



The Global Language of Business

# GS1 Healthcare 2016 Strategic Priorities

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# GS1 Healthcare 2016 Strategic Priorities



**Vision:** To be the recognised, open and neutral source for regulatory agencies, trade organisations and other similar stakeholders seeking input and direction for global standards in healthcare for patient safety, supply chain security & efficiency, traceability and accurate data synchronisation.

**Mission:** 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.

## Our Strategic Objectives are:

### Healthcare Providers

- Roll out Project Imagine, the GS1 Healthcare provider engagement
- Healthcare provider (HCP) database
- Intensify cooperation with relevant hospital organisations, ISQua, IHF and EAHP

### Standards and Guidelines

- Global Solution Provider program (TBC)
- EDI Implementation Kit
- Global Healthcare Traceability Conformance (GHTC) Checklist
- Barcode Survey App

### Future Vision

- Continuation as UDI Issuing Agency for the US FDA
- Support harmonised EU FMD implementation
- APEC Roadmap
- Data Quality in Healthcare
- Position statement about Big Data & connected devices
- Support organisations such as GAVI, USAID, UNFPA to develop supply chain visibility

### Ongoing Activities

- Public Policy activities
- MO Support
- Global Member Activities
- Global GS1 Healthcare Conferences
  - Presentation at conferences and events
  - Liaising with other SDOs
  - Participation in eHealth activities

## Our Strategic Measures will be:

Total global number of pharma & medical device members reported by GS1 Member Organisations (MOs)

Number of Healthcare GTINs in Global Registry

% of products with GS1 barcodes in each country (surveyed at healthcare providers – hospital, retail pharmacy)



# Healthcare Providers

# Project Imagine



- The GS1 Healthcare strategy has been successfully focused on supplier enablement to use GS1 standards, Regulator/ Government engagement and driving a global harmonized approach.
- Today, implementation of GS1 standards by healthcare providers such as hospitals is not regulated, which in general has led to low levels of adoption in that part of the supply chain.
- Industry stakeholders believe that the strategy focus must now be implementation of GS1 standards by healthcare providers.
- Project Imagine, relevant for the next 5+ years, involves engagement of healthcare providers and patient advocacy organisations to drive understanding of the benefits of GS1 standards, particularly in an environment of increasing patient empowerment

Project Imagine will be launched at the end of June 2016, with roll out, further material developments and activities over the next years

# Healthcare Provider Database



- Develop a detailed repository to pool information about hospital implementation of GS1 standards worldwide
- Sharing what is happening and latest developments – between the MO's – with our users, with other important parties
- Combine the sources of information from MOs, conferences, networks, publications, global members to create a common knowledge base.
- Similar functionality to GS1 Healthcare Public Policy database – searchable and constantly updated

The Healthcare Provider Database will be developed during the second half of 2016

# Intensify cooperation with relevant hospital organisations: ISQua, IHF and EAHP



- International Society for Quality in Healthcare (ISQua) – global accreditation body for organisations such as JCI
  - Work towards MOU
  - Provide input to Fellowship Program
  - Reciprocal participation and presentation at conferences
- International Hospital Federation (IHF)
  - Common white paper about the benefit of GS1 standards for use with hospital C-Level executives
  - Mapping of existing of existing GS1 activities on local level and future opportunities
  - Reciprocal participation and presentation at conferences
- European Association for Hospital Pharmacists
  - Existing MOU
  - Drive identification on primary level packaging to enable bedside scanning
  - Joint activities at conferences in promoting global standards

# Standards and Guidelines

# Global Solution Provider program



- Accelerate the global transformation of the healthcare industry by ensuring that GS1 standards are included in solutions used by providers and manufacturers
- Increase use of GS1 Standards in healthcare related technology systems and business processes in order to facilitate the adoption and utilisation of these systems by healthcare providers and their supply chain partners
- Indirectly to enhance Patient Safety and Supply Chain efficiency through increased use of GS1 standards in global healthcare delivery
- Increase the Global GS1 Healthcare initiative membership through the recruitment of solution provider members

The Global Solution Provider Program will commence in July 2016 (TBC)



# EDI Implementation Kit



## Driving a harmonised approach to implementation of EDI in Healthcare across the world

- 1. Support GS1 MOs and industry when rolling out the Harmonised EDI guidelines in healthcare.**
  - Sharing use cases and tools to get started
- 2. Increase adoption of GS1 EDI standards in Healthcare**
  - Support MOs and Industry by deploying best practices
  - Identify & measure opportunities for increased usage
  - Communicate our value proposition

The EDI Implementation Kit will be launched on 20th April in at GS1 Healthcare Conference in Dubai

# Global Traceability Conformance Checklist



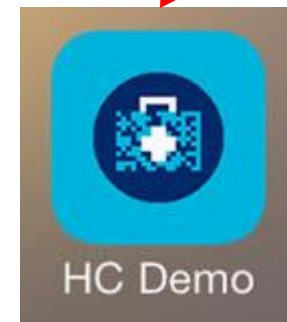
- The Global Traceability Standard for Healthcare (GTSH) published in 2009 and two implementation pilots have been undertaken using the current Global Traceability Checklist:
  - September 2009: National Centre for Hereditary Coagulation Disorders (NCHCD), St James's Hospital, Dublin, Ireland
  - 9th/10th October 2014: Bernhoven Hospital, UDEN, Netherlands
- This identified a need to develop a healthcare specific Global Traceability Checklist

During 2014 a Global Traceability Checklist for healthcare will be developed.

# Barcode Survey App



- A Healthcare specific “App” has been developed enabling a smartphone to read a GS1 barcode and access product information from a Manufacturer designated site as well as perform limited confirmation of data format
- Use of the app enables access to trends in the use of GS1 bar codes and related data



In 2016, the App will be enhanced based on additional user requirements

# Future Vision

# Continuation of GS1 as a UDI Issuing Agency for the US FDA



In 2016, accreditation to be **renewed** for 7 years, first accreditation was for 3 years (2013)

- GS1 GO was accredited to be an issuing agency, on behalf of all MO's, so that **every MO continues to provide the company prefixes to their users**: questions answered during the **monthly UDI for HIG calls** and via online **Yammer UDI for HIG group**
- All MO's are expected to support their users throughout implementation including training and education
- GS1 US is the first point of contact for the US FDA
- Every year in December GS1 must provide the US FDA with a **list of labellers** using GS1 for UDI

# Support harmonised EU FMD implementation



2016: Delegated Acts on harmonised safety features (tbc)  
2019 (+ 6 years if pre-existing measures : GR, IT, BE):  
requirements implementation

- GS1 GO working with EFPIA/EMVO and European Commission in order to support harmonised and clear implementation measures of the FMD across the EU
- GS1 MOs to leverage the use of GS1 standards (identification and marking) at the national level to implement the EU FMD requirement for a harmonised unique identifier encoded in a GS1 DataMatrix
- GS1 GO to coordinate with the MOs and support locally where needed.

# APEC Roadmap on medical products integrity and supply chain security



- GS1 leading the APEC Track and Trace WG (TTWG)
- Objective:
  - examine current practices and regulatory requirements
  - develop **recommendations** to regulators
  - develop **training programs** which will be made publically available through the APEC website
- Two-day training at Senior Officials Meeting (SOM) 3 2015
- Tool-kit finalised
- 2016: work on inclusion of the TTWG's Recommendations to the final Roadmap for approval in 2017

5 year project (Jan. 2013 - Dec. 2017)

# Data Quality in Healthcare



## Vision: Data fit for the intended purpose

Inconsistent, incomplete and incorrect data increase the risk of patient safety errors and the cost of healthcare across the entire supply chain.

Quality data means:

- Reduced rework caused by data correction and need for internal audits
- Improved care by ensuring data accuracy at the point of care
- Consistent use of data attributes across all stakeholders

The guidance of healthcare providers will be critical in ensuring that the data quality guidelines meet the needs of the internal processes within hospitals, pharmacies and other data recipients.

Develop data quality guidelines for healthcare during Q4 2016 via a Global Standards Management Process (GSMP) work group.



Potential savings from improved data quality<sup>3</sup>

*By conservative estimates, more than \$100 million in potential savings can be achieved by addressing product data quality issues by making only minor adjustments to existing processes.*



# Position Statement about Big Data and Connected Devices



Big data is a broad term referring to very large data sets that may be analysed computationally to reveal patterns, trends, and associations, especially relating to human behaviour and interactions. For healthcare this presents many opportunities to better understand relationships between diseases, treatment, patient safety and recovery.

Connected devices define types of objects whose primary purpose is not to be computing devices or web interface, but when adding an Internet connection they help to bring additional value in terms of functionality, information, interaction or use, in the healthcare sector.



These concepts are playing a role in today's healthcare environment and **during 2016** GS1 Healthcare will develop a position paper defining the role of GS1 standards in this context.

# Support organisations such as GAVI, USAID and UNFPA to develop supply chain visibility

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- **WHO/GAVI - Vaccines**

- Secretariat for VPPAG barcode subgroup on implementation of global standard for vaccines
- WHO/VPPAG recommendation for all packaging levels except primary and logistic: GTIN plus lot plus expiry date
- Objective of workgroup now to provide information about ongoing implementation and ROI studies

- **USAID/UNFPA – Reproductive Health (RH) Products**

- Secretariat for forum of subject matter experts from industry/public sector for to provide recommendations for usage of global standards in the RH supply chain to enable visibility

# Ongoing Activities



# Public Policy Activities

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- All Public Policy activities are open to GS1 Healthcare **global members** and GS1 MOs
- Comprehensive and “real time” documentation about existing and developing regulatory and customer requirements from across the world relating to use of GS1 standards. Three levels of information:
  - Overview slide deck summarizing the “country adoption” trends and overall roadmap
  - Country-level summary slides
  - Detailed information and references in GS1 Healthcare Public Policy Database
- Development of position papers and input to requests for regulatory consultation to drive global harmonisation
- Public Policy Work Team meetings held every two weeks via teleconference
- Open face-to-face sessions twice per year during GS1 Healthcare Global Conferences



# Member Organisation Support

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- Support and information from GO subject matter experts both remotely and face-to-face as needed
- Monthly Healthcare Interest Group (HIG) meetings via teleconference for information exchange and update
- Face-to-face meetings during global GS1 Healthcare conferences and Global Forum
- Reference materials, value propositions, presentations, deployment kits, images, and videos accessible via Healthcare MO Zone
- “Real time” information sharing via Yammer
- For MOs with local user groups, annual voting and nomination rights for representatives on global GS1 Healthcare Leadership Team which drives the strategy and direction



# Global Member Activities

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- Onboarding new global members
- Annual voting and nomination rights for global GS1 Healthcare Leadership Team which drives the strategy and direction
- Monthly meetings with global updates about all GS1 Healthcare activities
- All documents online in respective Community Rooms (LT and global members)
- Discounted access to GS1 Healthcare Conferences as well as participation in strategic side meetings
- Access to Public Policy work efforts
- Support and information from subject matter experts for global issues

# Global GS1 Healthcare Conferences



- Organisation of two global GS1 Healthcare conferences on a geographically-rotating basis
- 2016 – Dubai (April), Beijing (October)
- A three-day event for healthcare leaders from private industry and government agencies to exchange information on the progress of worldwide efforts to improve patient safety, supply chain security and efficiency using GS1 standards
- Benefits of participation:
  - Sharing the latest news on industry and regulatory developments in automatic identification, traceability and electronic product catalogues
  - Learning more about existing supply chain data standards
  - Hearing how GS1 works with hospitals, pharmacies and patients
  - Networking with other stakeholders from around the world using this unique, neutral and global platform

# Presentation at Conferences / Events



- In 2015 GS1 Healthcare presented at 36 conferences in 13 countries
- Some examples include:
  - Access to safe medicines, 15-16 September, London, UK
  - IARMM World Congress on Clinical Safety, 28-30 September, Vienna, Austria
  - 3rd Cool Chain Association Conference – Pharma & Biosciences, 1-2 October, Basel, Switzerland
  - Pharma Anti-counterfeiting & Brand Safety World Summit 2015, 1-2 October, London, UK
  - ISQUA, 32nd International Conference, 4-7 October, Doha, Qatar
  - IHF World Congress, 6-8 October, Chicago, US
  - LogiMed, 17-19 November, Amsterdam, The Netherlands

Detailed list available upon request



# Liaising with other SDOs



- Liaising with standard development organisations to strengthen GS1's perception as the most used standard for supply chains
- Memorandums of Understanding with:
  - ICCBBA - terminology, coding and labeling of medical products of human origin (blood, tissue, organs)
  - HL7 (Health Level Seven International) – standards for electronic health information that supporting clinical practice (e.g., eHealth records)
  - IHTSDO (The International Health Terminology Standards Development Organisation, Snomed) - global standards for health terms
  - JIC (Joint Initiative Council) – Group of key healthcare SDOs, ISO, CEN, HL7, CDISC, IHTSDO, IHE, DICOM, and GS1 working to ensure interoperability between their standards

# Participation in eHealth Activities



- Educating Health Informaticians about GS1 standards and their applicability in the Healthcare industry
- Influencing standard developments so that GS1 identification key (and, where relevant GS1 EDI standards) are taken in consideration at least as examples in new / revised standards
- Participate to regulatory implementations for adverse event reporting, identification of medicinal products, so that GS1 standards are considered as the preferred enabler where applicable
- Participate to European projects to provide demonstrator of GS1's efficiency for cross-border prescription and dispensation (including EU-US)
- Raise awareness of stakeholders at eHealth Stakeholder Group\*

(\*nomination pending)

# The GS1 Healthcare Team



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