementation guides for
  • (bar) coding,
  • EDI (NL Healthcare Order, Order response, Despatch Advice, Invoice),
  • traceability
Conclusion:

• Dutch hospitals, caregivers and suppliers adopted GS1 standards
• We have the tools!

The Dutch market is ready to implement GS1 standards to improve patient safety and supply chain efficiency!
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Michio Hamano
GS1 Japan
Standardization in Healthcare Sector in Japan

MHLW
( Ministry of Health, Labour & Welfare )

JFMDA
The Japan Federation of Medical Devices Associations

FPMAJ
The Federation of Pharmaceutical Manufacturers’ Associations in Japan

GS1 Japan

Guideline

Medical Devices

Drugs

Medical Material Manufacturers
Medical Equipment Manufacturers

Prescription Drug Manufacturers

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History of Bar Code Implementation in Healthcare Industry in Japan

1980s

1999

Guideline (JFMDA)

2000

Database for All Healthcare Products (MEDIS)

2001

Revised Pharmaceutical Affairs Law delivered

2002

Revised Guideline (JFMDA)

2005

Followed by Dental Trade Association

2006

Direct Marking Guideline

2007

Guideline (MHLW)

(Issued in March 2008)

2008

Time Limit for Implementation

(March 2009 / March 2010 / March 2011)

2009

2010

2011

Start using JAN(EAN-13)

(Issued in March 2008)

(Issued in Sept. 2006)

(Sept. 2008)

Revised Guideline (MHLW)
Objective
Promotion of efficient distribution systems & medical administration, securing traceability and prevention of medical accidents

Contents
• Marking Subjects – Medical Devices, in Vitro Diagnostics and Consumable Supplies
• Data to be Placed – Product code, Expiry Date and Lot or Serial No.
• Setting of Product Codes – GTIN recommended
• Bar Code Symbol – GS1-128 recommended
• Registration in Medical Device Database – MEDIS-DC
• Date of the Implementation of Bar Code Marking – 1 to 3 years after the issuance of the guideline

Date of Marking Requirement for MDs in Japan

Mar.2008 Notification Issued
Mar.2009 Partly Enforced
Mar.2010 Partly Enforced
Mar.2011 Fully Enforced

1 year after the issuance of notification
2 years after ---
3 years after ---
1 year after the issuance of notification

① Designated insured medical materials
② Specially controlled medical device and Specially designated maintenance management required medical device (Excluding ① above)
③ Medical devices (excluding ① & ② above) and Consumable supplies
④ In vitro diagnostics

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Marking Requirement of MHLW Guideline for Medical Devices

< Individual Package >

GS1-128

2D Barcode standardized by ISO

< Inner Box >

GS1-128

AI (01) GTIN

(partly required) AI (17) Expiry Date

(partly required) AI (10) Lot No. or AI (21) Serial No.

< Outer Box >

GS1-128

AI (01) GTIN

AI (17) Expiry Date

AI (10) Lot No. or AI (21) Serial No.
Example of Bar Code Marking on Medical Device (Individual Package)

AI(01) GTIN

AI(17) Expiration Date

AI(10) Batch/Lot No.
MEDIS-DC Healthcare Products Database

MEDIS-DC: The Medical Information System Development Center
MHLW: Ministry of Health, Labour & Welfare
J FMDA: The Japan Federation of Medical Devices Associations
FPMAJ: The Federation of Pharmaceutical Manufacturers' Associations of Japan

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## Rate of Bar Code Marking on Medical Devices

[Annual Survey by MHLW in Sep. 2010]

<table>
<thead>
<tr>
<th></th>
<th>Rate of Items with GTIN</th>
<th>Rate of Items Registered to MEDIS-DC Database</th>
<th>Rate of Bar Code Marking Items (Individual Package)</th>
<th>Rate of Bar Code Marking Items (Inner or Outer Box)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Devices</td>
<td>96.1%</td>
<td>70.3%</td>
<td>72.6%</td>
<td>88.8%</td>
</tr>
<tr>
<td>In Vitro Diagnostics</td>
<td>98.4%</td>
<td>64.7%</td>
<td>76.7%</td>
<td>98.1%</td>
</tr>
<tr>
<td>Consumable Supply</td>
<td>88.5%</td>
<td>48.0%</td>
<td>---</td>
<td>64.2%</td>
</tr>
</tbody>
</table>
Contact Details

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NHS and Coding for Success

- Over 300 Acute Trusts registered with GS1 UK in England
- GS1 standards beginning “production” ratification by NHS Health and Social Care Information Standards Board
- All Acute Trusts in Northern Ireland centrally registered with GS1 UK
- In discussion with Scotland and Wales on central registration
“There is a need for much greater transparency on prices paid to suppliers by individual Trusts and the DH should require the NHS to adopt GS1 to improve procurement data and enable price comparisons” January 2011

“Each Trust’s procurement strategy should include:
• analysis of current practices;
• assessment of e-commerce systems and scope for improvement;
• proposals for product standardisation in key categories;
• proposals to improve control over purchasing and adherence to contracts;
• assessment of stock control and its effect on procurement costs
• e.g. small order costs”
15th March 2011

House of Commons Public Accounts Committee Hearing

Recent National Audit Office report criticised the NHS for lack of data, variation in prices paid and products used, and poor procurement processes – all leading to poor value for money.

Sir David Nicholson KCB CBE CEO of NHS gave evidence.

GS1 standards are fundamental to securing efficiency savings in cost to serve and procurement in NHS.
Forthcoming DH policy

- We want to accelerate the adoption of GS1 in the NHS and its supply chains

- Intend to give a clear statement of intent for industry that by end of 2012 all products supplied to the NHS should be identifiable through the use of an appropriate GS1 Code

- We want to encourage the NHS to make effective use of the opportunities that GS1 makes available to increase patient safety, generate savings, and improve the quality of patient care
What is the DH going to do

- Everything we can to drive forward GS1 adoption by industry and the NHS, the benefits are mutual if both parties work together.

- Greater use of
  - e-Catalogues
  - Exchanges
  - Stock Management solutions

- Start including GS1 as a procurement requirement

- QIPP
Procurement

Last modified date: 14 March 2011
Gateway reference: 15349

Background

NHS providers spend over £17bn each year on non-pay goods and services using a range of procurement routes – from nationally-leveraged contracts (Buying Solutions and NHS Supply Chain) to local, low-volume direct contracts with suppliers. This expenditure typically represents 30% of hospitals’ operating costs but Trust boards give little attention to it. As a result, there is wide variation in prices paid, inefficient logistics and processes, invisibility of spend data, and an overly complex landscape of procurement service providers.

Workstream aims

To help NHS provider Trusts reduce and optimise non-pay expenditure by 10-20%, without compromising quality of patient treatment and care.

Workstream offer

The workstream will offer to all NHS providers:

- Adoption of GS1 coding as the sole product identification code system in the NHS. Both NHS and supplier side
GS1 UK Healthcare User Group

- Joint GS1 UK industry event on UDI with the Association of British Healthcare Industries in February 2011 – 150 delegates and speakers included US FDA, European Commission, GHTF, Department of Health, Industry

- In addition Sector Stakeholders have come together to set up a GS1 2D Data Matrix Working Group on use of Pharmaceuticals in Secondary Care.

- Over 150 participants in this group including those from hospitals, manufacturers, wholesalers, industry associations, solution providers and regulators.