



USAN - UDI / Standards Adoption Network

Chicago, 30 Sept 2010





GS1 Healthcare Topics

- About GS1 Healthcare
- GS1 Healthcare Workstreams
 - Traceability
 - Public Policy
 - AIDC
 - GDSN
- Questions





About GS1 Healthcare

Mike Wallace

Tri-Chair

GS1 Healthcare Leadership Team



GS1 Healthcare

Voluntary, Global Healthcare User Group

To lead the Healthcare sector to the successful development and implementation of global standards by bringing together experts in Healthcare to enhance patient safety and supply chain efficiencies.



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.





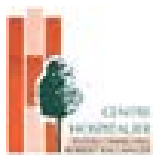
Leading healthcare organisations pave the way...

Corporate members of the global user group



Leading healthcare organisations pave the way...

Healthcare providers and Group Purchasing Organisations going global



France



Germany



Netherlands



Hong Kong



Switzerland



Austria



Germany



USA



Austria



USA



Ireland



Netherlands



France





USA



USA

Healthcare GS1 Standards for Healthcare

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

- 
- ✓ 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
- 

Healthcare MoU with IHTSDO/Snomed



INTERNATIONAL HEALTH TERMINOLOGY
STANDARDS DEVELOPMENT ORGANISATION



GS1 and IHTSDO join forces to support safe and efficient patient care

Two complimentary global standards organisations will collaborate to ensure compatibility between their standards and promote adoption

Contact:

- Jennifer Zelmer, CEO, IHTSDO, media@ihtsdo.org
- Jan Denecker, Marketing Manager, GS1, jan.denecker@gs1.org

BRUSSELS, BELGIUM and COPENHAGEN, DENMARK, 4 August 2010 - The International Health Terminology Standards Development Organisation (IHTSDO) and GS1 have announced today that they have signed a Memorandum of Understanding to collaborate and ensure compatibility between their respective standards systems, where appropriate.

GS1 Healthcare MoU with EAHP



EAHP and GS1 team up to advance patient safety in Europe
*Promoting global coding standards for medical products
to improve hospital pharmacy processes*

Contact:

- Dr. Roberto Frontini, President, EAHP, president@eahp.eu
- Jan Denecker, Marketing Manager, GS1, jan.denecker@gs1.org

BRUSSELS, BELGIUM, 7 September 2010 - The European Association of Hospital Pharmacists (EAHP) and GS1 have announced today that they have signed a Memorandum of Understanding to collaborate in promoting patient safety.

"In hospitals, personalised treatments are prepared in the pharmacy or ward, and administered by nurses to the patients. A complete and unambiguous identification of the drug, up to the moment of administration, is a key element of a safe dispensing procedure when drugs are dispensed," said Roberto Frontini, President, European Association Hospital Pharmacists (EAHP). "We encourage the adoption and harmonisation of GS1 Standards in Europe to enable the effective and efficient implementation of bar codes on all packages of drugs."

- MoU signed in September
- Agreed on collaboration and closer involvement of hospital pharmacists in standards development
- Great interest in unit-dose marking



GS1 Healthcare Workstream Overview

Traceability





Traceability for Healthcare... Using GS1 Standards

Traceability is **the ability**...

- ▶ **to track forward** the movement through specified stage(s) of the extended supply chain and...
- ▶ **to trace backward** the history, application or location of that which is under consideration



Traceability = Track & Trace

Traceability in Healthcare-I (TH-I) Completed

DELIVERED:

Global Traceability Standard for Healthcare (GTSH)

PUBLISHED 27th February 2009

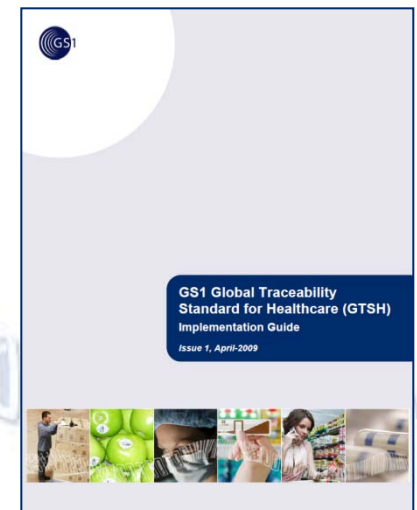
http://www.gs1.org/docs/gsm/traceability/Global_Traceability_Standard_Healthcare.pdf



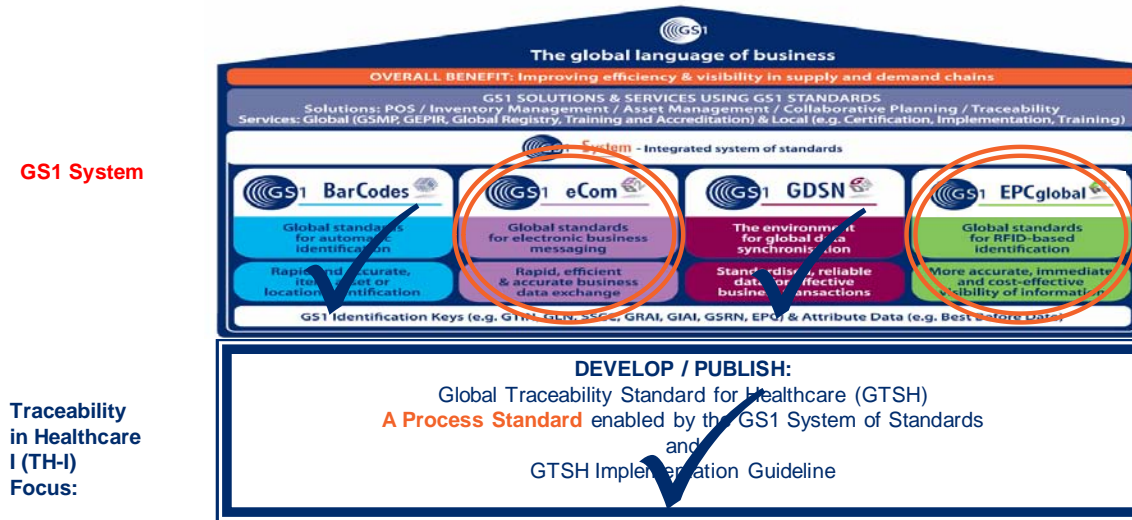
GTSH Implementation Guideline

PUBLISHED 24th April 2009

http://www.gs1.org/docs/gsm/traceability/Global_Traceability_Implementation_Healthcare.pdf



- Focus on EPCglobal and eCOM areas:



- Identified, prioritised and drafting **Core Use Cases:**

- Chain of Custody / Chain of Ownership
 - EPCglobal JRG formed for Event-Based ePedigree
 - BRs accepted
 - Technical Gap Analysis underway
- Product Identifier Authentication
 - BRAD in development
- Product Recall



GS1 Healthcare Workstream Overview

Public Policy



GS1 Healthcare Increasing global recognition



And many more...



GHTF

Last meeting in Ottawa – AHWG closed, report out to SC in November, the publication for comments for nine months. New AHWG on implementation?
Requested

EU Commission created UDI working group with member states, third meeting in October with invited speakers, the opening for industry participation



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



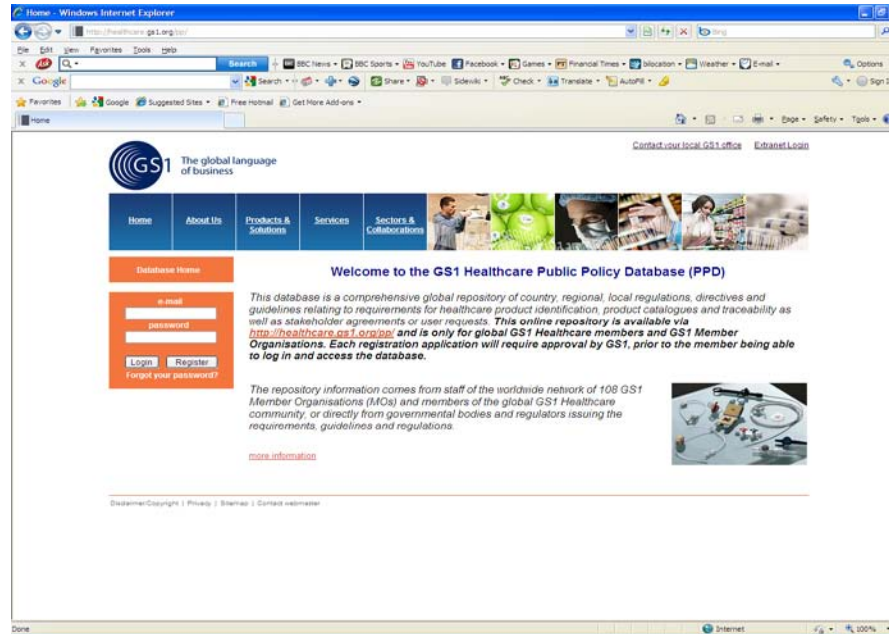
Turkey – Ministry of Health and SKG

- 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

- Analysis of Danish Amgros requirements and feedback in coordination with GS1 Denmark
- Traceability White Paper – final improvements
- GTIN/NTIN/NHRN discussion paper finalised
- **Letter to MoH Turkey on MD and Vaccines**
- **Resolution of GTIN-14 issue with SAS**
- **Input to EU Consultation on R&TTE directive**
- Update on FDA-FCC meeting and new US IP policy
- India and counterfeiting
- **Legislation landscape**
- Response to FDA barcode question
- EFPIA letter and survey analysis



Healthcare Public Policy - Database



- Public Policy Database contains now over 80 dossiers/more than 60 countries
- Working with MO's to confirm/clarify information
- First query/search possibilities live, further functionalities planned for October/November



Healthcare Provider Advisory Council



Healthcare Provider Advisory Council (HPAC)

- Decision of HC LT in Geneva to establish work group for Healthcare Providers
 - Thought leaders and early adopters of GS1 Healthcare Standards
 - Identify projects supporting the adoption of GS1 Healthcare Standards in healthcare institutions and retail pharmacies
 - A source of expertise and provide feedback and advice to:
 - those involved in GS1 standards development
 - the wider healthcare stakeholder community and
 - senior executives/decision-makers to gain buy-in / support for implementation of GS1 Healthcare
 - A forum sharing and discussing the practical realities of implementation in the care giving environment





GS1 Healthcare Workstream Overview

AIDC



Automatic Identification & Data Capture (AIDC)

“Automatic Identification and Data Capture (AIDC) refers to the methods of **automatically identifying** objects, **collecting data** about them, and **entering those data** directly into computer systems (i.e., without human involvement).”

Wikipedia, 2009





Healthcare AIDC Application Standards

Defines
the **data** to carry
using specific **data carriers**
for every healthcare **product**
at every **packaging level**



AIDC II Priorities

GS1 Healthcare – Projects

Healthcare Priority	Project Subject / Title
High	UDI Reference Number – UDIR
High	GLN Registry Communications
High	Level Below Each / Unit Dose – Potential Application Standard
High	National Healthcare Reimbursement Number – NHRN – Potential Application Standard
Medium	GTIN Reuse
Medium	Direct Part Marking – Potential Application Standard
Medium	Kit Marking – Potential Application Standard
Medium	Complex and/or Configurable Med Devices; Medical Software – Potential Application Std
Medium	2D Minimum Quality Specifications and 2D Quality Reports
Low	Guideline Maintenance, Technical Corrections, AIDC-GDSN Alignment
Low	Data Carrier Placement Rules
Not planned at this time	Product Samples, Radiopharmaceuticals, Custom Assistive Device, Dental, Service GTINs

AIDC II Priorities

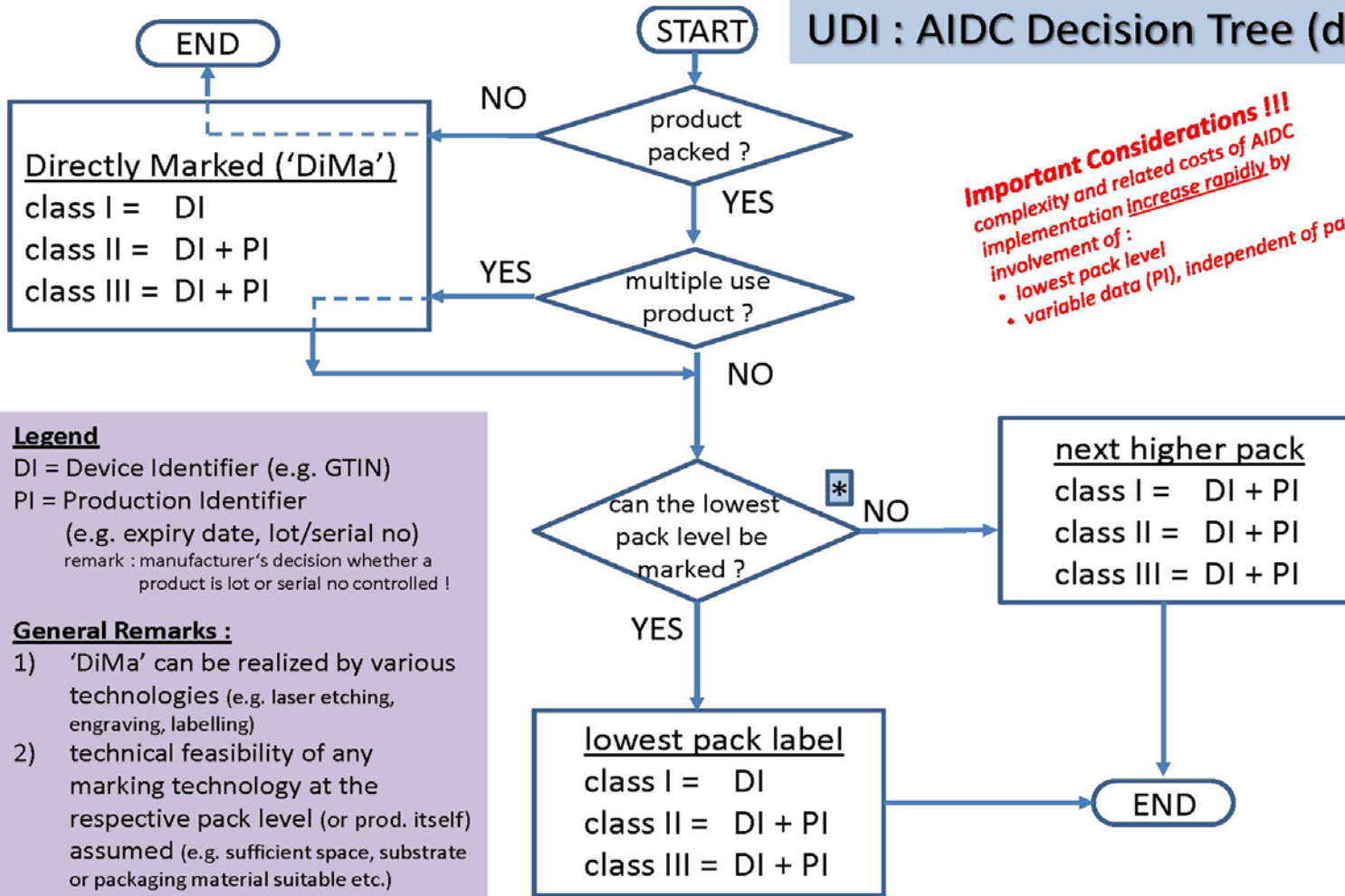
GS1 Healthcare – Joint Industry Initiatives

Healthcare Priority	Project Subject / Title
High	Managing Multiple Bar Codes – MMBC
High	GS1 DataMatrix Migration – Strategic AIDC Initiative
High	EPC / Bar Code Interoperability
High	Serial Number Allocation Rules
Medium	2D Quality Reports
Medium	Human Readable Interpretation Phase 2
Medium	2020 Vision
Low	GTIN on non-Retail Packs, GTIN-14 at POS, Indicator Digit Significance
Low	Tag Data Standard / Gen Spec Alignment
Not planned at this time	Trade Item vs. Asset ID, Serialization Services, Returnable Transport Item - AIDC App Standard, Returnable Transport Item – Evaluation of HC Needs



Healthcare AIDC Markings for UDI

UDI : AIDC Decision Tree (draft)



Important Considerations !!!
 complexity and related costs of AIDC implementation increase rapidly by involvement of :
 • lowest pack level
 • variable data (PI), independent of pack level

Legend

DI = Device Identifier (e.g. GTIN)
 PI = Production Identifier
 (e.g. expiry date, lot/serial no)
 remark : manufacturer's decision whether a product is lot or serial no controlled !

General Remarks :

- 1) 'DiMa' can be realized by various technologies (e.g. laser etching, engraving, labelling)
- 2) technical feasibility of any marking technology at the respective pack level (or prod. itself) assumed (e.g. sufficient space, substrate or packaging material suitable etc.)
- 3) in case of non-sterile products PI can be limited (e.g. only lot/serial no or expiry date) or even not exist

* e.g. due to technical constraints (space, unsuitable packaging material, ...)

Healthcare **How to get started**

1. Contact your local **GS1 Member Organisation** for guidance
2. **Get familiar** with the standards / guidelines
 - Attend breakout sessions this week!
 - Participate on GS1 implementation projects / team
3. Do a **gap analysis**...your items vs. GS1 Standards
 - Focus on key items and facilities...don't 'boil the ocean'
 - Build action plans, budgets, management approval
4. Implement your **action plan**
 - Start small, conduct Pilot Projects, "learn by doing", "crawl before you walk / run"...



More information / help during Friday's Working Session!



GS1 Healthcare Workstream Overview

GDSN

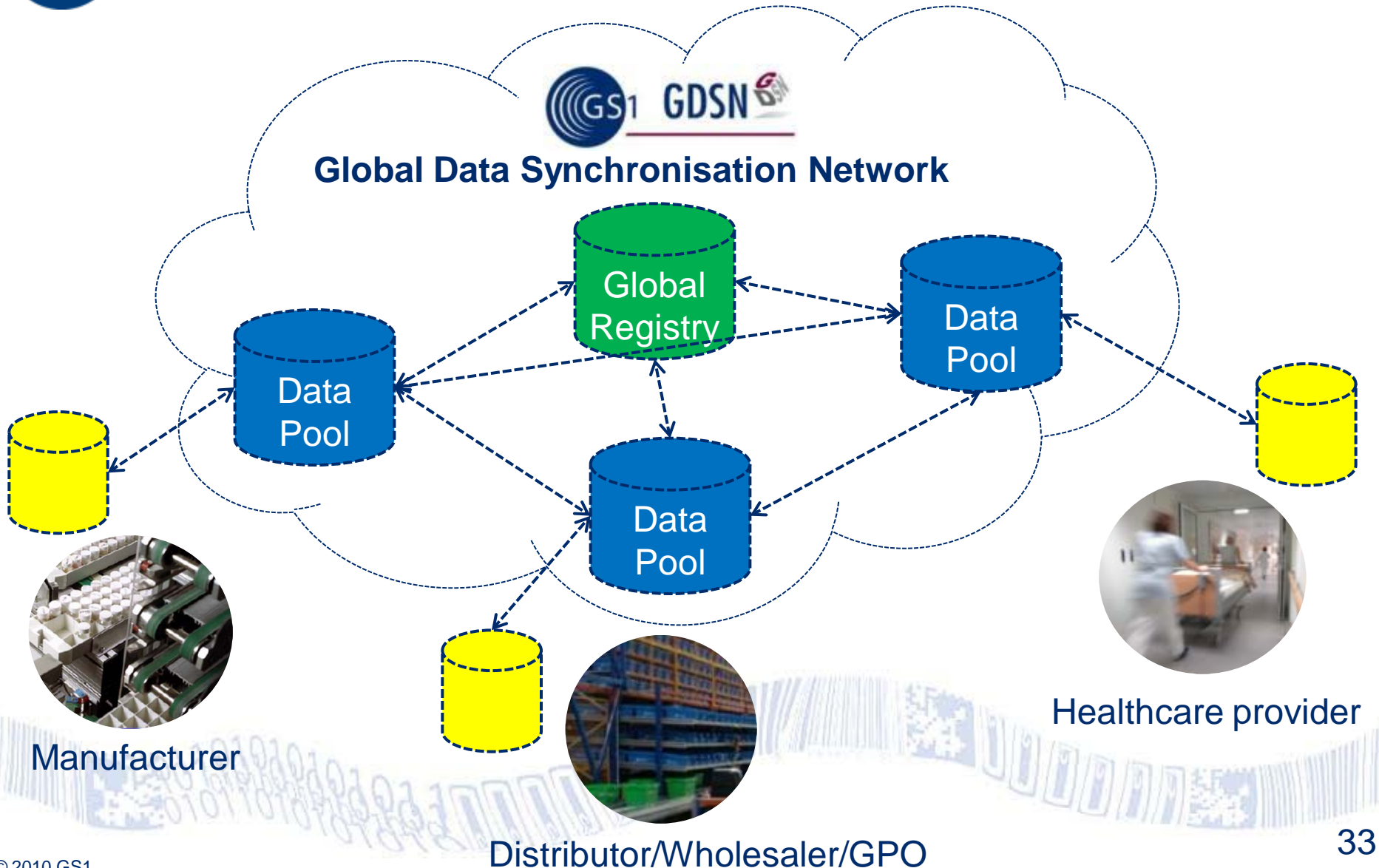




Global GDSN Implementation Initiative for Healthcare

A global implementation initiative to use the GDSN's unique position to **meet current and emerging requirements for electronic product catalogue data**, including pending regulatory demands and commercial needs for reliable product data between healthcare trading partners.





Global GDSN Implementation Initiative for Healthcare



- Launched June 2009
- Today
 - Participation: 27 healthcare organisations
 - Connections: 61 live
 - Finalised Phase 2 report *sharing lessons learned*
 - 40 'Healthcare Attributes' *(pending final GHTF list)*

GDSN Healthcare Implementation

GTIN

Trade Item Unit Descriptor

Additional Trade Item Identification Type

Additional Trade Item Identification Value

Parent GTIN

Child GTIN

Quantity of Children

Total Quantity of Next Lower Level Trade Item

Information Provider of Trade Item

Target Market Country Code

Name of Brand Owner

Brand Owner

Name of Manufacturer

Manufacturer GLN

Functional Name

Brand Name

Additional Trade Item Description

Height +UoM

Width + UoM

Depth + UoM

Gross Weight +UoM

Net Content +UoM

Is Trade Item a Consumer Unit?

Is Trade Item an Orderable Unit?

Is Trade Item an Invoice Unit?

Is Trade Item a Despatch Unit?

Is Trade Item a Base Unit?

Is Trade Item a Variable Unit?

Is Packaging Marked Returnable?

Has Batch Number?

Is Non Sold Trade Item Returnable?

Bar Code Type

Classification Category Code

Additional Classification Agency Name

Additional Classification Category Code

Additional Classification Category Code Version

Additional Classification Category Description

Start Availability Date Time

Effective Date

Minimum Trade Item Lifespan from Time of Production

Minimum Trade Item Lifespan from Time of Arrival

Healthcare Trade Item Reusability Information

Does Trade Item Contain Latex?

Under Consideration by the GHTF

Size (if applicable)

Special Storage and/or Handling Conditions (if applicable)

"Sterility - Packaged Sterile Y/N Need to be sterilized before use Y/N"

License of Marketing Authorization

URL for additional information (optional)

Critical Warnings or Contraindications (optional)



Healthcare GDSN Current Activities

- Phase 3 of Global Implementation Project
 - Expansion to more countries and more participants
 - Aligning with all GDSN Sectors → update Trade Item Implementation Guide
 - Finalise Healthcare Attributes (pending GHTF final list)
 - Publishing 'Global GDSN Adoption Metrics' (monthly)
- Continue support for GHTF regulators
- Continue gaining support for 'Healthcare Attributes'

More information / help during Friday's Working Session!

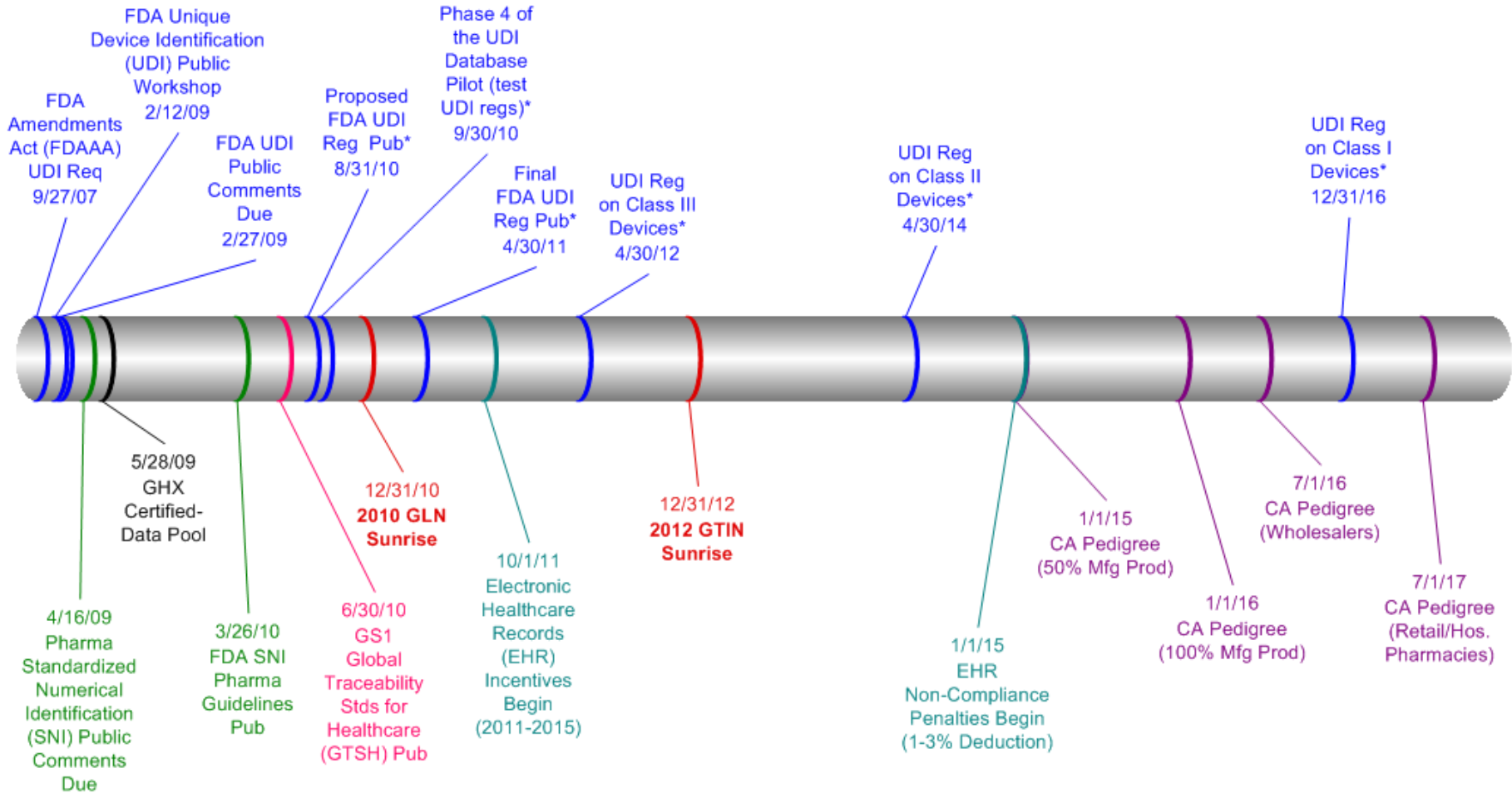


GS1 US Healthcare Update



U.S. Healthcare Community Initiatives

5/10/2010



* Estimated dates based on FDA presentations

O:\GS1 Healthcare US\Presentation Library\STANDARD DECKS\GS1US MO Slides\Timeline GS1HCUS



2010 GLN Sunrise

- 240,099 GLNs in Registry
- 89% increase in manufacturers subscribed to the GLN Registry
 - 2009 - 28
 - 2010 YTD - 53
- 29 IDNs (representing 370 hospitals) GLN ready by Mid 2011
- 31 manufacturers/distributors/GPOs/solution providers GLN ready by 12/31/10.

2012 GTIN/GDSN Sunrise

- Pending FDA “Unique Device Identification” regulations
- 26 healthcare companies in GDSN (2010)

2015 Readiness Program

- Traceability (simulation program)



GS1 Healthcare

Summary and Q&A





GS1 Healthcare **Summary and Conclusions**

- GS1 Healthcare works hard to be the global leader in solutions facing the healthcare sector
- We have a demonstrated track record of success with the most important initiatives
- We have the standards and solutions for UDI today
 - We also have the solutions for other challenges facing our industry...
- Our global workteams enable global solutions across many workstreams
- Our global Leadership Team ensures that solutions are truly global

Join Us and contribute to the solution!



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