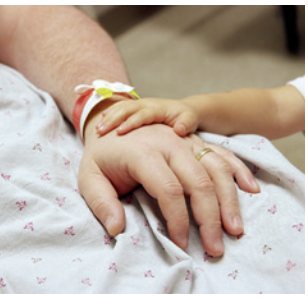
GS1 Healthcare

GS1 Healthcare Newsletter

No. 17 – Winter 2010





ALSO IN THIS ISSUE:

Canada embraces GS1 Standards for bar coding pharmaceutical products

In collaboration with pharmacy supply chain stakeholders, the Institute for Safe Medication Practices (ISMP Canada) and the Canadian Patient Safety Institute (CPSI) have launched a national project to promote automated drug identification in Canada using GS1 global bar coding standards.

"Relying only on human vigilance to ensure medication safety is not enough; better use of available technology will be important in the 21st century," says David U, President and CEO, ISMP Canada. "With over 20,000 commercial drug products in the marketplace, there is a significant and overdue need for a coordinated approach to bar coding pharmaceuticals in order to enable automated identification throughout the Canadian Healthcare system."

Collaboration between ISMP Canada, CPSI, GS1 Canada and Healthcare industry stakeholders has resulted in a national consensus on using GS1 bar codes as the standard format for labelling medication packaging in Canada.

"Changes in practice need to occur to promote a more collaborative and standardised approach to medication traceability to keep Canadian patients safe, while retaining current supply chain efficiencies," says Pierrette Leonard, Senior Leader, National Partners, CPSI. "In working with GS1 and with the success of creating a Joint Technical Statement with over 34 organisations representing six Healthcare sectors, we are one step closer to achieving this objective."

New AIDC Application Standards enable global harmonisation

Sector-wide implementation of Automatic Identification and Data Capture (AIDC) systems will improve patient safety, including reducing medication errors, fighting counterfeiting and enabling effective product recalls and adverse event reporting. It will also help remove inefficiencies throughout the Healthcare supply chain.

This new standard provides industry stakeholders with a common set of data and data carriers for medical products at every packaging level, including specific guidance on selection and use of product Identification Keys, additional product and production data [for example; lot number, expiration date and/or serial number (where applicable)] and data carriers.

Over the last three years more than 100 experts contributed to the development of this standard. In over 150 meetings, or more than 4,500 contact hours, the user group has carefully compiled and validated a set of business requirements, including allocation rules, serialisation, packaging size constraints, direct part marking and have mapped these in product marking grids.

Read the full press release at www.gs1.org/healthcare

The Application Standard for Small Medical / Surgical Instruments specifically covers AIDC marking of surgical instruments to enable traceability throughout the instrument reprocessing cycle, and in particular to and from the sterilisation department.

Read the full press release at www.gs1.org/healthcare
View the current standards development work groups at www.gs1.org/healthcare

Making electronic product catalogues a reality

The GS1 GDSN® (Global Data Synchronisation Network) enables supply chain partners to effectively exchange master data electronically and to keep it synchronised via a single point of entry. GDSN certified data pools serve as a repository where trading partners can obtain, maintain, validate and exchange product information in a secure, reliable, standards-based environment. In May 2009, GS1 Healthcare launched a user-led initiative to take steps towards the global use of the GDSN for Healthcare products. Twenty six leading Healthcare organisations have already joined this initiative, which has resulted in 50 live connections and 29 more are being planned.

A sub-work team is finalising a tool assisting all Healthcare supply chain participants in implementing the use of GDSN. The document will outline the key tasks in making sure the implementation moves forward with little to no disruptions, and provide guidance by documenting what processes users have implemented already and address any key learning's. The work team believes that implementation can be accelerated if everyone agrees to a few basic rules of engagement, in particular an agreed upon set of attributes and their use, and agreed upon responsibilities.

Global standards to achieve end-to-end traceability

The Traceability in Healthcare work group's mission is to develop both process and technical standards necessary to have full actionable visibility of all items in Healthcare, from point-of-production to point-of-use, globally across all geographies. This suite of standards will be the foundation for achieving an incremental implementation of traceability systems that enable patient safety, regulatory compliance, supply chain safety and integrity.

Download the Global Traceability Standard for Healthcare (GTSH) at www.gs1.org/healthcare
Download the GTSH Implementation Guideline at www.gs1.org/healthcare

Currently, one important sub-team of the work group is devoted to Chain of Custody / Chain of Ownership issues, and will shortly finalise business requirements to ensure they cover diverse national and regional requirements as well as Product ID Authentication and Product Recall use cases. The work group will also create a Global Traceability Conformance (GTC) Checklist for Healthcare, based on a recent audit at the St. James's Hospital in Dublin, Ireland.

GHTF releases UDI discussion paper

"When a global unique device identification (UDI) system is developed, it should consist of a unique code using a globally accepted standard format", the Global Harmonization Task Force (GHTF) says in a discussion paper released in December 2009, "The system should not be restricted to a particular method of automatic identification and data capture as it must be able to accommodate most methods of labelling, marking and identifying products".

Comments on the paper are due by March 31, 2010. GS1 Healthcare is currently preparing its official response in its Public Policy Work Team. If you would like to be involved, please contact Ulrike Kreysa at ulrike.kreysa@gs1.org.

Download the discussion paper
at http://www.ghtf.org/ahwg/ahwg-proposed.html

Chile: Network of public hospitals endorses GS1 Standards

The Servicio de Salud Metropolitano Occidente [SSMOCC – Western Metropolitan Healthcare Department] has embarked upon an ambitious process to modernise administrative and clinical management. It will implement GS1 Standards to monitor stock and to enable traceability of drugs and medical devices. This is "an important step toward quality and safety for patients" according to the responsible parties.

SSMOCC and GS1 Chile signing the collaboration agreement

The SSMOCC is overseen by the Ministry of Health of Chile. It manages and coordinates a Healthcare network of 6 hospitals, 1 diagnostic and treatment centre, 1 Healthcare centre of reference, 33 primary Healthcare centres and 23 clinics. There are 1,200,000 people assigned to the network, which is divided into the 15 municipalities of the Chilean capital.

India: Ministry endorses GS1 Standards

The Ministry of Health and Family Welfare (MoHFW) of India has announced that all medical supplies procured by the MoHFW will have to comply with GS1 Standards for bar codes as of 1 April 2010. The MoHFW is responsible for the procurement of drugs, medical devices and other medical supplies for government run Healthcare providers and for various national health programmes, including universal immunisation, tuberculosis control, malaria control and AIDS control.

"Programme divisions need to ensure that by the start of fiscal year 2010-2011 all medical supplies procured under MoHFW should comply with GS1 bar coding standards. With immediate effect, all tenders that are issued either by the Ministry or by procurement agencies (procuring on its behalf) should include GS1 bar code standards as one of the mandatory specifications."

View the MoHFW announcement at www.gs1.org/healthcare

Taiwan: Bureau of Pharmaceutical Affairs

With the support of the Bureau of Pharmaceutical Affairs (Taiwan Department of Healthcare), GS1 Taiwan hosted a Healthcare Conference in Taipei on 14 December 2009: "The key to patient safety and management efficiency". This conference, attended by 500 participants, established the important role of GS1 Taiwan in the consolidation and promotion of global standards in the Healthcare supply chain, in Taiwan.

Ms. Qian-Wen Hsu, the senior technical specialist from the Bureau of Pharmaceutical Affairs, indicated, in her keynote speech, that the e-Government strategy will be the basis for future Healthcare management in Taiwan. Ms. Hsu considered global standards to be critical in this process to allow the Taiwan Healthcare industry to upgrade and remain competitive in this global sector.

Considering the developments in the country, GS1 Taiwan will also launch a local user group in 2010 to support the deployment of global standards in this era of transformation.

Australia and New Zealand: User group continues to grow

Participation in the Australasia user group continues to grow, currently with more than 60 companies active. Nine Australasia Healthcare user group meetings have been held over the last 3 years, each focusing on a specific subject. The most recent meeting was held in November 2009 in Sydney, Australia and hosted by Abbott Australasia. Its focus was: "Regulatory developments relating to use of the GS1 System."

The presentation on the Australian Commission on Safety and Quality in Healthcare, made by Margaret Duguid, Pharmaceutical Advisor to the Commission, was particularly noteworthy. The Commission was established in 2006 and its remit is to lead and coordinate safety and quality in Healthcare in Australia, by identifying issues and policy directions, recommending priorities for action, disseminating knowledge and advocating for safety and quality and recommend nationally agreed standards, taking into account global standards, for safety and quality improvement.

Promoting and introducing systems that reduce the risks of errors in managing medications are of particular interest to the Commission. For example, reducing errors caused by similar packaging and labelling for dissimilar products, and of look-alike and sound-alike names through the use of machine-readable bar code checking systems when dispensing and administering medicines. The Commission advocates machine-readable standards-based bar codes on all medicines at the unit of use level.

Read all of the presentation from the november 2009 Australasia Healthcare user group meeting at http://www.gs1au.org/assets/documents/industry/healthcare/i_aus_presentation_271109.pdf

Belgium: GS1 DataMatrix pilot

The Belgian Healthcare sector in general, and its hospitals in particular, are becoming increasingly aware of the challenging context surrounding medical and pharmaceutical product identification at different packaging levels. Current identification and labelling practices in Belgium do not allow hospitals to properly trace medical products, primarily due to lack of standardised methods and systems. This creates potential confusion and errors in situations where products are re-labelled at hospital pharmacies.

A GS1 Belgium & Luxemburg pilot project has been launched to face these challenges. Its main objective is to improve processes in hospitals and across the sector's entire supply chain, in order to better ensure patient safety. The participating suppliers (Baxter, Johnson & Johnson, and Pfizer) have selected the products that will be part of the pilot project and will now start marking these products at the unit of use with a GS1 DataMatrix bar code including the GTIN; other packaging levels and other data will be part of a next phase of the pilot project.

France: Advancing implementation of GS1 Standards in Healthcare

Standards-based Healthcare in France took several leaps forward in 2009, and further progress is expected in 2010. Traceability regulations are partly behind this: on January 1, 2011, any medicine sold in pharmacies must have a GS1 DataMatrix bar code encoding its name, lot number and expiration date. GS1 France will be working hard to accompany its member companies across the migration phase, and will be offering a selection of training courses during the year.

The French national committee of university hospital directors (CNDG – Conférence nationale des Directeurs de CHU), as well as hospitals which are members of the hospital purchasing association known as UniHA (Union des Hôpitaux pour les Achats), have formally selected GS1 Standards to reference their products and will make GS1 Standards a selection criteria in their requests for pricing processes.

UniHA
GCS des CHU et grands CH

To make it easier to deploy standards across the Healthcare supply chain and to stay in touch with the needs of users, a Healthcare Steering Committee was formed in France in 2009. It is led by Pascal Mariotti, director of the Saint Egrève Hospital and François Versini, Quality Control Director for Pierre Fabre Laboratories and counts among its members a wide variety of people from across the Healthcare sector in France.

- A number of French hospitals have implemented standards-based solutions with the support of GS1 France:
- The logistics department of Dijon University Hospital ensures traceability of all of its deliveries using the SSCC (Serial Shipping Container Code), linked to the delivery support identification using a GRAI (Global Returnable Asset Identifier), the point of departure, arrival and storage of all items using GLNs (Global Location Numbers) and the items themselves using GTINs (Global Trade Item Numbers).

- The Strasbourg University Hospital combines bar codes with RFID to ensure the traceability of its medical products; and beyond the GS1 Identification Keys indicated above, also uses the SSCC, which is put on all deliveries leaving the location.
- The Toulouse University Hospital uses GS1 Standards in all their logistics projects to be able to trace all the movements of products within the hospital. The project is being deployed across all the items managed by the logistics pole: blood, patient samples, medicines and more.

- The Rene Dubois Center at the Pointoise Hospital has recently been equipped with a system to manage automatic heavy transport. It is important to use a global and unique codification system with this sort of equipment, so that there is no confusion and to ensure it is compatible with future traceability systems. As a result, each container is being identified with a SGTIN on a GS1-128 bar code and each functional unit/destination with a GLN.
- The Robert Ballanger Intercommunal Hospital (CHIRB) in the suburbs of Paris, uses GS1 DataMatrix to mark its reusable (sterilisable) medical equipment. Today, more than 800 surgical instruments and 1,800 patient care instruments have been laser-engraved with a GS1 DataMatrix bar code.

Japan: User group off to a strong start

As of December 2009, over 70 organisations were involved in GS1 Healthcare Japan. An Executive Council was established, with representatives from the Kanto Medical Center NTT EC, Eisai Distribution, Edwards Life Sciences, Olympus Medical Systems, Sakura Seiki, Johnson & Johnson, Tyco Healthcare Japan (Covidien), Terumo Corporation, Nippon Becton Dickinson, Banyu Pharmaceutical and Mediceo Paltac Holdings.

Three work groups were launched:
- AIDC work group, whose 39 members have the mission to investigate standardised bar code solutions for the pharmaceutical and medical devices supply chain from manufacturers, wholesalers to hospitals;
- RFID work group, whose 30 members have the mission to explore a model of RFID applications for Healthcare logistics and hospital management;
- International work group, whose 26 members are focused on collecting and sharing information concerning International standardisation activities in the Healthcare sector.

Spain: FENIN endorses GS1 Standards

FENIN has approved a position paper promoting the use of best practices to efficiently manage the Healthcare supply chain. The paper recommends FENIN members to use the GS1 System of Standards for product identification and electronic data interchange in the Healthcare supply chain.

FENIN's membership in Spain includes over 520 national and International (large, medium and small) suppliers of products for hospital and laboratory use, including prostheses, medical devices and accessories, diagnostic, monitoring, therapy and hospital equipment of a very diverse nature.

UK: NHS ISB ratifies GS1 Standards

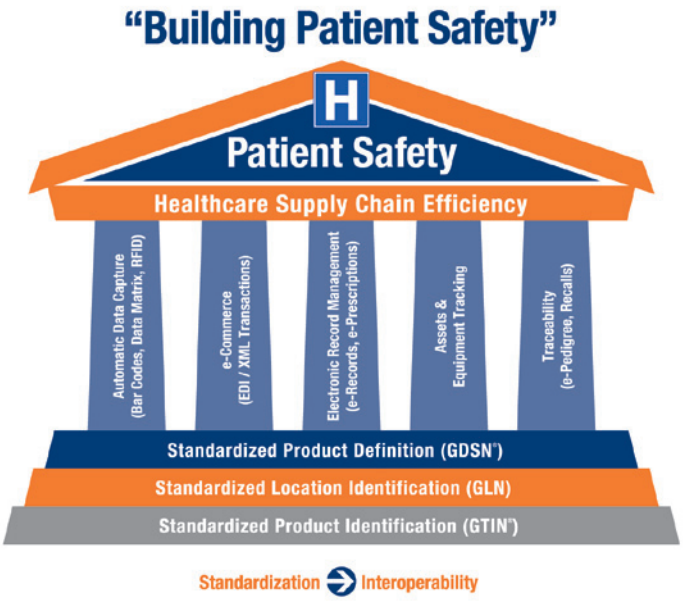
GS1 Standards have been ratified by the NHS ISB (Information Standards Board).
The ISB has issued an advance notification, which heralds the introduction of a bar code standard for the auto-identification of patients using an identity wristband. The notification states that: "NHS organisations and those organisations delivering NHS commissioned services, deploying bar coding systems for patient identifiers on the wristband, will need to implement a bar code system that will enable them to print bar codes to GS1 Standards on the wristband. This will require the procurement and installation of a software and hardware system at all points in the hospital where a patient wristband is printed e.g. at patient registration, together with the implementation of procedures to manage the system."

Submission of the full Standard to ISB is planned for 1 July 2010. If approved, a mandate for full compliance across the NHS is expected from 1 July 2011.

USA: Building patient safety

GS1 Healthcare US was formed in January 2008, to support U.S. Healthcare patient safety and supply chain efficiency goals. Since that time, membership has grown to 112 Healthcare companies representing all areas of the supply chain.

GS1 Healthcare US is structured around five active work groups: Product Identification (GTIN), Location Identification (GLN), Global Data Synchronisation Network (GDSN) Implementation, Traceability Adoption, and Application & Implementation.



Some major accomplishments include the following:

- Developed a guiding implementation model "Building Patient Safety" that illustrates the foundational GS1 Standards used to achieve patient safety and supply chain efficiency.
- Established two key adoption dates with associated plans and measures that the U.S. Healthcare community is working towards: 2010 GLN Sunrise and 2012 GTIN Sunrise.
- Developed numerous educational and implementation tools, including: Online Healthcare Provider and Supplier Tool Kits; "C" Level Provider Awareness Brochure
- Developed a GDSN "early adoption" programme that resulted in 27 Healthcare participants in the GDSN this year.
- Supported development of industry surveys to determine adoption benchmarks: The State of Healthcare Logistics: Cost and Quality Improvement Opportunities; Material Management Information System (MMIS) Readiness. The survey reports are available on the GS1 Healthcare US website in the 'library'.

A new traceability programme has recently been launched. The "2015 Readiness Program" allows the simulation of various traceability scenarios in the U.S. pharmaceutical supply chain and provides a reference model for companies to test their state of readiness for GS1 traceability systems.

USA: UPS and Genzyme to go live with GS1-compliant traceability system

UPS Healthcare Logistics, Genzyme and Accenture have worked together since January 2008. Despite the postponement of California's e-pedigree legislation (until 2015), they have established a GS1-compliant, unit-level serialisation system that is expected to go live this quarter.

The effort is a follow-through on Genzyme's longstanding position to protect its product from diversion throughout the supply chain. For UPS, the project represents a stake in the ground that the company will facilitate track-and-trace technologies for its clients.

According to Dan Gagnon, a director in the UPS group, the decision was made early on to sidestep use of RFID tags in favour of 1D and 2D bar codes: "the impacts of RFID on sensitive Healthcare products are still unknown and the investment is not cost-effective for companies." Genzyme then proceeded to build in the necessary bar coding technology, while UPS needed compatible bar code readers and to rework its warehouse processes. In a major undertaking, UPS revamped its internal IT systems to accept bar code information in an EDI-compatible manner while meeting GS1 Standards. The company says this was "the largest system change the company had made in nearly a decade." The EDI/GS1 capability can now be offered to other customers, although there will be coordination necessary to bring new clients into the system.

Phase 1 of the project involves exchanging order-processing information between Genzyme's and UPS' facilities. Phase 2 will engage downstream trading partners. UPS expects to see immediate benefits in better tracking of items within a lot or shipment.

New Healthcare videos

- How do GS1 Standards help to meet the challenges of today's Healthcare supply chain?
- How did GS1 Standards enable the implementation of a traceability project at the university hospital CHU Dijon (France)?
- Why does Sweden support the EFPIA anti-counterfeiting pilot?

Visit www.youtube.com/gs1healthcare

New Public Policy Database

The GS1 Healthcare Public Policy Database is a comprehensive global repository of regulations and directives related to requirements for Healthcare product identification, product catalogues and traceability. A new user friendly online tool, making it easier to perform queries and updates, is now available for all GS1 Healthcare global members.

Visit www.gs1.org/healthcare/ppd

Voting membership for 'solution providers'

As GS1 Healthcare shifts its focus and work efforts towards implementation and adoption activities, we encourage all solution providers to become member of the global Healthcare user group and help shape the future of patient safety and supply chain efficiency in Healthcare.

View the announcement at www.gs1.org/healthcare

Upgraded resource library

Looking for information, case studies, links on GS1 Standards in Healthcare? Visit our upgraded resource library on our website [link to www.gs1.org/healthcare/library] – we have restructured it and added more resources, including for example 25 case studies from various countries.

Visit www.gs1.org/healthcare/library

GS1 supports LogiPharma

LogiPharma Europe 2010

LogiPharma 2010
27-29 April, Intercontinental Hotel, Geneva
www.logipharmaeurope.com

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Join us in São Paulo and Geneva

The global GS1 Healthcare user group holds three conferences per year in different regions worldwide. These conferences provide a unique platform for your key local Healthcare stakeholders to meet, network and benchmark with other experts from all over the world. The plenary sessions feature expert speakers presenting the latest on regulatory and industry developments related to patient safety, automatic identification, product catalogues and traceability. The GS1 Healthcare Leadership Team, work groups and work teams also convene to present and discuss the current status of global activities and standards development.

To date, GS1 Healthcare has held 15 global conferences; 6 in North America, 7 in Europe and 2 in Asia-Pacific. You can "re-live" the plenary sessions of the last two conferences in Hong Kong and Washington DC.

Videos Hong Kong plenary sessions
Videos Washington DC plenary sessions
at www.gs1.org/healthcare

Join us for the upcoming global conferences:

- Sao Paulo, Brazil, 16-18 March 2010
  More info at www.gs1.org/healthcare
- Geneva, Switzerland, 22-24 June 2010

Global GS1 Healthcare Conference

16-18 March 2010 in São Paulo, Brazil
Hosted by GS1 Brazil
Opening keynote by Dr. Dirceu Raposo, President ANVISA
For further details, visit www.gs1.org/healthcare

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