# 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.
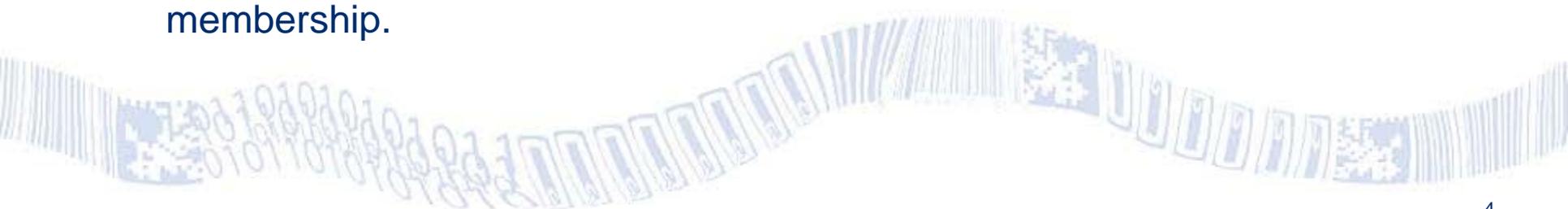
Current WT activities

- 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.
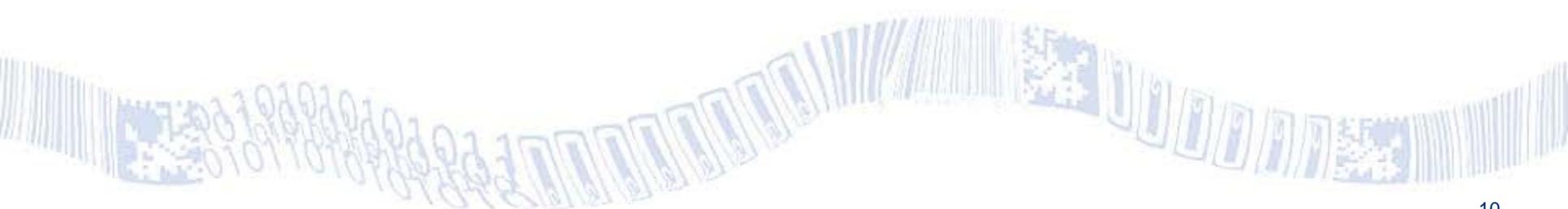
Online Demo

- 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!
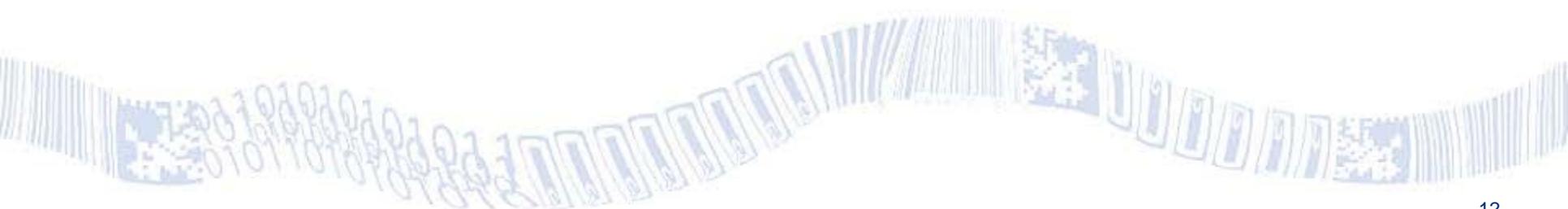
- Contact:

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  Public Policy Manager Europe

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Brazil

Brasil

- 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: revogues the IN 11/2010 which had defined the use of the Seal, supplier as Casa da Moeda and timeline.

Brasil – continued
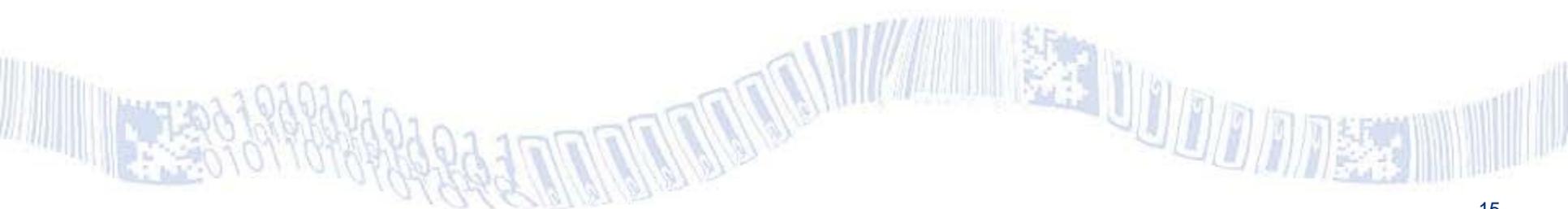
- ANVISA Ordinance 225/2011 - Establishes a Working Group to evaluate technology solutions for the traceability from production to consumption of drugs. The WG needs to conclude the studies in 60 days after the nomination of all participants. The participants are:
  I - representative from the ANVISA´s Presidency;
  II -representative from the ANVISA´s Drug Department;
  III - represetative 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).

Canada
Alicia Duval
GS1 Canada

Healthcare in Canada

Population	34,000,000
Healthcare system	•Public Healthcare System •Federal Funded, provincially administered •Some specialty care and pharmacy not covered by public system •Employs the most people in the country
Healthcare Expenditue per Capita	$5,000
Healthcare expenditure % of GDP	11%

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

GS1 Healthcare

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.**

Provincial Engagement

Healthcare

Phramcy Retailers	Wholesalers/GPOs
*Familiprix (270 Pharmacies)	AmerisourceBurgen Canada
*Katz Group – Rexall (1,800)	Canadian Pharmaceutical Distribution Network
*Le Group Jean Coutu (378)	Gamma Wholesale
*Loblaws (500)	HealthPRO
*Metro (186)	*Kohl and Frisch Services multiple pharmacy chains , including Walmart Canada
Overwaitea	*McKesson Canada 6,300 retail pharmacies / 1,350 institutional pharmacies
Pharmachoice	*Medbuy
PharmaSave	UniPharm
*Shoppers Drug Mart (1,180)	
*Sobeys Pharmacy Group (200)	*denotes compliance notices issued to their vendor community

Automatic Identification of Vaccine Project (AIVP)

Canadian Vaccine Bar Coding Recommendations

GS1 Healthcare

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.

Public Health Agency of Canada / Agence de la santé publique du Canada — Canada

PUBLIC HEALTH AGENCY of CANADA
www.publichealth.gc.ca

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Home > Immunization & Vaccines > Canadian Consensus Statement on Proposed Standards for Bar Codes on Vaccine Products

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Chronic Diseases

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Canadian Consensus Statement on Proposed Standards for Bar Codes on Vaccine Products

Automated Identification of Vaccines Projects Advisory Task Group

Introduction

In Canada, several million doses of vaccines are administered every year. Each time a dose of vaccine is administered, a health care provider must manually record details of the event in the patient's health record. Studies have shown that between 5 and 15 percent of immunization records are missing important information and up to 24 percent contain errors, causing delays in the follow-up of adverse events following an immunization. The outcome is an increased cost to the health system and may result in adverse health outcomes for Canadians.

In light of these findings, the National Advisory Committee on Immunization (NACI) passed a resolution in 1999, recommending that bar codes be placed on all vaccine products to improve record keeping and the safe use of vaccines.

Background

The Public Health Agency of Canada initiated the Automated Identification of Vaccines Projects (AIVP) in response to the NACI recommendations. Between 2002 and 2005, the AIVP completed a number of initiatives including:

- A feasibility study for the bar coding of vaccine products conducted in consultation with vaccine manufacturers, international partners and other stakeholders;

Canadian Healthcare Supply Chain Standards Project

GS1 Healthcare

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.

Ontario

BC Health Authority Shared Services Organization

Government of Saskatchewan

FacilicorpNB

NOVA SCOTIA NOUVELLE-ÉCOSSE
Health Santé

Alberta Health Services

HealthPRO
Choice. Support. Results.

Life Is Easier...
URMED
SMART BUSINESS • SMART SOFTWARE

St. Michael's
Inspired Care.
Inspiring Science.

TELUS®

ACART
Healthcare Storage Solutions

COVIDIEN

MEDICALMART

Implementation Roadmap

Milestones

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

Timeline: 2009 – 2014

Milestones: A, B, C, D, E, F, G, H

Carenet Healthcare Community Groups

Product ID and Location ID

- Product ID (GTIN) → Global Trade Item Number (GTIN) Implementation
- Location ID (GLN) → GLN Implementation

E-commerce and Data Synchronization

- Product Description Standardization Guidelines → Product Description Standardization
- Develop GLN Registry → GLN Data Synchronization
- Develop Canadian Healthcare Product Registry → Healthcare Product Data Synchronization
- Standardize EDI Transactions → Implementation of EDI Transactions

Supply Chain Standards Project – Phase 1

Sector Implementation – Phase 2

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

GS1 Healthcare

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

GS1 Healthcare

Source Product Information

Pharmaceutical

Food Service

Grocery

Consumer Goods

Medical/ Surgical*

Manufacturers

Data Loading Solutions

Data Integrity/ Data Validation/ Normalization

Data Integrity/ Data Cleansing

GS1 Canada

GS1 Canada Data Pool

Global Data Synchronization Network

Available July 2011

Data Retrieval Solutions

Hospitals/ Retail Pharmacy

GPOs

Shared Services Organizations/ Distributors

Ontario Hospital Prefix and GLN Assignment

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
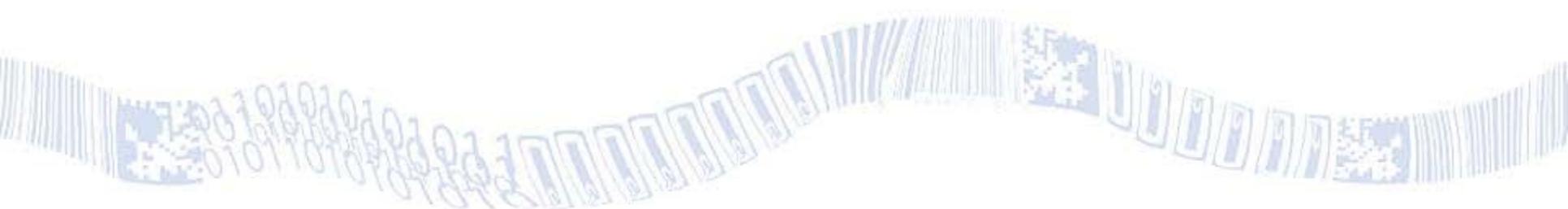
France
Valérie Marchand
GS1 France

Healthcare in France : 2011

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 request 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!

Agenda

The Dutch Healthcare Market

GS1 Healthcare

Dutch Hospitals

G Standaard Logic

Traceability

AIDC and Tools

Conclusion

Overview Dutch Market

- **16.500.000 people**

- **Average Healthcare expenses € 5000 p/y**

- **100 Hospitals, incl 8 University Hospitals**

- **1950 public pharmacies**

GS1 Healthcare in the Netherlands

- **Focus on:**

  - **Patient safety improvement**

  - **Supply Chain Efficiency improvement**
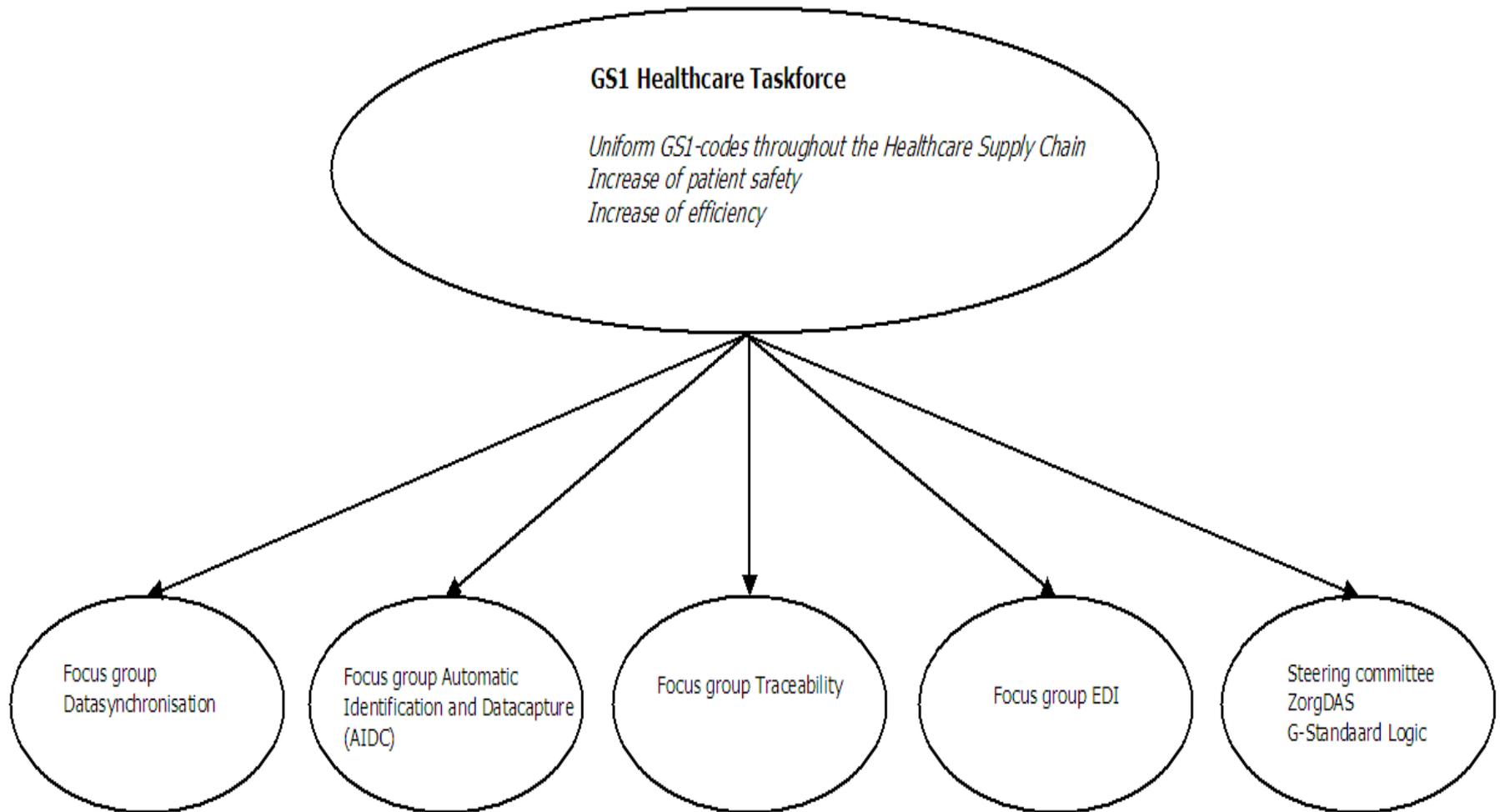
Statement Dutch Hospitals

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 secundary packaging

Surgical Implants

32%

68%

■ GS1

■ GS1/HIBC

Pharmaceuticals

24%

76%
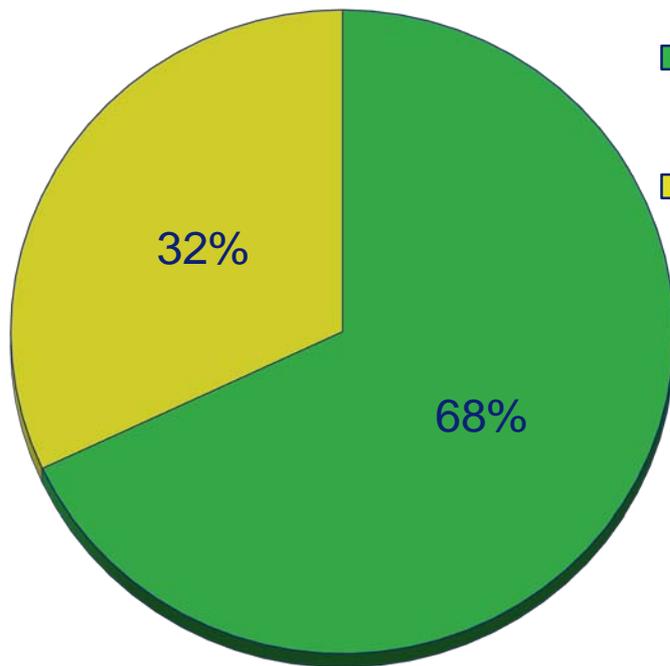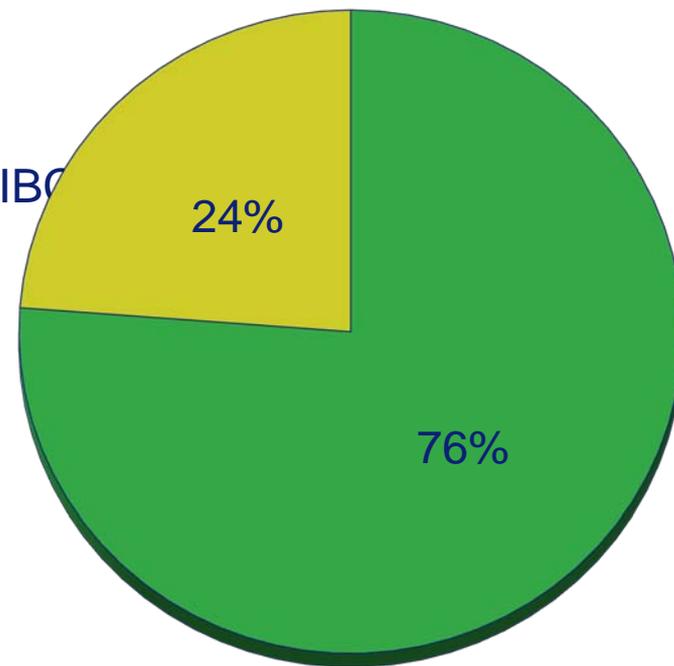
How do we support this goal?

- **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 = G-STANDAARD LOGIC

1SYNC-datapool (GDSN)

G-Standaard Logic

EDI ASSPRI for information on assortment and prices

Hospital / -Pharmacy

Care and logistic information

G-STANDAARD LOGIC

Wholesaler

Supplier

Public Pharmacy

GLN-registry

GS1 Nederland

samen *werkt*
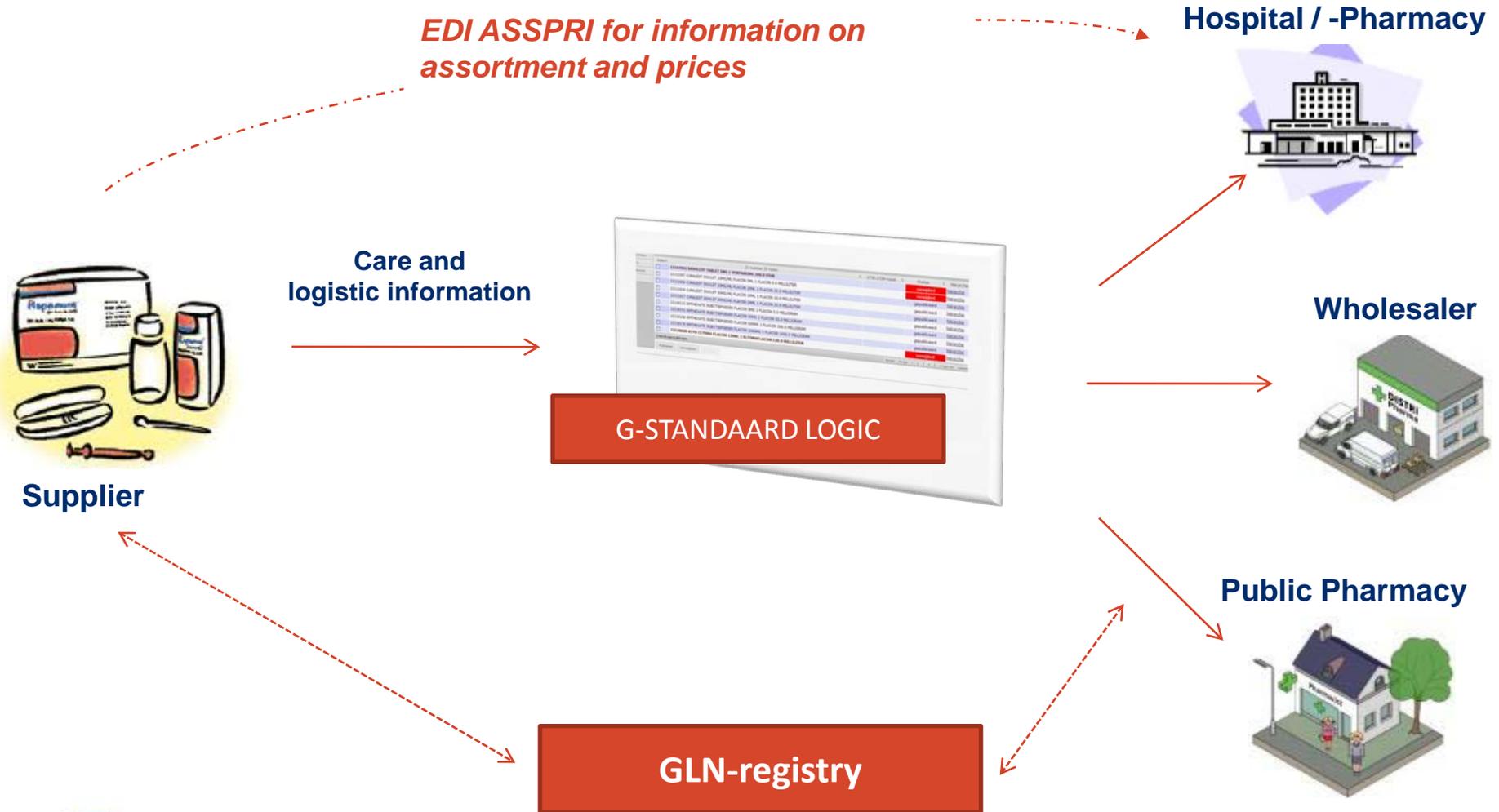
Who will connect?

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**

Traceability

Traceability in Hospitals:

- **6 Usecases have been defined with hospitals and suppliers**

Key findings:

- **Involve Solution providers to capture and use information in hospitalsystems**
- **Use 1 international standard**
- **Use 1 datacarrier, i.e GS1 Datamatrix, containing article/batch/serialnumber and expiry date**

Traceability

Next steps:

- **Deliver businesscase 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

- **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!

GS1 Nederland

samen *werkt*

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samen *werkt*

Japan
Michio Hamano
GS1 Japan

Standardization in Healthcare Sector in Japan

Medical Devices

Drugs
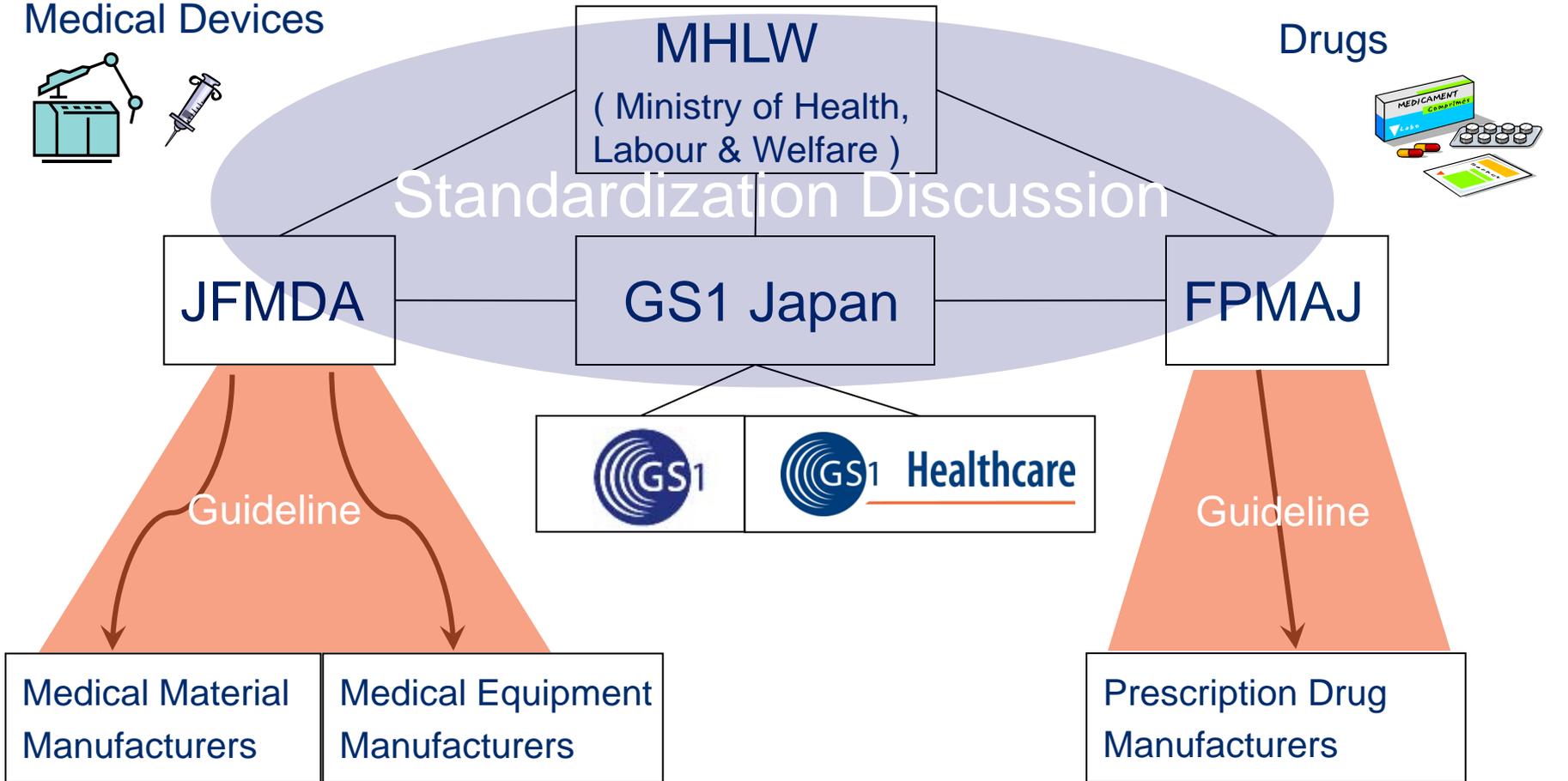
Standardization Discussion

MHLW
(Ministry of Health, Labour & Welfare)

JFMDA

GS1 Japan

FPMAJ

GS1

GS1 Healthcare

Guideline

Guideline

Medical Material Manufacturers

Medical Equipment Manufacturers

Prescription Drug Manufacturers

JFMDA : The Japan Federation of Medical Devices Associations

FPMAJ : The Federation of Pharmaceutical Manufacturers' Associations in Japan

History of Bar Code Implementation in Healthcare Industry in Japan

Medical Materials	Equipment	Prescription Drugs

1980s =

Prescription Drugs: Start using JAN(EAN-13)

1999 — Medical Materials: Guideline (JFMDA)

2000 — Database for All Healthcare Products (MEDIS)

2001

2002 — Revised Pharmaceutical Affairs Law delivered

2005 — Revised Guideline (JFMDA)

2006 — Followed by Dental Trade Association | Direct Marking Guideline — Prescription Drugs: Guideline (MHLW) (Issued in Sept. 2006)

2007

2008 — Medical Materials: Guideline (MHLW) (Issued in March 2008) — Prescription Drugs: Time Limit for Implementation (Sept. 2008)

2009

2010 — Time Limit for Implementation (March 2009 / March 2010 / March 2011)

2011 — Prescription Drugs: Revised Guideline (MHLW)

58

MHLW Bar Code Guideline for Medical Devices (Issued on Mar. 28, 2008))

Objective

Promotion of efficient distribution systems & medical administration, securing traceability and prevention of medical accidents

Contents

- **Marking Subjects – <u>Medical Devices</u>, <u>in Vitro Diagnostics</u> and <u>Consumable Supplies</u>**
- **Data to be Placed – <u>Product code</u>, <u>Expiry Date</u> and <u>Lot or Serial No.</u>**
- **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**

http://www.gs1jp.org/pdf/006.pdf

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 1 year after the issuance of notification

② 2 years after - - -

③ 3 years after - -

④ 1 year after the issuance of notification
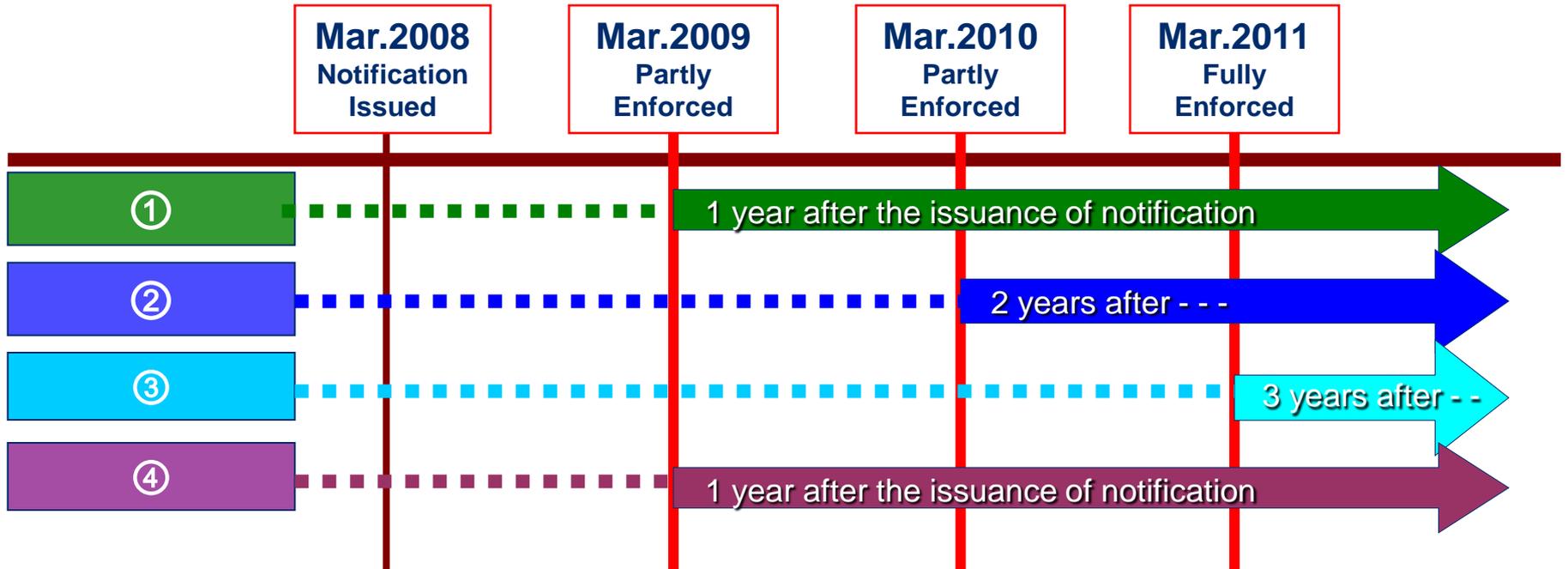
① Designated insured medical materials

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

Marking Requirement of MHLW Guideline for Medical Devices

< Individual Package > < Inner Box > < Outer Box >

| GS1-128 | GS1-128 | GS1-128 |

2D Barcode standardized by ISO
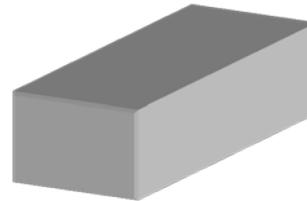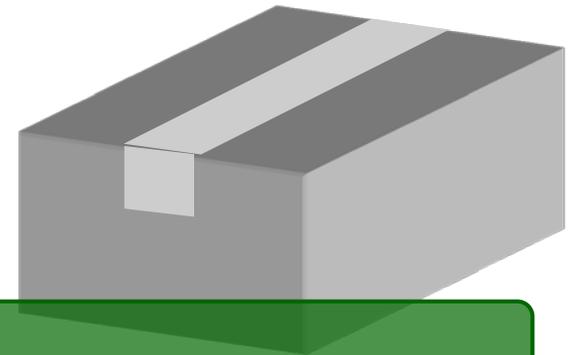
AI (01) GTIN

(partly required) AI (17) Expiry Date

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

Example of Bar Code Marking on Medical Device (Individual Package)

AI(01) G T I N

AI(17) E x p i r a t i o n
D a t e

AI(10) B a c h / L o t
N o .

MEDIS-DC Healthcare Products Database

Manufacturer or Supplier

❶ Apply for Company Prefix
❷ Allocate Company Prefix

GS1 Japan

❸ Register Product Data

MEDIS-DC Database

❹ Inquiry Search Download

MHWL

FPMAJ

JFMDA

❹ Inquiry-Search-Download

Distributor

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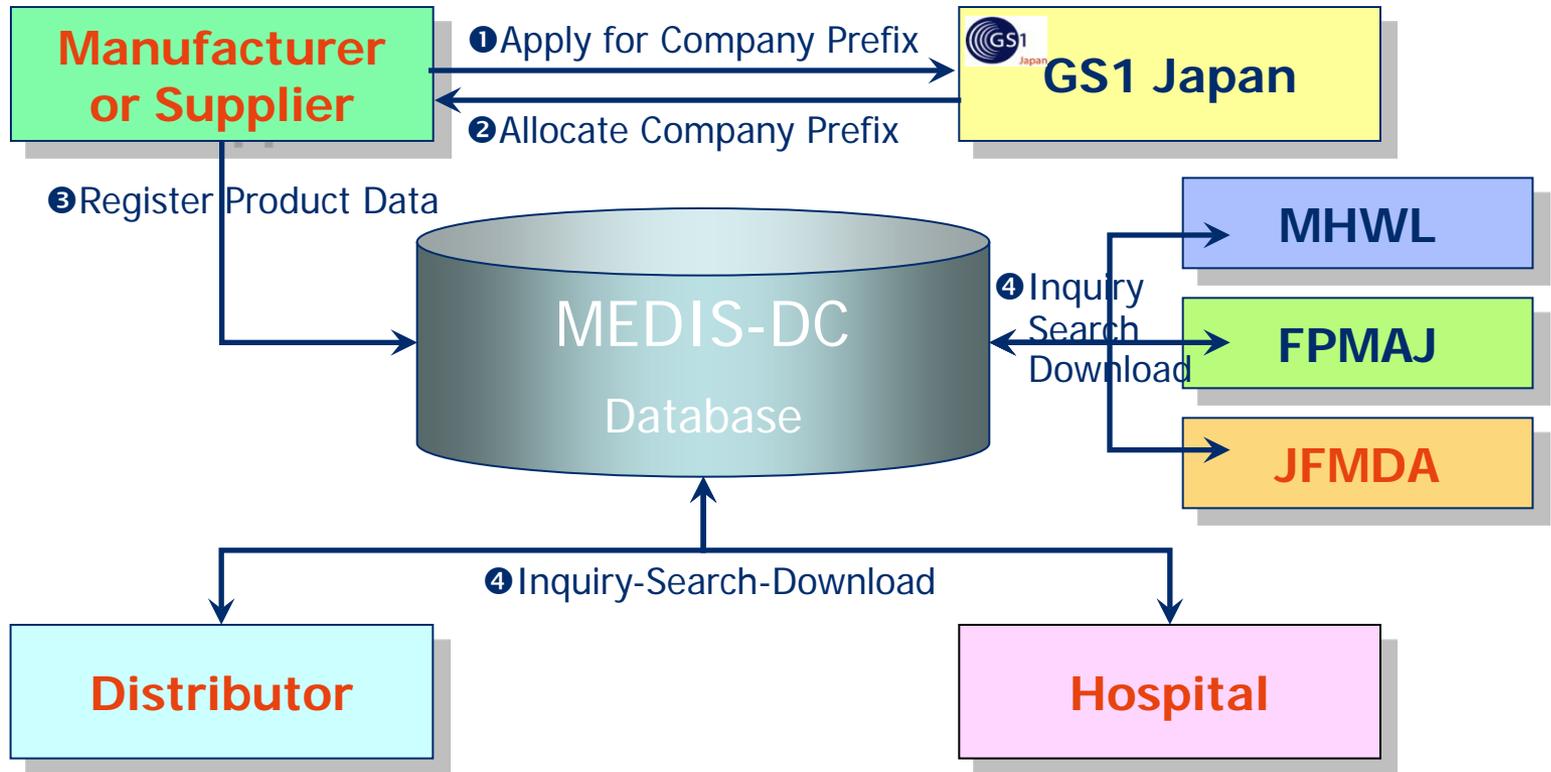
MEDIS-DC: The Medical Information System Development Center
MHLW : Ministry of Health, Labour & Welfare
JFMDA : The Japan Federation of Medical Devices Associations
FPMAJ : The Federation of Pharmaceutical Manufacturers' Associations of Japan

Rate of Bar Code Marking on Medical Devices

[Annual Survey by MHLW in Sep. 2010]

	Rate of Items with GTIN	Rate of Items Registered to MEDIS-DC Database	Rate of Bar Code Marking Items (Individual Package)	Rate of Bar Code Marking Items (Inner or Outer Box)
Medical Devices	96.1%	70.3%	72.6%	88.8%
In Vitro Diagnostics	98.4%	64.7%	76.7%	98.1%
Consumable Supply	88.5%	48.0%	---	64.2%

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UK
Roger Lamb
GS1 UK

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

"Coding for Success – Simple technology for safer patient care" becomes a reality

DH Department of Health

Coding for Success
Simple technology for safer patient care
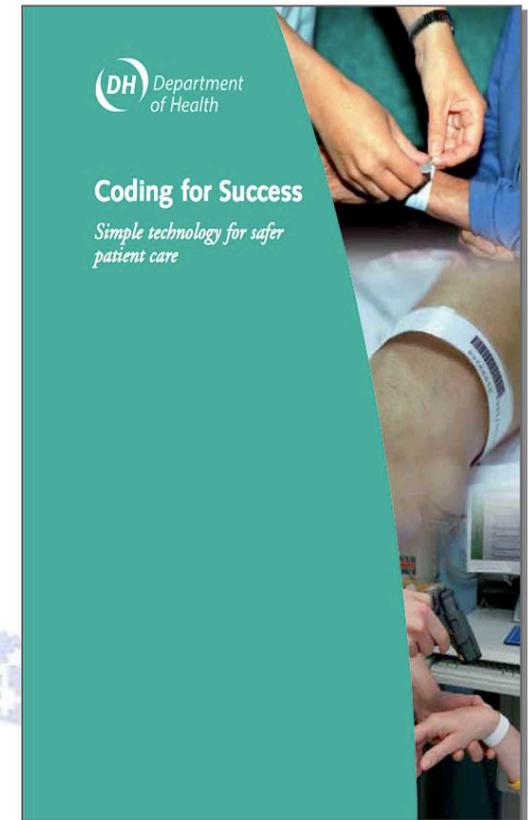
UK National Audit Office Report

"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"

House of Commons

- 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
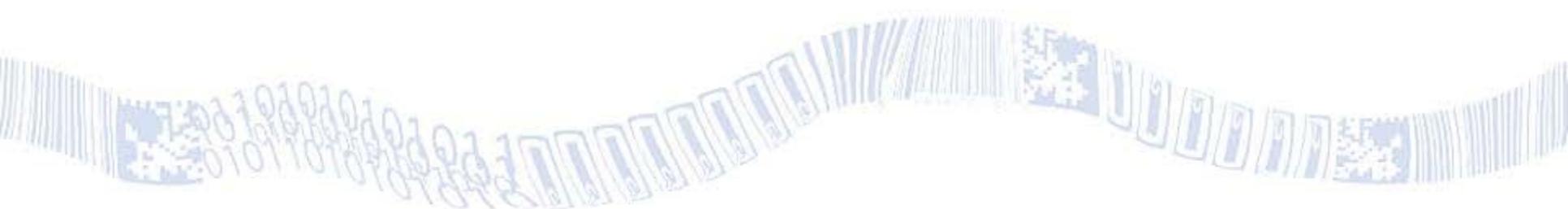
Quality, Innovation, Productivity, Prevention

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.