The global Healthcare User Group
GS1 HUG™ Newsletter No. 6 - April 2007

Welcome to the sixth edition of the GS1 HUG Newsletter! This newsletter aims to inform you about our activities and progress in the global Healthcare User Group, GS1 HUG. We look forward to receiving your comments, feedback, and questions, possibly for inclusion in future newsletters. More information can be found on our website: www.gs1.org/hug

The Council of Europe's Expert Group on Safe Medication Practices makes a strong recommendation to use the GS1 System

The Expert Group on Safe Medication Practices was established by the Council of Europe in 2003. Their mission is to "prepare recommendations to specifically prevent adverse events caused by medication errors in European Healthcare".

This Expert Group has now made a strong recommendation to European Healthcare organisations and other related stakeholders "to update the national and European legislative framework to require labelling of every single unit of use of all licensed medicinal products… The data matrix bar code should contain a GS1 GTIN in addition to the expiry date and batch number."

The complete report "**Creation of a better medication safety culture in Europe:** Building up safe medication practices" is available online at www.coe.int and www.gs1.org/hug

The Department of Health in the UK clearly sees "real improvements to patient safety when using coding systems to match patients to their care"

"The case for coding is compelling, but all stakeholders need to work to commonly agreed standards if the benefits are to be realised fully. The Department of Health is recommending that the GS1 System should be adopted throughout the healthcare system in England, both for manufactured products and for coding systems used within healthcare settings, such as patient identification codes on wristbands." That is why the Department of Health is endorsing the GS1 System:

- requires all NHS organisations to become GS1 members
- engages itself in the activities of the GS1 HUG
- encourages manufacturers to code their products using the GS1 System
- recommends all hospitals to introduce bar coding or RFID using the GS1 System

The complete report "**Coding for Success** - *Simple technology for safer patient care*" is available online at www.dh.gov.uk and www.gs1.org/hug

GS1 HUG advocates global approach for Automatic Identification Standards in Healthcare

On the 20th April, GS1 HUG published a Position Statement advocating a global approach in the development and implementation of global standards for automatic product identification in Healthcare. The GS1 System of Standards is extremely well suited to fit the specific needs of Healthcare. Therefore, GS1 HUG strongly recommends governments worldwide to endorse the use of the GS1 system, and more in particular the usage of GTINs (Global Trade Item Numbers). Further details are available on the HUG website at www.gs1.org/hug/about/news.html

Key messages from the 6th GS1 HUG Conference in Berlin

GS1 and Healthcare

- GS1 is committed to the Healthcare sector working with the user community to develop global supply chain standards and to facilitate its adoption and implementation and focused on patient safety.
- The global Healthcare User Group's members endorse the GS1 system.

Associations and GS1 Healthcare

- GIRP, the European Association of Full-Line Wholesalers, urges that a balance is found between advancing technologies and practical solutions. GS1 numbering system and GS1 are the most suitable, in their opinion.
- EAHP, the European Association of Hospital Pharmacists, strongly advocates the use of bar coded unit-dose drugs. The GS1-128 standards and GS1 DataMatrix fulfil these needs.
- Survey by EUCOMED, the European Association of Medical Device Manufacturers, indicates trend towards GS1 in Auto-ID standards for medical devices. Survey by EUCOMED, the European Association of Medical Device Manufacturers, indicates trend towards GS1 in Auto-ID standards for medical devices.

Hospitals and Supply Chain Management

- Several Spanish hospital networks have implemented the GS1 system to comply with the regulation on traceability of implants and improve supply chain efficiency.
- Six hospital representatives from 6 different European countries shared their experiences with automatic product identification and bedside scanning. They all came to the conclusion: Auto-ID at the bedside improves patient safety, but to optimise the process, they reach out to the manufacturers and wholesalers to adopt global standards for product identification.

GS1 Development Activities

- Several HUG Work Teams and Support Teams are up and running with very active participation from users and GS1 member organisation representing local stakeholders. Activities include Auto-ID Data, Serialisation, Public Policy and Communication.
- Local and regional HUG initiatives, driven by GS1 member organisations, are mushrooming and contributing to the standards development and facilitating adoption and implementation.
- Data synchronisation and classification are needed to facilitate accurate and complete information exchange of product data.

Sixth HUG Conference from 30 January to 1 February 2007 in Berlin, Germany

The Langenbeck Virchow House in Berlin, Germany was the remarkable venue for this HUG Conference. A historic building with a long tradition in healthcare and … politics. It served as the home of the German Surgical Society from 1915 until it was occupied by the Russians, during WWII. It then served as the Eastern-German parliament until 1976. The building was completely renovated in 2004, with support from B.Braun. It now also hosts the Aesculap Academy and the B.Braun Expertisium.

Our gratitude goes to B.Braun and GS1 Germany for their hospitality.

More than 165 people attended the 6th HUG Conference, which was hosted by B.Braun. A very diverse: representatives from hospitals, wholesalers and distributors, manufacturers, governments, associations, and GS1 member organisations, from all over the world represented a large number of local stakeholders.

GS1 is committed to the Healthcare sector

In his opening speech, Miguel Lopera (President GS1) emphasized GS1's commitment to the Healthcare sector. Consumer goods retailers have experienced the power of global supply chain standards for many years now (decreased supply chain costs and increased customer satisfaction because of fewer out-of-stocks, faster customer check-outs, …). In the same way, Miguel Lopera is convinced that the Healthcare sector, by nature also global, will find its own advantages of global supply chain standards. In the first place, ensuring the 5 patient rights, but also combating counterfeiting and enabling traceability.

Jörg Pretzel shared the experience of GS1 and Healthcare in Germany: for more than 15 years, GS1 Germany has been active in the sector with clear results, including the development of implementation guidelines for EANCOM messages and GS1-128 transport labels. Implementation has shown clear cost savings. GS1 Germany will establish a local HUG to further push the harmonization of national identification systems with the GS1 standards, support the global activities on a local level and articulate local requirements to the global group. They will also look at first pilots, once the standards are developed.

The Global Healthcare User Group endorses the GS1 system

Rich Hollander (Pfizer and HUG Co-Chair) added: the GS1 HUG was formed to develop global standards in the Healthcare industry when it comes to automatic identification and act as the leading voice for the Healthcare industry. The GS1 HUG is developing global healthcare application standards relying on the GS1 system.

Some thoughts of a former controller: "…as good as necessary"

Supply chain standards for automatic identification are clearly needed to improve the safety of pharmaceuticals and medical devices, and at the same time save costs, according to Jürgen Völlkopf (Senior Vice President Controlling and Business Administration of B.Braun). However, in its implementation the industry is faced with a paradox: on the one hand extensive and country specific data requirements on a GS1 DataMatrix symbol which might increase production costs; on the other hand, there is constant pressure to reduce costs. Therefore, Mr. Völlkopf concluded that B.Braun is dedicated "to every activity that makes the use of our products safer" with the philosophy of "not as good as possible, but as good as necessary". To give an example: "Does it make sense in a hospital to track a standard syringe with a sales price of less than € 0,10?"

Find the right balance between advancing technologies and practical solutions

By engaging all stakeholders in the Healthcare supply chain (manufacturers, wholesalers, pharmacists, and authorities), suitable supply chain standards solutions can be implemented:
- smooth integration of national product identification, expiry date, and batch number
- allowing speed of delivery
- globally harmonized
- at a competitive cost of implementation

This was the starting point of the GIRP (European Association of Full-Line Wholesalers) presentation. Lothar Jenne (Chairman GIRP Technical Committee) shared the conclusion of a GIRP study: GIRP members want to implement the GS1 numbering system and use GS1 DataMatrix as a data carrier. RFID is considered to be a technology for the longer term.

Needed: single dose-packed drugs with a bar code on each single dose (part 1)

EAHP, the European Association of Hospital Pharmacists, wants to improve patient safety and to ensure the highest quality in medical treatment. That is why the production of single dose-packed drugs with a bar code on each single dose is required.

Dr. Werner Kittlaus (Chairman Drug Packaging Committee of ADKA, the German Association of Hospital Pharmacists) strongly advocates the use of bar coded single doses with variable data. From their perspective, the GS1-128 standard in a GS1 DataMatrix symbology is most suited.

Spain at the forefront of adopting supply chain standards for traceability

A Spanish Royal Decree, dating back to 1996 required the implementation of traceability of implants. Meritxell Gavira (Purchasing Manager ICS Institut Català de la Salut) explained how the ICS network of 8 hospitals, with more than 4,000 beds, has fulfilled this legal requirement by using GS1-128 bar codes to track implants from production to patient. At the same time, this has improved supply chain efficiency, including avoiding out-of-stock, warehouse tracking, and cost assignment.

ICS wants to continue GS1 standards implementation on a short term for other product groups, including high risk medical products, laboratory products, high cost products,

and a number of pharmaceutical products, as required in a new regulation. In the mid-term, Meritxell Gavira aims to have full implementation of the system.

Also the S.A.S. (Servicio Andaluz de Salud) serving 29 hospitals, with 15,366 beds, implemented a Surgical Implant Register using GS1 standards. The VIGIA project aims to expand this to other medical products, as explained by Jesus Gavira (Sub-Director Purchasing and Logistics S.A.S.). Furthermore, the intention is to implement an integrated logistics management platform, also allowing automating commercial transactions using EDI.

SERGAS is a Healthcare logistics project for the Galicia region in Spain. Benjamín Rodriguez Nespereira (Project Manager SERGAS and Sub Director Economic Resources Ourense Hospital) explained what this encompasses. Automatic product identification with GS1 bar codes and EDI are used as tools towards an intelligent supply chain. GTINs are the universal language for the item codes in the SERGAS product catalogue. Suppliers are expected to mark their medical devices or packaging with GS1-128 bar codes. Already, 56 suppliers are connected to the system and in only 3 years the number of "SERGAS" orders vs. total orders increased from 10% to more than 20% last year. This represents more than €50 million.

SERGAS is ensuring traceability as well as optimising supply chain efficiency (including stock management and reduced administrative costs). It is crucial to comply with the Royal Decree on traceability for implants. However, if the supplier does not identify the prosthesis with a GS1 bar code, manual data entry is needed, resulting in additional costs and risks. Further adoption of the GS1 bar code system is therefore needed to enable automatic product identification from production to patient.

Implant traceability and the Shanghai regulation

The Shanghai regulation issued on 7 November 2006 requires, as of 2007, to implement a traceability system for implantable medical devices. Every implant needs a unique identification. Zexia Huang (GS1 China) explained that 12,000 Chinese Healthcare companies are already applying the GTIN allocation rules. GTIN and batch/lot number are now mandatory for implants because of this new regulation in Shanghai. Patient/product databases need to be established and maintained and monthly updates need to be provided to the local authorities.

Experiences with automatic product identification at the bedside

Twenty five years of unit-dose systems have diminished the number of medication errors in some countries, but the introduction of bar coded unit-dose packages can further decrease errors, according to Albert Lenderik (Director of Pharmacy at Hospital Pharmacy Midden-Brabant, Netherlands). The existing distribution system is old-fashioned and insufficient, including:

- only 35% of manufacturers bar code, and if they do, no uniform standard
- trend towards fewer unit-dose forms
- often in-house re-packaging and re-labelling needed

The hospital has implemented Theriak, a Therapy Management System, including Medication Administration. C.O.W.s (computer-on-wheels) were introduced, facilitating bedside scanning. However, bar coded unit-dose packages are needed to further optimise the system and to reduce risks of errors, thus improving patient safety.

Also the Forlì Hospital in Italy has re-engineered several supply chain processes, as explained by Dr. Martina Minguzzi (Forlì Health Board) and Silena Sistu (Head of ICT Forlì Health and Social Services). The hospital uses a Swisslog machine to create, for themselves, unit-doses of drugs and uses those in combination with bar codes for patient identification to ensure that the five patient rights are respected. The collected data serves also to automate planning, quality control, and delivery of drugs.

Bar codes increase the quality of data transmission, but coding needs to be unique, international, and generalised in the hospital. Frankie Meuleman (Hospital Pharmacist at AZ St. Jan Hospital in Bruges, Belgium) shared his experience in the implementation of bar coded unit-doses. This distribution system has distinct advantages, including error reductions, fast identification, and cost reductions. But, with 1,900,000 registrations per year and limited availability of adequately bar coded unit-doses, this involves a lot of re-packaging and re-labelling.

A number of unit-dose-projects were launched by the KAV (Vienna Hospital Association) for quality reasons. Experience learned that not only quality will be improved, but that cost savings will be an additional side effect.

To improve patient safety, the ideal process should indeed be much more automated, according to Dr. Pascal Bonnabry (Chief Pharmacist at the Geneva University Hospital, Switzerland). A pilot study to reduce errors was performed for a high-risk process, i.e. chemotherapies. electronic prescription, automatic product and patient identification were implemented. The system was very well accepted by the caregivers (about 90% preferred the new process) although close support was helpful. Furthermore, significant time was saved by eliminating a few manual steps, so that caregivers could spend more time with the patient and improve patient care. But to optimise this system and to extend it to other applications, bar coded unit-doses are needed!

Dr. Wolfgang Gerold (Head of Medical Economics and Pharmacy, KAV, Vienna, Austria) explained how a network of 13 hospitals, with more than 14,000 beds, are partnering to ensure quality and safety during pharmacotherapy, at the same time optimising logistics efficiency and taking advantage of synergies. After approving the business case and selecting the suppliers at the end of last year, KAV will run test pilots in the second half of 2007 and further roll out the system as of 2008. The new system will include electronic prescribing, automatic dispensing, and bedside scanning.

The Chelsea and Westminster Hospital has a system in place with electronic prescribing, automatic dispensing, and patient identification (with RFID tags). India Hardy (Hospital Pharmacist, Chelsea and Westminster Hospital, UK) confirmed that this has clearly reduced medication errors. For example, wrong dose and wrong frequency (accounting for respectively 19% and 10% of all medication errors) were reduced by implementing electronic prescribing, using a compendium and default dosing.

Needed: single dose-packed drugs with a bar code on each single dose (part 2)

The conclusion from these testimonials, from hospitals all over Europe, is apparent: hospitals recognise the potential of automatic product identification and bedside scanning to prevent medical errors and want to implement optimal solutions for improving patient safety. But for this, they reach out to manufacturers and wholesalers to adopt global standards for product identification.

As some would say: "**No bar code, No business**".

EUCOMED survey indicates trend towards GS1

A recent survey, amongst medical device manufacturers and related stakeholders, revealed a trend towards GS1 for auto-ID standards. This analysis was based on results from 210 surveys, from 19 European countries. About 8% of the survey population mentioned that they will change to GS1, while others are considering GS1. This comes on top of 40% already exclusively using GS1 and 20% a combination of standards, including GS1. These results were shared by Mike Kreutzer (EUCOMED, the European Medical Technology Industry Association) and Janice Kite (Johnson & Johnson).

Data Synchronisation and Classification in Healthcare

Product data in the Healthcare industry is traded in many different ways:

- Peer-to-peer, either on paper or via eFiles
- One-to-many and many-to-one via a Service Provider/Internet, including GHX, U.S. Department of Defense, Health eMarketplace (NSW), ECCNet (GS1 Canada), Product Data Utility (CHeS), UniHA (France), Cenabast (Chile), and UBB (Turkey)

This has resulted in an unmanageable multitude of product identification numbering systems, buyer/seller identification numbering systems, and attributes. That is why Tom Werthwine (Johnson & Johnson) urges the Healthcare industry to adopt the Global Data Synchronisation Network (GDSN) after it has been adapted to the specific needs of Healthcare.

This will then also require exploring and aligning classification categories, as this is one of the required fields in GDSN. As explained by Zoltan Patkai (GS1), the UNSPSC should serve as the primary basis, whereas the GPC bricks will be integrated and provide the needed granularity.

This is in line with what hospitals want, according to Frank Brüggemann (Comparatio Health): one master classification system! This will enable the international exchange of medical data, based on global standards, insuring greater accuracy and productivity among all supply chain partners.

A new HUG Work Team was convened on 16 February to kick off this project.

Auto-ID Data Work Team

(www.gs1.org/hug/work_teams/auto_id_data/index.html)

This Work Team is defining business and data requirements for the development of global standards for automatic product identification in Healthcare. This will streamline the global supply chain from 'finished goods' to 'end of treatment', improving patient safety.

A lot of valuable input has already been gathered through an extensive hospital survey and through input of individuals representing all stakeholders and participating in this Work Team. The hospital survey generated some interesting conclusions:

- very strong need for product identification number, lot/batch number, and expiry date, both on a unit-dose level and case level, and for both medical devices and pharmaceutical products
- about 40% of surveyed hospitals are currently using bar code scanning, of which less than half actually use it for patient safety purposes
- about 70% of surveyed hospitals using bar code scanning have implemented a system to bar code products themselves (at least for part of the products)
- about 5% of surveyed hospitals are using RFID for capturing data regarding patient safety

Based on this input, the aim of the Work Team was to approve business requirements in March, then define data requirements, with the ultimate target to submit the final report in quarter 2 of 2007.

Serialisation Work Team

(www.gs1.org/hug/work_teams/serialisation/index.html)

Initial discussions addressed current and potential USA regulations regarding controlled substances and electronic pedigree. It has now moved to global work, covering all healthcare products. This Work Team will determine the size and structural requirements for specific data elements, for example lot numbers and serial numbers. The team is therefore currently gathering business requirements. Everyone was invited to contribute via a questionnaire or via participation in the Work Team meetings.

Public Policy Work Team

(www.gs1.org/hug/work_teams/public_policy/index.html)

This Work Team intends to organise the Healthcare industry around a single position to drive future standards and influence regulations around auto identification of healthcare products.

The team works closely with existing healthcare industry organisations, such as AdvaMed, EUCOMED, GIRP, EGA and EFPIA as well as with regulatory bodies like the Ministries of Health in the UK and New Zealand, and authorities of the USA, Canada, Australia and China.

Communication Support Team

(www.gs1.org/hug/work_teams/communication_coordination/index.html)

Establish the HUG as the leading voice in the area of automatic data identification in the Healthcare industry. That is the main objective of this Support Team. Activities include:

- HUG website (www.gs1.org/hug), with more than 38,000 page views and 10,000 downloads in March
- HUG press releases, position statements, newsletters, collateral and media coverage

The following or updated brochures are now available as downloads:

HUG brochure (English)
www.gs1.org/docs/patient_safety/hug_brochure.pdf

GS1 Standards in the Healthcare Supply Chain (English)
www.gs1.org/docs/patient_safety/GS1_Standards_in_Healthcare.pdf
(French/Français) - www.gs1.fr/gs1_fr/secteurs_d_activite__1/sante/a_la_une/une_plaquette_pour_la_sante

EPCglobal and Healthcare

In the Healthcare & Life Science Industry Action Group (HLS IAG) a Work Team was established to address the California regulation on Pedigree. In the mean time, a Pedigree Messaging Standard was developed and ratified. Next step is a High Frequency Standard for item level RFID tagging. In collaboration with the HUG Serialisation Work Team, the global requirements for serialisation will be defined.

European Healthcare Initiative

Since 2003, the European GS1 member organisations joined forces to increase awareness of the GS1 system in the Healthcare sector. This initiative is now also actively participating in the standards being developed by the HUG. EHI will continue to promote GS1 standards in Healthcare in Europe.

Local/Regional HUGs

(www.gs1.org/hug/work_teams/local_hugs.html)

Several GS1 member organisations have already created local or regional HUGs to engage stakeholders in the standards development process, to promote adoption, and to facilitate implementation of GS1 standards.

Today, local HUGs exist in Australasia, Chile and Switzerland. Many other GS1 Member Organisations are also kicking off local HUGs including; Austria, Canada, France, Germany, Malta, Serbia & Montenegro and Macedonia, USA, UK …

Auto-ID in action at PHOENIX

6 to 8 June 2007
Orlando, Florida, USA

GS1 HUG™
Global Healthcare User Group

EPCglobal
Healthcare & Life Science
Industry Action Group

The culmination of the 6th HUG conference was the opportunity for delegates to visit to the Phoenix warehouse and distribution centre in Berlin, which was organised by GIRP. Presentations were made by Phoenix staff with frequent emphasis on the importance of standardised bar coding of healthcare items, to make the supply chain process more efficient and accurate. During the visit and warehouse tour delegates had the opportunity to see Auto-ID in action. With 155 distribution centres in 23 European countries and 185 million packages per month, serving 53,000 customers, the Phoenix Group is a market leader in many European countries.

We would like to invite you to our first joint GS1 HUG & HLS IAG Conference, which takes place from Wednesday 6 to Friday 8 June during UConnect in Orlando, Florida.

Further details and a registration form can be found at: www.gs1.org/hug/meetings/060607/index.html

For more information on the GS1 HUG, please visit the website at www.gs1.org/hug/ or contact Ulrike Kreysa at ulrike.kreysa@gs1.org

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