



GS1 Healthcare – Improving Patient Safety

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Healthcare Standards – why do we care?

Regulations emerge worldwide

Supply Chain costs increase

Electronic Health Records

Medication errors

Counterfeiting





GS1 Standards in Healthcare ...

Our vision

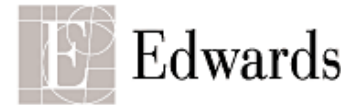
GS1 Healthcare envisions a future where the healthcare sector utilises **GS1 global standards** for all items, locations, people and processes to drive **patient safety and supply chain efficiency improvements**-- starting with the manufacturer and ending with procedures or treatments for a specific patient.





Leading healthcare organisations pave the way...

Corporate members of the global user group



Leading healthcare organisations pave the way...

Healthcare providers and Group Purchasing Organisations going global



France



Germany



Netherlands



醫院管理局
HOSPITAL
AUTHORITY

Hong Kong



Switzerland



Austria



Germany



USA



Austria



USA



Ireland



Netherlands



France



USA



USA



Healthcare GS1 Healthcare around the World

Members global user group

Local participation

Manufacturers

Abbott Laboratories
 Alcon Labs
 Amgen
 Astra Zeneca
 Baxter
 Becton Dickenson
 B. Braun
 Boston Scientific
 Bristol Myers Squibb
 Cook
 Covidien
 Edwards Lifescience
 Fresenius
 Glaxo Smith Kline
 Johnson & Johnson
 King Pharmaceutical
 Medtronic
 Merck & Co.
 Novartis Pharma
 Pall Medical
 Pfizer
 Schering Plough
 Smiths Medical
 Sakura Seiki

Distributors/Healthcare providers/GPOs/T&L

Cardinal Health (U.S.)
 CH Aulnay sous Bois (France)
 Comparatio Health (Germany)
 CVS (U.S.)
 DHL Exel Supply Chain
 Erasmus MC Rotterdam (NL)
 UNI.HA (representing 17 French university hospitals)
 Hong Kong Hospital Authorities
 McKesson (U.S.)
 Novation (U.S.)
 Orthopädisches Spital Speising Wien (Austria)
 Premier (U.S.)
 St. James Hospital, Dublin
 Marienhospital Herne (Germany)
 UMC Groningen (NL)
 University Kentucky Healthcare (U.S.)
 Wiener Krankenanstaltenverbund (Austria)

Non-voting members

AHRMM
 Cladimed
 Instituto Brasileiro de Ética Concorrencial – ETCO
 Council of Europe/EDQM
 Public Health Agency of Canada
 US DoD

Manufacturers

3M
 Bayer
 Becton Dickinson
 Boehringer Ingelheim
 Coloplast
 Draeger Medical
 Genzyme
 Hospira
 Kimberly-Clark
 Novo Nordisk
 Purdue Pharma
 St. Jude Medical
 Stryker
 Teva Pharmaceuticals
 Terumo
 UCB
 Upsher-Smith

Distributors/Wholesalers

Aexxdis
 Amerinet
 Amerisource Bergen
 CH2
 Depolabo
 Galaxis
 GAMMA Wholesale
 Geodis
 McMahan
 Owens & Minor

Healthcare providers/Retailers

Alfred Hospital (Australia)
 Ascension Health (U.S.)
 Capital District Health (Canada)
 CHU de Québec (Canada)
 CHU Dijon (France)
 HUG Geneva (Switzerland)
 London Drugs (U.K.)
 Mayo Clinic (U.S.)
 Sisters of Mercy (U.S.)
 Sobeys Pharmacy (U.K.)
 UHCS Augusta VA (U.S.)
 Walgreens (U.S.)
 Wal-Mart (U.S.)

...

Associations

AHA (U.S.)
 CIP/ACL (France)
 CHes (U.S.)
 EFPIA (Europe)
 Eucomed (Europe)
 FENIN (Spain)
 GIRP (Europe)
 HDMA (U.S.)
 International Hospital Federation
 JFMDA (Japan)
 Medical Industry Association of Australia
 NACDS (U.S.)
 Patient Safety Foundation (U.S.)

Advancing global standards in Healthcare



- **Global Healthcare User Group**
 - Develop global healthcare standards
 - Drive global harmonization
- **Local Healthcare User Groups**
 - Drive adoption & implementation of GS1 Standards
 - Help develop global healthcare standards





Local Healthcare user groups driving adoption



Healthcare GS1 Standards for Healthcare

Standards development continues, but global standards are ALREADY available to build on:

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- ✓ AIDC Application Standards for 90% of medical products
 - ✓ AIDC Application Standards for small instruments
 - ✓ Healthcare extension in next GDSN release
 - ✓ Global Traceability Standard for Healthcare
 - ✓ GTIN Allocation Rules for Healthcare
 - ✓ Guideline for plasma derivatives
- 

Government & regulatory developments



FDA Amendments Act of 2007

Serialised Numerical Identifiers (SNI) system for drugs – aligned with GS1 standards (AI(21))

Authority to develop regulations establishing a Unique Device Identification (UDI) system for medical devices



“Pharma Package” - Prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source, introducing a harmonised coding system to enable traceability

Recast of Medical Device Directive - To establish a UDI System

EDQM Project: Track & Trace Service

Phase 2 (live demo development) start Q2 2010



Government & regulatory developments (cont'd)



China – Shanghai Regulation 7 November 2006 – Established a traceability system for implantable medical devices in 2007



Government of India

India – Ministry of Health & Family Welfare –

Tender requirements for GS1 Standards for all medical supplies procured by the MoHFW

Australia – National eHealth Transition Authorities –

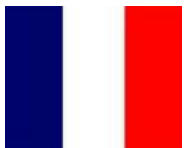
To accelerate the adoption of eHealth established:

- National Product Catalogue based on GS1 Standards
- GLN Registry with GS1 Australia



Turkey – Ministry of Health and SKG

- National databank for medical devices
- Track and Trace for pharmaceuticals based on GS1 standards – GS1 DataMatrix with GTIN, lot/batch number, serial number and expiry date – already in place



France – enabling traceability

Identification of drugs with GS1 Data Matrix containing GTIN, lot/batch number and expiry date – no serialisation - from 1 January 2011 onwards



Healthcare Industry developments



US – Sunrise dates – GLN 2010 and GTIN 2012 – targeting for the adoption of GLN and GTIN by 2010 resp. 2012

US – Tender requirements – Endorsement by GPO's and healthcare providers envisioning tender requirements for GS1 Standards



Canada – Sunrise dates – GLN 2010 and GTIN 2012 – targeting for the adoption of GLN and GTIN by 2010 resp. 2012

Canada – Tender requirements – Endorsement by GPO's and healthcare providers envisioning tender requirements for GS1 Standards

Canada – Pharmaceutical Bar Coding Project - ISMP Canada and CPSI



Healthcare DataMatrix on pharmaceuticals

France: AFSSAPS regulation (2011)

Belgium: Pilot project unit dose marking

Serbia: Pilot

Spain: Pilot

Korea: pharma regulatory requirement (2011)

Switzerland: SmartLog Pilot

Turkey: Regulatory requirement (2010)

Japan: option for instruments marking

Brazil: traceability pilot successfully completed – ANVISA regulation



= country requires DataMatrix

= country using DataMatrix in pilots and/or developing requirement for DataMatrix



Position Statement

GS1 HUG recommends investing in Camera-Based bar code scanners to address specific needs for Automatic Identification in Healthcare

Because of the increased capabilities of camera-based bar code scanners, the GS1 HUG™ (Global Healthcare User Group) strongly recommends to invest in such scanners when introducing bar code scanners or when replacing existing laser bar code scanners. This will facilitate the future adoption of global standards for automatic identification in the Healthcare supply chain.

Global standards for automatic identification provide the opportunity to make the Healthcare supply chain more efficient and accurate, and thus safer. It will also help enable the patient to receive the five patient rights: *the right patient gets the right product at the right time, in the right dose, and using the right route.*

GS1 HUG promotes the adoption and implementation of the GS1 System of standards to automatically identify patients, products, caregivers, and locations. It is the most widely used system worldwide, with more than 5 billion transactions per day based on GS1 standards. The system is built on a scheme of identification keys (such as the GTIN, Global Trade Item Number) and attributes (such as the expiry date), which remains the same independent of the data carrier. Identification can be based on GS1 BarCodes (such as the GS1-128 bar code symbology) and on GS1 EPCglobal (using an RFID tag).

Compared to product coding in for example, a grocery retailer environment, pharmaceuticals and medical devices coding has very specific requirements, including:

- a large amount of data (product ID, batch/lot number, expiry date, date of manufacture, serial number, ...) to be stored on a small space
- variable information (such as unique identification number at unit dose level) to be marked at high production rates
- direct marking (e.g. surgical instruments and implants)
- unscannable bar codes do not only impact supply chain efficiency, but more importantly, patient safety

The above requirements may not always be achieved with the 'traditional' linear bar codes, but a solution is available:



The two examples contain identical data

GS1 DataMatrix

This is a 2-dimensional (2-D) data matrix symbology enabling, in an efficient way, all of the above requirements:

- enables coding more fixed and variable information, while maintaining a small size
- technologies are available for direct part marking
- allows error correction to circumvent some degree of physical damage

To read the GS1 DataMatrix symbology, camera-based bar code scanners are required. Laser bar code scanners cannot read data matrix bar codes. Camera-based bar code scanners can read both linear and 2-D bar codes.

Preparing members, solutions providers and end users for the future...



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Get your copy at:

http://www.gs1.org/docs/healthcare/GS1_HUG_ps_Camera_Based_Scanners.pdf



Healthcare The need for global standards



- Healthcare is **local**
 - Healthcare providers are local
 - Regulations are local
 - Healthcare is **global**
 - Healthcare supply chains often cross borders
-

Country-by-country solutions are not sufficient nor effective





Healthcare **GS1 Standards in Healthcare**



- Enable automatic identification systems
- Enable traceability systems
- Enable « clean » data

**GS1 Standards in Healthcare
improve patient safety worldwide**



18th Global GS1 Healthcare Conference



Singapore
9-11 November 2010

More information: www.gs1.org/healthcare

Supporting Organisations:





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