

GS1 Healthcare around the world

Update GS1 Member Organisations





GS1 Healthcare Local user groups



Local user groups can best work with key partners on local level

- Reach out to and engage key partners on local level for adoption and implementation of global standards
- Contribute and influence global standards
- Work with local regulatory bodies and associations

The power to engage local stakeholders









Germany



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GS1 Healthcare Australasia (Australia and New Zealand)

Gary Hartley, General Manager, GS1 New Zealand (In Person) Tania Snioch, Senior Advisor, GS1 Australia (In Spirit) **GS1 Healthcare Product ID & Traceability**

Pharmaceuticals

- **Australia** GTIN Allocation for use of NPC with Health Jurisdictions
- Traceability none

Medical devices

- **Australia** GTIN Allocation for use of NPC with Health Jurisdictions
- Traceability none

Pharmaceuticals

- **New Zealand** Proprietary coding system (Pharmac)
- Traceability none

Medical devices

- New Zealand none
- Traceability none

GS1 Healthcare GS1 Healthcare Australasia

Established	October 2006
Priorities	 Provide Australian and New Zealand input into the work of the global HUG Address and document Australian and New Zealand specific Healthcare issues and bring these to the attention of GS1 Healthcare for incorporation into this group's work plan Drive implementation of the GS1 standards in the Australian and New Zealand Healthcare sectors.
Work Teams	LeadershipComplete group
Strategic Partnerships and Collaboration	 Medical Industry Association of Australia Medical Industry Association of NZ Standards Australia



Healthcare Participants (as at 13th June 2008)

Manufacturers

3M Australia Pty Ltd Abbott Australasia Pty Ltd **Aventis Pharma** B. Braun Australia Pty Ltd **Baxter Healthcare BD** (Becton Dickinson) **Biomet Australia Boehringer Ingelheim Pty Limited** Bosco Medical Australia **CSL** Bioplasma Dade Behring ANZ **Douglas Pharmaceuticals (NZ) Draeger Medical GSK** Australasia **Kimberly-Clark** Merck Sharp & Dohme **Novartis** Pfizer Pty Ltd **Rem Systems** Resmed Smiths Medical St. Jude Medical Australia Pty Ltd Sydney IVF **Terumo Corporation** Welch Allyn Australia Pty Limited Wyeth Australia Pty Ltd

Distributors/Wholesalers

Aaxis Pacific Australian Pharmaceutical Industries (API) Central Hospital Supplies CH2 [HUG Australasia Chair]

Hospital/Pharmacy

National Pharmacies The Alfred Hospital Southern Health

Associations

GS1 Australia GS1 New Zealand Standards Australia Researched Medicines Industry Medical Industry Association of Australia Medical Industry Association of NZ Australia Post

Governmental Bodies

Department of Health (South Australia) Health Corporate Network - WA Health Health Technology - NSW Health National Blood Authority NEHTA Health Support - NSW Health Queensland Health Taranaki District Health Board



- 8 physical meetings to date
- Membership continues to grow
- Survey of membership aspirations and current status
- Identification of education needs
- Education program in place to be repeated 3x pa
 - 6 sessions, 1 hour webinar
 - What's happening in Healthcare?
 - GS1 numbering for Healthcare
 - GS1 bar codes for Healthcare
 - National Product Catalogue Overview
 - eMessaging for Healthcare
 - EPC/RFID for Healthcare



- Repeat education series October/November
- Next meetings -
 - July 21st 2008 (Kimberly-Clark) (AIDC focus) incl:
 - Brigham and Woman's Tom Cooley
 - Prof Alan Merry University of Auckland
 - November 26th 2008 (Pfizer)
- Commence case study and implementation drive



GS1 Healthcare Austria

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UMA

HHHHH

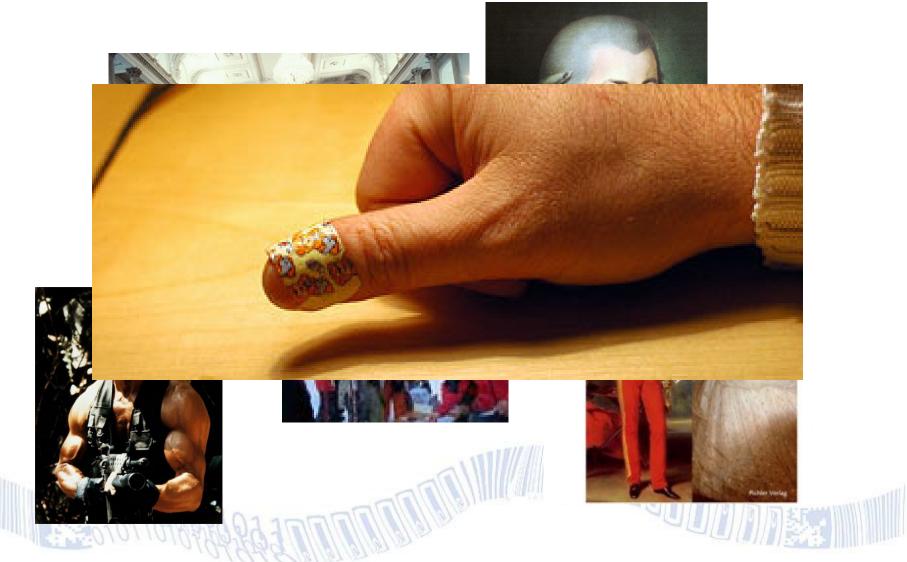
Barbara Dorner





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GS1 Healthcare Product ID & Traceability

Pharmaceuticals

Pharmaceuticals which are sold in pharmacies (not Rx only) have to have a PZN.
PZN is embedded in EAN13: 90 + 8888 + PZN + checkdigit



Medical devices

 instruments (used in surgery) have to be traced (MPG §91-93)



GS1 Healthcare GS1 Healthcare Austria

Established	June, 2007
Priorities	 Motivation of as many participants as possible Changing marking pharmaceuticals from PZN embedded in EAN-13 to GTIN + Lot + Exp. Date (GS1 DataMatrix?)
	 Marking medical devices (different international requirements)
Work Teams	•Appl.Stand. + carrier (established March 08) – Main focus on PZN in EAN13
Strategic Partnerships and Collaboration	 Austrian Federal Ministry of Health Pharmig (Association of pharmaceutical manufacturers)
	•ARGE Pharmazeutika (Association of pharmaceutical wholesalers)



Manufacturers

- Baxter
- Ebewe Pharma
- MedEL
- Boehringer Ingelheim
- GSK
- Croma Pharma

Distributors/wholesalers

- Herba Chemosan
- Richter Pharma

Hospital/Pharmacy

- Vinzenz Gruppe (7 hospitals)
- AUVA (12 hospitals)
- Wiener KAV (24 hospitals)

Associations

- Pharmig
- Austromed
- ARGE Pharmazeutika
- Austrian Chamber of Pharmacists
- Austrian Chamber of Medical Doctors
- University of applied sciences, Krems

Governmental bodies

- Austrian Federal Ministry of Health, Women and Youth
- AGES



- Setted up awareness of importance of global standards in healthcare
- Setting off project with hospital association re. marking containers/trays for sterilisation processes following GS1 Standards
- Members of the HUG Austria are already »making acquisitions« of prospective members



- Working on a study regarding taking the PZN out of the EAN-13 benefits and costs
- Biggest Austrian hospital association requested for marking instruments/containers/trays in sterilisation (24 hospitals) + logistics in the hospital pharmacy
- Coming closer with pharmaceutical manufacturers
- Motivating participants in healthcare especially politics activity
- GS1 standards should be recommended in law for traceability and marking
- Enforcing role of GS1 Healthcare Austria as platform No.1 for traceability in healthcare
- Training courses for healthcare sector
- Supporting projects with hospitals (patient ID, staff ID, sterilisation)



Proud to present



GS1 Healthcare Conference Vienna / Austria March 17 – 19, 2009



GS1 Healthcare Canada

Alicia Duval Vice President, Healthcare



Pharmaceuticals/medical devices

Product ID

•No regulatory requirements exist for bar codes on pharmaceuticals or medical/ surgical devices

• Regulatory issues regarding voluntary bar coding may arise if suppliers need to change their labels to accommodate a bar code

• Regulatory concerns are based on the labelling and packaging requirements outlined in the Food and Drug Regulations (FDR). Bar code content, specification and/or symbology are not concerns as long as the product label its human readable language adhere to existing labelling and GMP requirements

Traceability



•Bill C51 (April 2008)- GS1 Canada Applauds the Federal Government for Prioritizing Food, Product and Consumer Safety



June 18, 2008 Canadian Press: The CNA is calling for the health-care system to speed up the introduction of electronic health records.

"We're so far behind in a system that costs Canadian citizens billions of dollars - we need to have that infrastructure. For nurses it means being able to have the right information at the right time at their fingertips as they're caring for patients," states Marlene Smadu, President, Canadian Nurses' Association.

Estimate shortages of 25% by 2015.

GS1 Healthcare GS1 Healthcare Canada

Established	December 2007; Official Launch - June 2008
Priorities	 Healthcare eSupply Chain Standards Proposal – OntarioBuys (Ministry of Finance) Community management Standards development Education & communication Implementation support
Work Teams	 Healthcare Board Healthcare Technical Standards Work Group Pharmacy Board Pharmacy Technical Standards Work Group
Strategic Partnerships & Collaboration	 CareNET Services Inc. (430+ hospitals) Federal & provincial governments Industry associations Patient safety agencies



Healthcare Canadian tipping point of action



Associations Align to Advance Patient Safety and Healthcare Supply Chain Efficiencies

Toronto, ON, May 26, 2008 – Members of CareNET Services Inc. (CareNET) voted on Friday in favour of aligning with GS1 Canada. Together, the organizations will dedicate collective focus on making Canada's healthcare system safer and more efficient through the development and implementation of global supply chain standards.

CareNET represents 54% of Canadian hospitals, leading suppliers, GPOs and Solution Providers

GS1 Healthcare CareNET Healthcare Board

Manufacturers/Distributors

- 3M Canada
- Baxter Canada
- Canadian Hospital Specialties
- Cardinal Health Alaris Products
- HealthPro Procurement
- Hospira Healthcare Corp
- Johnson & Johnson Medical Products
- Medical Mart
- Source Medical
- Trudell Medical
 - Tyco Healthcare

Hospital

- Chatham-Kent Health Alliance
- Hamilton Health Sciences
- Healthcare Materials
 Management Services
- Health Sciences Centre
- Humber River Regional Hospital
- Interior Health Authority
- Medbuy Corporation
- Sault Area Hospital
- Shared Services West

Healthcare Healthcare Technical Work Group

Manufacturers

GS1

- Baxter Corp.
- Cook (Canada) Inc.
- Cardinal Health Alaris Products
- Johnson & Johnson Medical Products
- Medical Mart
- Nestlé Canada Inc.

• Distributors/GPOs/ Solution Providers

- McKesson Provider Technologies
- Emergis A Telus Company
- GHX Canada
- HealthPro Procurement
- Logibec Groupe Informatique Ltée
- Medbuy Corporation
- Medical Information Technology
- Ormed Information Systems Ltd.

Hospital

- Capital District Health
- Capital Health
- Centre Hospitalier Universitaire de Québec
- Grey Bruce Health Services
- Hamilton Health Sciences
 Corporation
- Healthcare Materials Management
 Services
- Interior Health Authority
- Plexxus

Healthcare Healthcare Pharmacy Board

Manufacturers

GS1

- Apotex
- Sanofi Pasteur

Distributors/wholesalers

- McKesson Canada
- GAMMA Wholesale Drugs
 (London Drugs)

Hospital/Pharmacy

- Katz Group Canada Ltd.
- London Health Sciences --Canadian Society of Hospital Pharmacists
- METRO Inc.
- Shoppers Drug Mart Corporation

Associations

- Canadian Association of Chain Drug Stores (CACDS)
- Canadian Association for Pharmacy Distribution Management (CAPDM)

GS1 Healthcare Pharmacy Task Group

Manufacturers

- Apotex
- AstraZeneca Canada Inc.
- Bayer Inc.
- Merck Frosst Canada Ltd.
- Novopharm
- Pfizer Consumer Healthcare
- Sandoz Canada
- Sanofi-Aventis
- Schering Canada
- Wyeth Consumer Healthcare

Distributors/wholesalers

- McKesson Canada
- McMahon Drug Wholesaler

Hospital/Pharmacy

- Le Groupe Jean Coutu
- London Drugs
- Metro Inc.
- Proxim
- Purdue Pharmacy
- Shoppers Drug Mart
- Sobeys Pharmacy/Lawton Drugs

Associations

Rx&D

- Canadian Association of Chain Drug Stores (CACDS)
- Canadian Association for Pharmacy Distribution Management (CAPDM)



ECCnet Registry: Canada's national product registry

Over **370,000** unduplicated products loaded

• Identified by the Global Trade Item Number (GTIN Bar Code)

Over 13,000 prescription (Rx) products

• Approximately 50 Rx Vendors

Over **10,000** over-the-counter (OTC) products Over **450** behind-the-counter (BTC) products Over **55,000** foodservice products Over **2,500** suppliers participating

Next – Medical Devices



GS1 Canada won the 2008 Voluntary Inter-industry Commerce Solutions (VICS) Award for Supply Chain Excellence for enhancing ECCnet Registry with the addition of over **30 new Rx-related** attributes

- Efficient: Allows trading partners to exchange accurate, up-to-date product data
- Sustainable: Eliminates paper processes



- Community management
 - Engage national stakeholders
- Standards development
 - Product identification standards
- Communications outreach
 - Multiple resources to keep stakeholders informed & engaged
- Implementation support
 - Education modules
 - Implementation guidelines



GS1 Healthcare France update

UMM

Valérie Marchand

GS1 Healthcare Product ID Pharmaceuticals





AFSSAPS Regulation Avis au JO du 16.3.2007 / SAN M 0720920V

1.01.2011

All lots sold on the French market must have a Datamatrix using GS1-128 Al's and including :

(01) Authorized market code in a GS1 structure (CIP 13)

+ Lot nb + expiry date

We are working on a document with CIP in order to help suppliers to manage the transition period with some identified issues :

- When pharmacies will be able to read Datamatrix ?
- Do suppliers have to maintain a linear barcode ?
- When do they have to migrate all the products ?

Datamatrix with CIP 13 + lot + expiry date from janvier 1st 2011



ACL, association of MD suppliers maintain a database for MD and send the data to the pharmacies. They need to manage different codes : GTIN, ACL 13 and ACL 7, as the reimbursement organisms don't integrate 13 digits.

Reason why we agreed to "re-sign" the agreement.

The agreement stipulates that companies can choose to identify their product with a «global GTIN» or an ACL code in a GS1 structure «ACL 13»

3401 X ACL C

The Social Security still use 7 digits to register the products and ensure the reimbursement ACL allocates ACL13 and ACL7 to suppliers choosing GTIN solution

(they need to be ACL member)



Established	May 2007
Priorities	 Data Sync Traceability in the hospitals A global Classification Answer the regulations : drugs, instruments, acts pricing
Work Teams	 Healthcare user group CologH (hospital logisticians) Work with suppliers to describe their products
Strategic Partnerships and Collaboration	 Cladimed for classification Europharmat (MD traceability) CIP/ACL GCS UNIHA (51 hospitals)



Manufacturers

- 3M France
- AGA MEDICAL
- AIR LIQUIDE SANTE FRANCE
- AMGEN
- B BRAUN MEDICAL
- SAS BAXTER BIOSCIENCES
- BOSTON SCIENTIFICS FRANCE SA
- COLOPLAST MANUFACTURING
- FRANCE COOK FRANCE
- EVOLUTIS SAS
- HEMODIA SAS
- HOSPIRA SAS
- KCI MEDICAL
- KYPHON EUROPE
- L.F.B. LABORATOIRE FRANCAIS
- LABORATOIRE GAMIDA
- LANDANGER
- LILLE HEALTHCARE SAS
- MERIAL SAS
- NOVO NORDISK PHARMACEUTIQUE
- S.A.S ORTHOMED
- SA PETERS SURGICAL
- PFIZER FRANCE
- SANOFI AVENTIS FRANCE
 - SMITH & NEPHEW SAS
 - SOPHYSA
- STRYKER FRANCE
- TERUMO EUROPE

Hospitals

- CH BICHAT CLAUDE BERNARD
- CH EUROPEEN GEORGES POMPIDOU
- CH SAINT LOUIS HOSPICES CIVILS DE LYON
- GCS UNI.H.A (52 hospitals)
- CH ARMAND TROUSSEAU
- CH PONTOISE
- CHRU LILLE
- CHRU STRASBOURG
- CHU AMIENS
- CHU DIJON
- CHU NANTES
- CHU NICE
- CHU ROUEN
- CACH NANTERRE
- AP HP NSI/SIR
- H AP HM

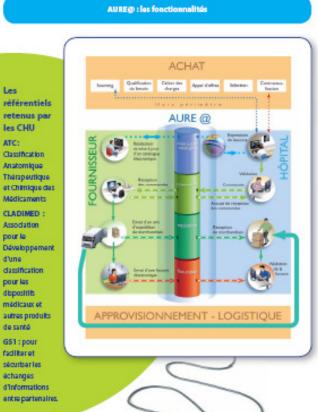
Associations

- GMSIH
- SYNDICAT INTER HOSPITALIER DE BEAUVAIS
- EUROPHARMAT
- CIP/ACL

Governmental bodies

- Ministère de la santé
- •Distributors/wholesalers
 - AEXXDIS
 - DEPOLABO PHARMA LOGISTIQUE
 - GEODIS
 - CERP ROUEN / CERP FRANCE





AURE@

o involve suppliers and hospitals on the e-procurement platform



eaded by 17 university hospitals)

We tried to explain on both side why do they need to use it, and what kind of benefit they could expect

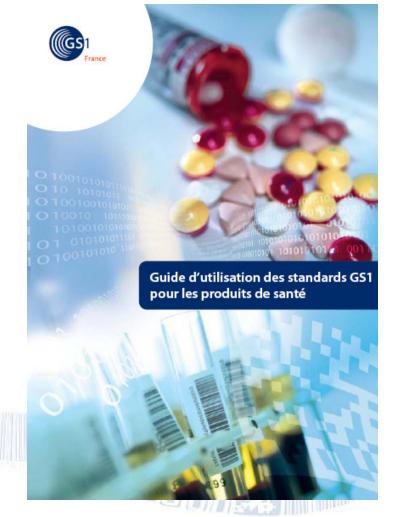
GCS UNIHA at GS1 France board



Healthcare GS1 user guide line :

- To help new healthcare members, give them an overview of GS1 standards
- which GS1 standards are used for the healthcare sector,
- where could they find more technical information.

Mostly to be downloaded to be updated when needed.





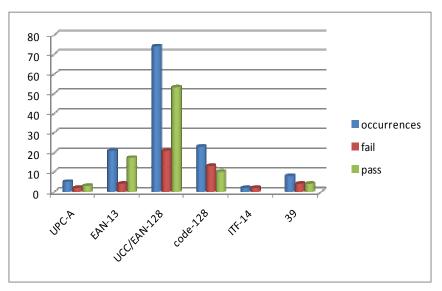
- GTIN allocation rules in French
- And still translate all the GS1 Healthcare news letters, press realease, etc.





Audit of MD stock in a clinic in France :

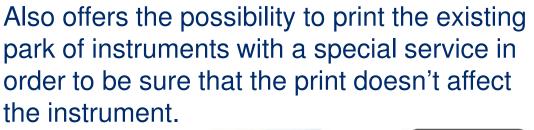
- 200 beds
- 171 suppliers
- 91 barcodes read
- 849 references (idem in Dijon)
- Status :



- 50% of the suppliers print a GS1 barcodes (some of them can't be read for different reasons, size, quality, wrong codification, etc.)
- This represent 80% of the references
- We have listed all the suppliers registered in this clinic and the type of data printed in their barcodes

GS1 Healthcare « first mini Datamatrix »

Landanger, French surgical instruments suppliers is able to print quite 100% of his production using a new technology and print a "mini Datamatrix" (on needle for ex.) with GTIN and serial number.





Taille x-module = 0,110mm





- What data do we need to manage to answer the different traceability requirements
- Start a pilot for healthcare waste management process
- Help suppliers to fill the e-procurement catalog
- Set up a group and a pilot on anti-counterfeiting using both solution : RFID and Datamatrix with secured information



GS1 Healthcare Germany

Bettina Bartz, Senior Projectmanager GS1 Germany

GS1 Healthcare Product ID & Traceability

Pharmaceuticals

•Regulatory requirement for bar coding: unique bar code must be on the packaging

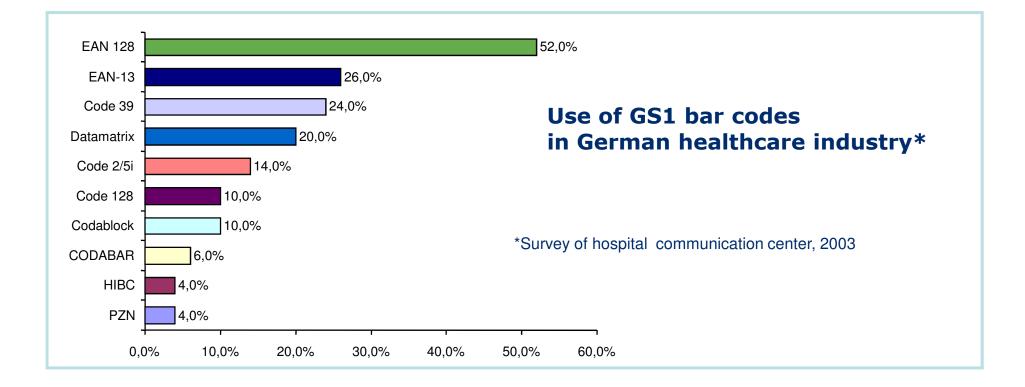
•Pharmaceutical associations & Health Insurance agreed to use PZN in code 39

Medical devices

No regulatory requirements
Many manufacturers use EAN13 and EAN128 to identify the products









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GS1 Healthcare GS1 Healthcare Germany

Established	12. June 2007
	 Allocate the needs and requirements of the german healthcare Give information transfer from the german group to GS1 Healthcare and back
Priorities	 Translate results of the GS1 Healthcare and disseminate into the german market Spread the results in best practice examples and application recommondation Starting pilot projects and enhance the implementation
Work Teams	•Expert team: product database in healthcare
Strategic Partnerships and Collaboration	 Associations from wholesaler and manufacturer VFA – Verband forschender Arzneimittelhersteller e. V. BPI – Bundesverband der pharmazeutischen Industrie PHAGRO Bundesverband des pharmazeutischen Großhandels e.V. BVMed – Bundesverband Medizintechnologie e.V.



Steering Committee GS1 Healthcare Germany

Pharmaceuticals

Carsten Büttner Boehringer Ingelheim Pharma GmbH & Co.KG

Medical Devices

Volker Zeinar B. Braun Melsungen AG

Medical Devices

Alfons Rathmer 3M Medica GmbH



Hospitals

Holger Raphael Marienhospital Herne

Hospitals

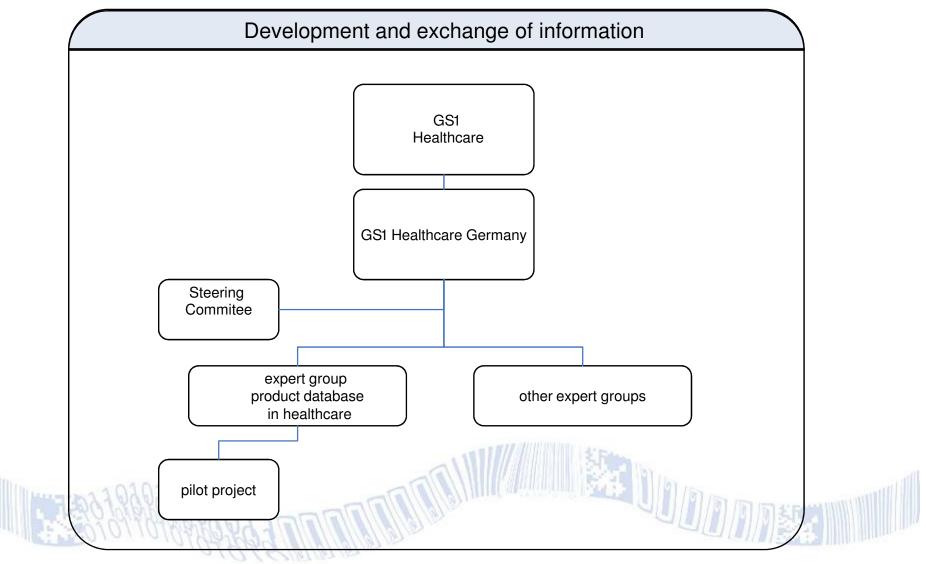
Frank Brüggemann Comparatio Health GmbH

Medical Devices

Klaus Schüler P.J. Dahlhausen & Co. GmbH



HealthcareDevelopmentGS1 Healthcare Germany



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 memorandum of understanding has been agreed by major lobbying groups like



- beraten analysieren handeln
- want to use GS1 Standards for product identification of pharmaceuticals



- implement DataMatrix including expiry date, batch and serial number
- however prefix solution has to be embedded within GTIN structure including the national drug code (PZN)
- => solution suggestion by GS1 Germany :
 - pharmaceutical EAN for pharmaceuticals
 for the time being, no change for medical devices
 - long term solution will use GTIN



GS1 Healthcare Russia

George Nasonov COO – GS1 Russia Head of GS1 Russia Healthcare

S¹ Healthcare Product ID & Traceability

Pharmaceuticals

 Healthcare Ministry regulation (since 1997) requiring that all pharmaceuticals sold in Russia must be identified with a GTIN. GTINs are used as unique identifiers in the Russian Healthcare Ministry database of pharmaceuticals

• Traceability requirements - none

Medical devices

- No regulatory requirements
- Traceability requirements none

GS1 Healthcare GS1 Healthcare Russia

Established	Jan. 16, 2008
Priorities	 Patient safety by preventing and reducing errors by data capture, better (reliable) documentation, adoption of global standards, with the primary focus on automatic identification More efficiency in the internal supply chains
Work Teams	 GOST R / Technical Committee 355 « Automatic Identification » Subcommittee 8 « GS1 Healthcare Russia »
Strategic Partnerships and Collaboration	 Not yet – under discussion



Manufacturers

- Alsi Pharma Ltd
- Akhtamar Ltd
- Diagnostic Systems Ltd

Distributors/wholesalers

Service providers

- Service Plus Ltd (Moscow)
- DataKrat Ltd (Ekaterinburg)
- SA2 WorldSync Russia (formerly SINFOS Russia)

Hospital/Pharmacy

- Hematology Center at the Russian
 Academy of Medical Sciences
- Moscow City Blood Transfusion Center
- Ufa City Blood Transfusion Center

Associations

- GS1 Russia
- Automatic Identification and Mobility (AIM) Russia
- International Foundation for Automatic Identification (IFAI)

Governmental bodies

 Russian Federal Research Center for the Examination of Medical Products



- Preliminary consultations with interested parties from industry and regulatory bodies
- GS1 Standards in Healthcare & GS1 Healthcare User Group - Russian editions of brochures will be available in hard copies in July





- Speed up outreach and engagement of hospitals
- Contact and involve local regulatory bodies and trade associations so that they are aware of global activities and developments





GS1 Healthcare Serbia

/HEALING

.

Branislava Mitic

GS1 Healthcare Product ID & Traceability

Pharmaceuticals

Law on Medicinal Products and Medical Devices:

•Article 75 (Marketing of Medicinal Products)

The holder of the wholesale authorization for medicinal products and the manufacturer, shall keep records on the type and quantity of imported or exported medicinal products, records on sold medicinal products (per package type) in the Republic of Serbia as well as records on medicinal products imported for research and therapy Records referred to in Para. 1 of this Article shall contain:

1) The name of the medicine, the classification and identification (ATC, ATC-vet and EAN (GTIN) code, the form, strenght and packaging of the medicine)



... Pharmaceuticals

- •Article 88 (Labeling of Medicinal Products and Patient Information Leaflet)
- The marketed medicinal product must include at least the following data on its outer package:
- 7) The expiry date of the medicinal product
- 12) Number of the batch and EAN (GTIN) code
- <u>Regulation for medicinal products</u> (marking the basic outher package), 2008, obliged the use of GTIN EAN (ISO/IEC 15420)

. . .



Medical devices

Low on Medicinal Products and Medical Devices:

Article 129

(Labeling of Medical Devices and Patient Information Leaflet) Every medical device with a marketing authorization ... shall include at least:

5) Expiry date (indicated on both packages, individual and batch packaging);

6) Batch number;

. . .

11) Current identification code (EAN (GTIN) code)

GS1 Healthcare GS1 Healthcare Serbia & Macedonia

Established	24 October 2006
Priorities	 to strengthen legal regulation to gather representatives of participants in healthcare chain to agree what are the common requirements to reach the patient safety to help users (education, participation in projects, etc.) -marketing activities,
Work Teams	•No separate teams
Strategic Partnerships and Collaboration	Members of the Team



Manufacturers

. . .

Hemofarm

Distributors/wholesalers

- Apoteka Beograd
- Velefarm

. . .

Hospital/Pharmacy

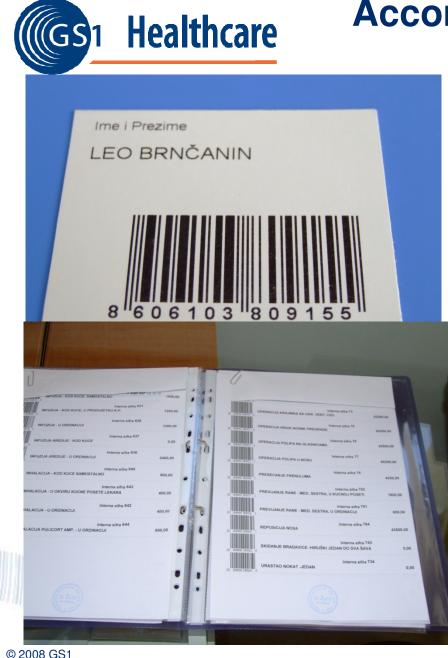
Zutic Clinic

Associations

Association of Medicines
 Manufacturers

Governmental bodies

- Ministry of Health
- Medicines and Medical Devices Agency
- Fund for Healthcare Insurance



Accomplishments

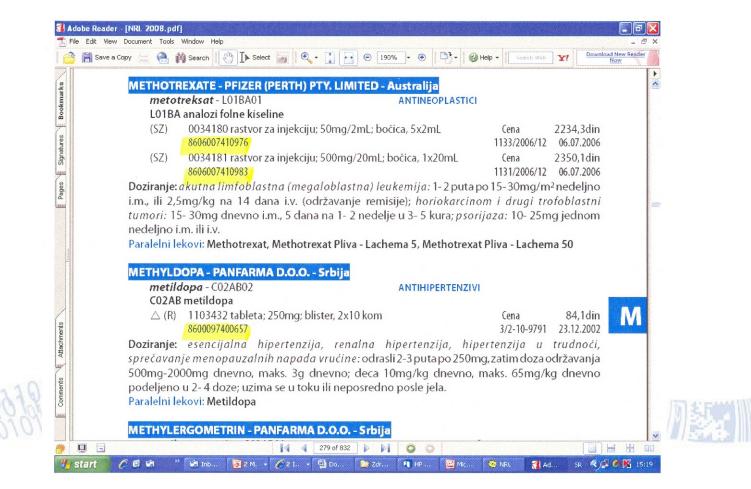
(use in one hospital)

1.Patients - GLN2.Services - GTIN3.Medicines - GTIN



GS1 Healthcare Accomplishments

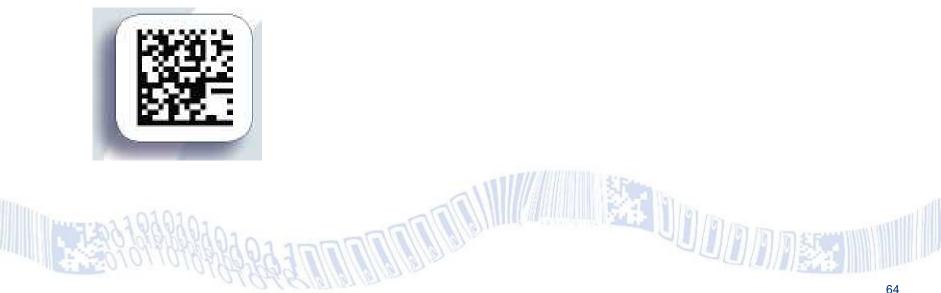
Medicines and Medical Devices Agency of Serbia published The National Register of Medicinal Products (2008) in which medicines are identified with GTINs.





Procedure for adoption the ISO standard for Data Matrix as national standard (ISO/IEC 16022) is in progress. It is translated on Serbian language.

We intervened for rapid adoption by Serbian Institute for Standardization.





Our big pharmacy institution, Apoteka Beograd, together with Serbian Fund for Health Insurance and one healthcare center started the pilot project of coding the data of medical prescription in DataMatrix format using Als.

It also use electronic messages for invoice and despatch advice. GLNs are used for identification of business partners.





Filijala Beograd 300339954229
Marinković Milutin .0.
PEKA PAVLOVIĆA 84
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Plan is to gather big manufacturers and convince them to use Data Matrix on primary containers with GTIN, batch number and expiry date

... and, also to mark logistic units.



Initiatives toward Ministry of Health for creating regulations for marking logistic units and unit doses.

Actions toward some hospitals for using GS1 standards. Continual educational and marketing activities.



GS1 Healthcare Slovakia

/ HAND IT

Ladislav Janco

GS¹ Healthcare Product ID & Traceability

Pharmaceuticals

•Regulatory requirements for bar coding - law 140/98 - EAN code (either EAn 8 or EAN 13) must be on the packaging

•Law is in force since 1998 enforced by distributors and pharmacists

Medical devices

•No law connected to labeling with barcodes

•New amendment of the law states the same conditions as for the drugs (not voted on yet)

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Established	29. 4. 2008
Priorities	 Better control of the labeling barcodes GS1 system for medical devices
Work Teams	Medical devicesPharmaceuticals
Strategic Partnerships and Collaboration	 Ministry of healthcare Slovak association for standardization of pharmaceutical information



Manufacturers

- Zentiva
- Pfitzer
- Chirana
- Boehringer Ingelheim Pharma
- Ozone Laboratories Slovakia
- Johnson & Johnson s.r.o.
- Roche Slovensko, s.r.o

Hospital/Pharmacy

Associations

- Chamber of pharmacists
- SK-Med (EUCOMED)
- Chamber of healthcare professionals

Governmental bodies

• Ministry of healthcare

Distributors/wholesalers

Phoenix



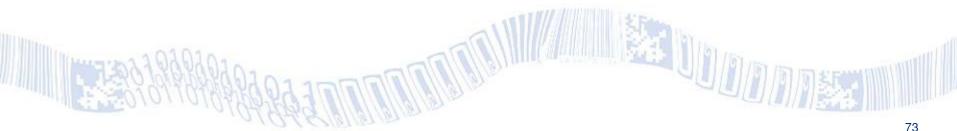
Amendment of the law concerning labeling of the ulletmedical devices with the barcode





Implementation of GS1 standards into the official ulleteHealth strategy

Better control of the assigned numbers by the Slovak ulletdrug administration





GS1 Healthcare [Switzerland]

[Christian Hay]

GS1 Healthcare Product ID & Traceability

Pharmaceuticals

- •registration # has to be printed in human readable form
- •GMP/GDP/GSP)
- •weak politic pressure



Medical devices

- •no legal requirement for barcoding
- •CE mark or equivalent mandatory
- •Reimbursement price is a problem
- •no special traceability requirement, except for implants

GS1 Healthcare GS1 Healthcare Switzerland

Established	9 December 2005
Priorities	Secure information link with Global HealthcareDynamise GS1 activities in Swiss HC
Work Teams	 Communication Delivery process enhancement Safe medication (bed side scanning)
Strategic Partnerships and Collaboration	SwissmedicRefdata Foundation

Healthcare Participants (only GS1-CH members)

Manufacturers

(GS1

- [Actelion]
- [Alloga]
- [AstraZeneca]
- [Basilea Pharmaceuticals]
- [CSL Behring]
- [Globopharm]
- [Janssen-Cilag]
- [JnJ Medical]
- [Novartis]
- [Pfizer]
- [Plus Ortho / S&N]
- [Salzmann-Medico]
- [Sanofi-Aventis]

[Ypsomed]

[Teva]

[UCB]

Distributors/wholesalers

- [Amedis (Phoenix)]
- [Galexis (Alliance-Unichem)]
- [Voigt]

Hospital/Pharmacy

- [Aarau]
- [Geneva]
- [Thun]
- [Bern]

Associations

- [GSASA (Hospital Pharmacists)]
- [Patient Safety Foundation]
- Governmental bodies
 - [Swissmedic]



- SmartLog project reports to be validated
- Patient safety in Bedside Scanning process: first barcoded single dose arrive on the market





- Enhance information and promote bedside scanning
- Enhancement of distribution process : work with authorities on pandemie vaccination



GS1 Forum für Effizienz im Gesundheitswesen Forum GS1 – efficience dans le domaine de la santé

Bedside Scanning Patientensicherheit durch eindeutige Identifikation Sécurité du patient par une identification univoque

Collaboration

Information

Learning

Support



GS1 Healthcare UK

Unn

Roger Lamb

S1 Healthcare Product ID & Traceability

Pharmaceuticals

•Strong Recommendation by Purchasing and Supply Agency for GS1 bar coding , product ID number in 2004

•National Procurement eEnablement Strategy launched June 2007

•National Procurement eEnablement Delivery Group

Medical devices

• Terms of Trading for NHS Supply Chain for bar coding, product ID number

•Member of National Procurement eEnablement Delivery Group

•NICE guidance IP196 and HSC 2000/32 on Traceability of instruments (Appendix 8, Volume 2, Schedule 6)



Established	September 2007
Priorities	 Increased use of GTINs within Hospital Supply Chain (especially devices)
Work Teams	•GDS and aligning the use of catalogues in the NHS and the NHS CfH Dictionary of Medicines and Devices.
	 Implementation of GLNs by the NHS to identify locations
Strategic Partnerships and Collaboration	 Government Agencies Industry Associations Manufacturers/Suppliers Healthcare Providers



Rachel Hodson Head of eProcurement PasA Quality Strategy Team DH Dr. Helen Lovell Head of Safer Practice NPSA Chris Ranger AIDC Project Manager NHS Connecting for Health Neil Lawrence Mike Kreuzer Director Technical & Regulatory ABHI **Commercial Affairs Manager ABPI** John Ferguson Mike Stubbs Director Bunzl Bryan Semple IT Solutions Director NHS Supply Chain Jonathon Kay Professor of Health Informatics City University Graham Medwell Information Manager Leeds Teaching Hospitals Jenny Gough Packaging Manager Molnlycke Healthcare Alan Hounsell Section Leader Smiths Medical International eBusiness Pharmacist PaSA Judie Finesilver



- 110 hospitals joined GS1 UK
- Working with DH on cross agency strategy
- Working with NPSA on patient identification
- Working with DH National Decontamination Team
- Working with Pharmacy National Advisory Board
- Holding joint Hospital and Supplier event in September 2008 event



Ann Keen MP, parliamentary under secretary for health services, has provided further support to the initiative by recommending the use of GS1 codes throughout the healthcare system, both for manufactured products and for coding systems used within healthcare settings. **Speaking at the recent Patient Safety** Congress in London she said, "We want to support the use of technology where this can lead to service improvement and are actively encouraging the uptake of coding in healthcare. We believe that this can help staff do what they want to do – deliver the right treatment, to the right patient, at the right time. We know it works - patient safety is improved and, therefore, we have recommended the use of GS1 codes."





- Extension of GS1 activity in Home Countries ullet
- **Discussions with Independent Healthcare Providers** \bullet





GS1 Healthcare US

Dennis Harrison President, GS1 Healthcare US



Product ID & Traceability

Pharmaceuticals

- Bar codes (GTINS) on all pharmaceuticals April, 2006
- 95% of manufacturers use GS1 system
- FDA: RFID allowed on solid dose medications
- Traceability:
 - Florida As of July, 2006 Non ADR's must pass Pedigree
 - FDA As of December 2006 All non authorized distributors (ADR) must pass Pedigree
 - 17 states require Pedigree
 - FDA must choose or develop unique identifier by April, 2010
 - California 2011 All participants must
 - pass Pedigree all items serialized

Medical devices

- No current regulations
- 85% of manufacturers use GS1 system
- FDA must choose or develop unique identifier by April, 2010
- Traceability: Limited activity

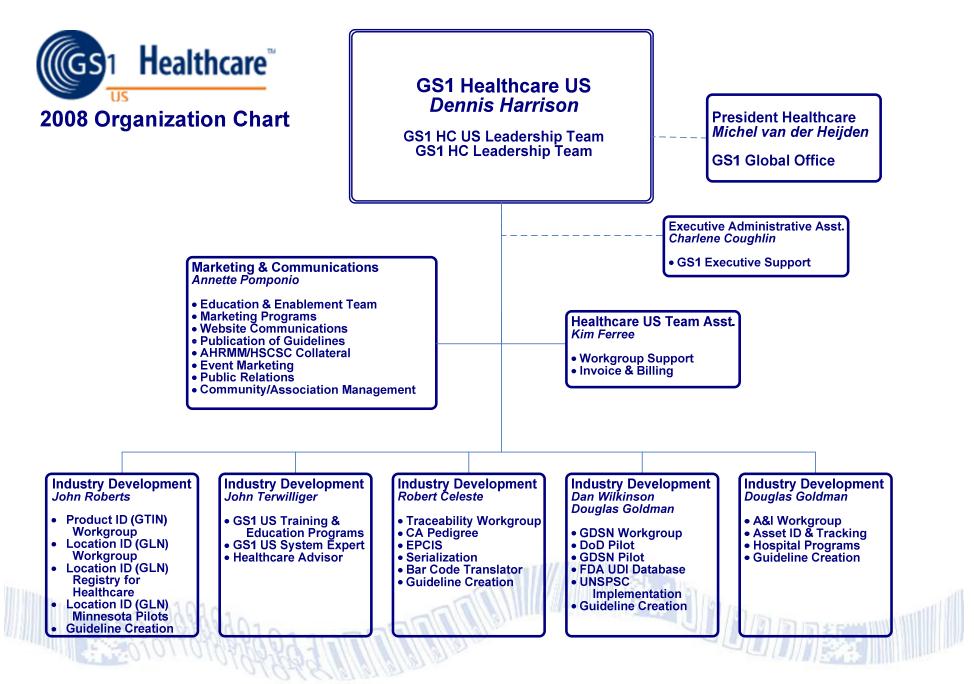


Established	1/01/08
Work Teams	 Product Identification (GTIN) Location Identification (GLN) GDSN Implementation Traceability Adoption Application & Implementation Communication Advisory Team Weekly Teleconferences Quarterly Face to Face Meetings
Strategic Partnerships and Collaboration	 CHeS - Coalition for Healthcare eStandards HSCSC - Healthcare Supply Chain Standards Coalition SMI - Strategic Marketplace Initiative AHRMM – Assoc. for Healthcare Resource and Materials Mgmt. HIGPA - Health Industry Group Purchasing Association



GS1 HC US "Ad hoc" Leadership Team

- AHRMM Deborah L. Sprindzunas
- Amerinet Mary Beth Lang
- Becton Dickenson Dennis Black
- Johnson & Johnson Michael Rose
- Mayo Joe Dudas
- McKesson Ron Bone
- Novation Dennis Byer
- SMI Dennis Orthman
- Univ. Kentucky Medical Center Jean Sargent
- Walgreens Steve Addante





Manufacturers

3M **Abbott Labs** Alcon Labs Amgen Amphastar Pharmaceuticals Apotex Baxter BD **Becton Dickinson Bristol-Myers Squibb** Covidien Genzyme Corporation GlaxoSmithKline Hospira Johnson & Johnson Kyowa Pharmaceutical, Inc. Medimmune Inc. Medline Medtronic Merck P&G Pfizer Purdue Pharma Sage Products **Teva Pharmaceuticals USA** Upsher-Smith Laboratories, Inc. **Solution Providers** AAkar Technology Inc **Accenture** Acsis Inc. Aegate Ltd Authentix Ltd Axway **Booz Allen Hamilton** Deloitte Consulting, LLP Domino Amjet Edge Dynamics Elge Inc. GHX Globe Ranger IBM Infosys Inmar/MedTurn Lawson Software Maxiom Consulting Group, Inc. Medical Imaging & Technology Alliance **RfXcel** Corporation SAP Labs, LLC Sensitech Supplyscape **Unisys North America** VCG & Associates



Healthcare Participants (Continued)

Associations

ASHP - American Society of Health System Pharmacists AHA - American Hospital Association AHRMM - Assoc. for Healthcare Resource & Materials Mgmt. CheS - Coalition for Healthcare eStandards GPhA - Generic Pharmaceutical Association HDMA - Healthcare Distribution Management Assoc. HIDA - Health Industry Distributors Association HSCSC - Healthcare Supply Chain Standards Coalition NACDS - National Association of Chain Drug Stores National Coalition of Pharmaceutical Distributors NCPDP - National Council for Prescription Drug Programs SMI - Strategic Marketplace Initiative VCG & Associates Verisign

Government Agencies

DoD - Department of Defense **FDA - US Food and Drug Administration** US Army

Third Party Logistics MedTurn



Distributors

AmerisourceBergen Corporation Cardinal Health McKesson US Pharmaceutical Owens & Minor US Oncology

Retailers

CVS Caremark Target Walgreens Wal-Mart

<u>Hospitals</u>

Ascension Health Geisinger Health System Intermountain Healthcare Mayo Clinic Norton Healthcare Novant Health Ridgeview Medical Center Sentara Sisters of Mercy (ROI)

University Healthcare System Augusta (UHCS) University of Kentucky Medical Center Veterans Administration Hospital



- Formed GS1 Healthcare US Vision, Mission, Charter
- Held first Workgroup Forum 3/11-3/12/08
- Second Workgroup Forum 7/23-7/24/08 in San Antonio, Texas
- Completed Workgroup plans
- Completed Phase 2 of the Minnesota GLN Pilot
- Submitted 27 page and 43 page responses to the FDA regarding Unique Identifiers and Drug Traceability.
- Continuing to meet monthly with the California Board of Pharmacy (date moved from 2009 to 2011).
- Created a marketing campaign
 - "Are You Ready?"
- Building Patient Safety

GS1 Healthcare US 2008 Strategic Plan: Global Data Synchronization Network® (GDSN®) Workgroup

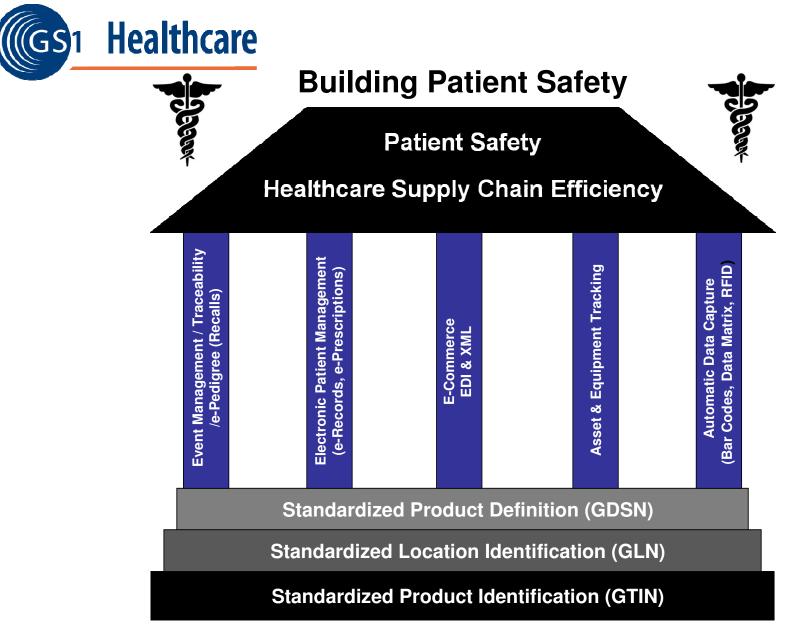
Mission: Accelerate the adoption of GDSN standards in U.S. Healthcare and ensure data accuracy.

Strategies	Initiatives	Deliverables	Due Date: Status
1. Formalize Global Data Synchronization Network (GDSN) workgroup.	 Develop & approve mission for the workgroup. Develop & approve workgroup plan. Complete integration of GS1 Healthcare US GDSN and HSCSC data sync workgroups. 	 Publish mission. Publish workgroup plan. Integrate meetings. 	Q1 2008: Complete Q2 2008: Complete Q1 2008: Complete
2. Define requirements for implementation of GDSN standards.	 Define U.S. requirements for the GDSN global standard. Develop attribute requirements/recommendations. 	 Deliver requirements to GS1 Healthcare. Publish attribute list. 	Ongoing Q2 2008: Complete
3. Create communication tools and provide information necessary for stakeholders in U.S. healthcare to understand how to trade using the GDSN.	 Develop GDSN Tool Kit to include: GDSN Package Measurement Requirements. GTIN Healthcare Allocation Rules. U.S. Market Attributes for Healthcare. Cost elements Healthcare industry communication templates for all early adopter participants (Mayo, Ascension Health). 	○ Publish Provider Tool Kit.	Q2 2008
	 Review and promote GS1 Healthcare US webinars about standards in healthcare and GDSN. 	 ○ Conduct webinars. 	Q4 2008
4. Coordinate GDSN promotional activities with specific healthcare	 Review and promote communications developed by GS1 US in collaboration with multiple healthcare organizations, including AHRMM, CHeS, HSCSC, HIDA, SMI, HDMA, HFMA & ADVAMED. 	• Publish summary of communications.	Ongoing
associations.	 Review and promote case studies and/or summaries of key findings about the following GDSN pilots: Dept. of Defense Global Pilot 	 Publish summary and key findings. 	Q2 2008
5. Connect with global activities.	• Monitor, review & comment on global information from GS1 Healthcare.	 Report feedback to GS1 Healthcare US. 	Ongoing
	 Demonstrate global interoperability of the GDSN by connecting DoD participants to trading partners outside the U.S. (e.g. Australia). 	 Write summary of success. 	Q2 2008



Accomplishments

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Standardization

Interoperability



Next Steps

- Continue to build GS1 Healthcare US membership
- Continue working the Workgroup plans ۲
- Embrace hospitals
- Complete tool kits ٠
- Grow the GLN Registry for Healthcare ٠
- Create a Healthcare video ٠
- Continue to move DoD GDSN participants into production ۲
- Participate in the Global GDSN pilot ٠
- Develop a hospital implementation team (consulting)
- Continue working with the California Board of Pharmacy





GS1 Healthcare US Community wants -

Less Talk, More Action!

GS1 Healthcare US Is All About Implementation!





Back-up



GS1 Healthcare Healthcare in New Zealand

Population	4,267,442* & 40 mil Sheep
Healthcare system	Combination of Public and Private
Healthcare expenditure (per capita)	NZ\$3728.00 (MoH 2006) NZ\$ = €0.49c
Healthcare expenditure (% of GDP)	9.45 % (MoH 2008)

Key Government Strategies

• The <u>New Zealand Public Health and Disability Act 2000</u> established the <u>New Zealand Health</u> <u>Strategy</u> and the <u>New Zealand Disability Strategy</u> as the key policy documents for the health and disability sectors. Under these overarching strategies are population-based strategies and service-based strategies.

• Population-based strategies include the <u>Health of Older People Strategy</u>, <u>He Korowai Oranga</u> <u>– Māori Health Strategy</u> and the <u>Pacific Health and Disability Action Plan</u>, while service-based strategies include the <u>Primary Health Care Strategy</u> and the <u>New Zealand Palliative Care</u> <u>Strategy</u>.



Population	21.2 million (as at Jan 2008)1
Healthcare system	Combination of public and private
Healthcare expenditure (per capita)	\$78,598 million AUD (as at 2003-4) ² \$ 3,707 AUD per capita ² 1 Australian dollar = 0.60 Euros
Healthcare expenditure (% of GDP)	9.6 (as at 2004) ³

Main challenges in healthcare re. patient safety and efficiency:

- Ensuring accurate master data
- Supply chain efficiency accuracy in communication and physical delivery
- Ensuring the correct drug, in the correct dose, is supplied to the patient
- Aligning medicines and device terminology throughout Australia



Healthcare Healthcare in Austria (based on OECD figures)

Population	8,340.924
Healthcare system	 Social health insurance scheme is compulsory – covering 99% of popul. Access for every citizen to medical + social services on the basis of legal compulsory insurance Social security system composed of legal health insurance, accident and pension insurance Financed by social insurance entities + various territorial bodies
Healthcare expenditure (per capita)	\$ 3.500,-
Healthcare expenditure (% of GDP)	10.3% 2/3 of this sum was paid for by the Austrian "Sozialversicherung"
AND THE REAL COLORING SPECIES	

(GS1



Priorities wrt patient safety:

- Increasing awareness for global marking in healthcare especially politics
- Motivating stakeholders for active participation
- Counterfeiting and online trading currently most discussed issues in Austria





Population	63,573,000
Healthcare system	Public & private
Healthcare expenditure (per capita)	€ 3, 318
Healthcare expenditure (% of GDP)	11%





Population	82.689.000
Healthcare system	combination of public and private
Healthcare expenditure (per capita)	3171,3 \$
Healthcare expenditure (% of GDP)	10,6 %

Main challenges in healthcare re. patient safety and efficiency:

- Improve patient safety
- Save money and improve supply chain efficiency
- Auto-ID

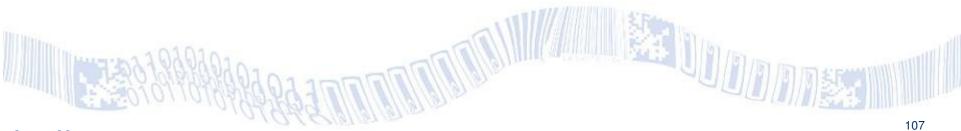
EDI

- Traceability effectively
- Catalogues
- Classification

Patient record



Population	148 mn
Healthcare system	Public hospitals – ca. 10,000, private hospitals – ca. 500
Healthcare expenditure (per capita)	US\$ 186.5
Healthcare expenditure (% of GDP)	4-5%





Population	7,5 milions
Healthcare system	Dominant is Public system but Private is also in rise
Healthcare expenditure (per capita)	230 EUR
Healthcare expenditure (% of GDP)	NA





Population	5 milion
Healthcare system	Public and private
Healthcare expenditure (per capita)	300 US\$ 1.5billion \$
Healthcare expenditure (% of GDP)	11%

Priorities wrt patient safety:

• Implementation of eHealth strategy - electronic patient record, interconected database for hospitals, pharmacies, distributors



Population	7'252'000
Healthcare system	Combination public-private ¹
Healthcare expenditure (per capita)	4011 US \$
Healthcare expenditure (% of GDP)	11.5

Priorities regarding patient safety:

- Foundation for patient safety ► learning with errors, enhancing error reporting systems, etc.
- Increased awareness about bedside scanning ► high risk drugs start to be labelled at unit level (injections, blisters)

¹ On June 2nd, 2008, a federal votation rejected that hospital should be funded exclusively by health insurances. Public hospitals are today funded by cantons for the investments and by the insurers for the care delivered to the patients (DRGs for in-patients and fees for service for out-patients)



Healthcare Healthcare in UK

Population	60,776,238 (2007 estimate)
Healthcare system	Free at the point of need
Healthcare expenditure per capita	£1500
Healthcare expenditure (% of GDP)	8.2%

- Main challenges in healthcare are patient safety and efficiency:
 - Medication errors Coding/Scanning & Positive Patient Identification
 - Iatrophic infection : human vCJD Marking and Traceability
 - Supply chain inefficiencies Product marking & Data Synchronisation