

GS1 Healthcare Newsletter

No. 14 - March/April 2009







ALSO IN THIS ISSUE:

Government and Regulatory Activities 2

- United Nations & International drug control systems
 European Commission and legislative proposals on
- counterfeit medicines

 The European Commission and UDI
- The European commission and obt
- FDA public workshop on UDI related issues
 Australia a world leader in Healthcare
- Chile bar codes modernise the Chilean Healthcare sector
- Brazil National traceability and authentication
 project
- UK GS1 UK submits recommendations to Health Committee's Inquiry into patient safety

News from around the world 5

- Europe EFPIA project for coding and identification of pharmaceutical products
- Europe, Austria and France Eucomed eBusiness & Supply Chain Task Force (ET F) perspectives
- Germany EK UNICO endorses GS1 Standards for Patient safety and process optimisation
- USA Survey results confirm progress on data standards
- USA SMI provider members announce support for data standards adoption
- USA Major Premier hospitals endorse GS1 Standards
- France GS1 Standards enable the AURE@ eProcurement platform
- USA Georgia Society for Healthcare Materials Management endorses supply chain standards
- France Traceability of sterilised medical devices at Robert Ballenger Hospital
- Austria From the national 'Pharmazentralnummer' to an international product identifier
- Japan Traceability of medical supplies at Kyoto Second Red Cross Hospital
- Austria Planning a new hospital: considering identification requirements
- UK Nurses lose up to 25% of working time looking for medical items

GS1 Healthcare Update9

- Enabling traceability of medical products from production to patient
- Overview from the
- GSMP Healthcare Work Teams
- Dates for your diary





Some healthcare supply chain stakeholders believe that Healthcare providers must be the driving force behind standards adoption. Although GS1 believes standards adoption and implementation is a joint effort by all supply chain stakeholders, the momentum amongst Healthcare providers continues to build around leading organisations endorsing GS1 Standards and getting ready to be early adopters or have already adopted some standards. In our previous newsletter, we had already reported on a number of leading Healthcare providers, group purchasing organisations and integrated Healthcare networks around the world. Further on in this newsletter, you'll find more on developments in Austria, France, Germany, Japan, UK and USA.



The 12th global GS1 Healthcare conference was held for the first time within a hospital. The Orthopädisches Spital Speising in Vienna (Austria) opened up its magnificent and historic 'Festsaal' [festival room] to more than 200 delegates from 35 countries. The hospital also invited



the participants to see GS1 Standards in action in the hospital. The Orthopädisches Spital Speising is one of seven hospitals from the Vinzenz Gruppe, an Austrian association with more than 4,700 employees and approximately 2,200 hospital beds, representing the largest group of private healthcare providers in Austria. Both Speising and another large Austrian hospital group, the KAV (Wiener Krankenanstaltenverbund), are members

of the GS1 global Healthcare user group.

(continued on page 2)

Page 1 of 11 pages

Hospitals in search of excellence

(continued from page 1) The Vinzenz Gruppe is also in search of excellence: "Despite the high cost pressure, European hospitals may never be allowed to turn into health factories. Economic goals are important, but only to create the framework for rendering the best service to people." said Dr. Michael Heinisch, chief executive officer of the Vinzenz Gruppe when opening the GS1 Healthcare conference in Vienna. Dr. Wolfgang Ecker, Head of Department, Pharmaceuticals, Medical Devices, Health Technology Assessment and Medical Radiation Hygiene at the Austrian Ministry of Health, added: "Patient safety and efficiency of healthcare services and products are primary targets of health policy. Standardisation and global harmonisation for automatic identification, traceability and data synchronisation in healthcare are important to achieve these goals."



GOVERNMENT AND REGULATORY ACTIVITIES

United Nations & International drug control systems

The International Narcotics Control Board (INCB), established in 1961, administers international control systems, ensures balance between supply and demand, and endeavours, in cooperation with governments, to prevent illicit narcotics activities. The control systems aim to limit the use of narcotic drugs and psychotropic substances, to legitimate medical and scientific purposes and to ensure that they are available for these purposes.

International collaboration [...] is necessary to work towards global solutions.

The INCB Annual Report analyses the global drug control situation and draws attention to any weaknesses in national drug control, suggesting possible improvements. The unregulated market is typically driven by the limited access to Healthcare facilities, the cost of drugs, lack of public awareness, inadequate drug control regulations and weaknesses in enforcement. *"Governments should establish a comprehensive legal framework and rigorously enforce existing legislation"*, said



Hanifa Rebbani, Drug Control Officer, Psychotropics Control Section, International Narcotics Control Board Secretariat, United Nations Office in Vienna. "The World Health Organisation should consider studying the dynamics of the unregulated market and should provide technical assistance to Member States to build capacity in drug regulatory authorities,

together with the United Nations Office on Drugs and Crime. International collaboration with organisations such as World Customs Organisation, World Trade Organisation, GS1, Healthcare associations and the industry, is necessary to work towards global solutions."



European Commission and legislative proposals on counterfeit medicines

In December 2008, the European Commission announced a renewed vision for the pharmaceutical sector on safe, innovative and accessible medicines. One area of focus is 'to tackle the growing issues of counterfeiting and illegal

distribution of medicines'. "The European Commission envisions a comprehensive response to healthrisks from counterfeit medicines as far as pharmaceutical legislation is concerned," said Stefan Fuehring from the Unit F2 Pharmaceuticals in the Directorate General Enterprise & Industry of the European Commission. "A first pillar will be dealing with product characteristics



and Good Manufacturing Practices (GMP). Obligatory safety features shall allow for; identification checking, authenticity checking and tracing, but the European Commission proposes changes to come to a legal basis for a harmonised approach in the European Community [proposed new article 54a] as well as an information obligation when there is suspicion about counterfeit medicines [proposed new article 46*q*]. A second pillar will be dealing with participants in the supply chain and Good Distribution Practices (GDP), including proposed changes to wholesaler requirements, accreditation and EudraGDP database. The third and last pillar will deal with Active Pharmaceutical Ingredients (API), including proposed changes to obligatory audits by the Manufacturing Authorisation Holder, accreditation by NCA, and notification requirements." said Stefan Fuehring. "It is not about re-vamping the system, but making the existing framework more efficient," he concluded, "Many measures will facilitate enforcement."

The European Commission and UDI

"At the moment, nothing has been developed nor has been officially decided," said Rodolphe Muñoz, DG Enterprise and Industry, Unit F-3 Cosmetics and Medical Devices, European Commission, "but we have started to reflect and brainstorm on UDI (Unique Device Identification) because of the evolution of the technology and because the US FDA is developing a UDI mechanism, and other countries will follow." The European Commission advocates an international approach to avoid the multiplication of

UDI is a useful instrument and it will develop globally in the years to come

different national UDI systems in each of the European Union member states. The European Commission was instrumental in establishing an ad hoc working group at the Global Harmonization Task Force (GHTF) last



October. The working group aims to ensure global compatibility of UDI systems and will propose the implementation of the UDI system into the GHTF model. The working group is currently analysing the results of the questionnaire it issued earlier this year and will present their findings at the upcoming GHTF Steering Committee Meeting

in May 2009 in Toronto. "UDI is a useful instrument and it will develop globally in the years to come, but it cannot lead to an excessive increase in costs for manufacturers. A balance needs to be found between the potential of UDI and its feasibility," concluded Rodolphe Muñoz.

FDA public workshop on UDI related issues



On 12 February 2009, the FDA held a public workshop, which was organised by Jay Crowley, Center for Devices and Radiological Health, U.S. Food and Drug Administration, for the industry to provide comments on a number of UDI related issues.

Four panels discussed the distinct steps towards a UDI system:

- Develop standardised Unique Device Identifiers (UDI)
- Place the UDI in human readable and/or Auto-ID on a device, its label, or both
- Create and maintain the UDI database
- Adoption and Implementation

GS1 US (John Roberts) and GS1 Global Office (Ulrike Kreysa) presented the GS1 and GS1 Healthcare perspective during the first panel and addressed the questions raised by the FDA, including, for example, according to what standard(s), how do we identify these standards, which devices or device types (if any) should be exempted, how do we handle the legitimate reuse of single use devices and how should kit components be identified? Several members of the global GS1 Healthcare Leadership Team (Jackie Elkin [Medtronic], Tom Werthwine [J&J] and Joe Pleasant [Premier]) and the GS1 Healthcare US Leadership Team (Jean Sargent [University of Kentucky] and Dennis Black [BD]) also presented their views on UDI. It was clear for all participants that it is no longer a question 'if' UDI will be introduced, but now the uncertainty is around timelines and the framework of implementation.

More than 300 delegates attended the workshop in Washington D.C., and more than 4,000 via the webcast.

All presentations and the transcripts and videos, of all panels are available at:

www.fda.gov/cdrh/meetings/021209workshop/ GS1 Healthcare US and GS1 Healthcare responded jointly to the FDA questionnaire. Details can be found at: www.gs1.org/docs/healthcare/GS1_Comment_to_ Docket_2008-N-0661022709_FINAL.pdf

Australia - a world leader in Healthcare

"We treat a lot of people, we spend a lot of money and we get excellent results," said Ken Nobbs, Programme Manager Medical Products, National eHealth Transition Authorities (NeHTA) of Australia, "but despite the current successes, there are opportunities to improve through the use of technology. IT expenditure in Healthcare is 1.4% compared with the finance sector which reaches 7-9%." NeHTA aims to develop better ways of electronically collecting and securely exchanging health information and facilitate eHealth systems that unlock; quality, safety and efficiency benefits.

Data synchronisation is core to improvements in eHealth. One health jurisdiction in Australia has estimated that the cost of cataloguing a new item in a hospital system costs AU\$47 an hour per record, or AU\$470,000 for a standard health catalogue (about 10,000 items), excluding data maintenance time. Bad data is also costly; for example,



one supplier calculated that 47% of all pricing errors in purchase orders result from public hospital data errors and cost AU\$40,000 per year. *"Lack of data synchronisation leads to an unnecessary replication of effort and errors leading to quality and cost issues in Healthcare,"* concluded Ken Nobbs. NeHTA has worked with GS1 Australia to develop the National Product Catalogue (NPC), hosted on GS1net, GS1 Australia's GDSN-certified data pool.

Chile – bar codes modernise the Chilean Healthcare sector

The Minister of Health in Chile, Álvaro Erazo, announced measures to call for the implementation of global GS1 Standards in the public Healthcare sector. Standards-based bar coding will permit the modernisation of stock management, enable traceability and reduce human errors. The sector-wide implementation will start by the middle of 2009, after some preliminary studies.

"This is an ambitious project that will significantly improve the information systems for all medical products supplied to hospitals in Chile. The programme will improve patient safety by enabling traceability and improving logistics management efficiency" said Carlos E. Jorquiera, president of the national Chamber of Commerce, which is supporting this initiative.

Brazil - National traceability and authentication project

Earlier this year, the Brazilian government passed legislation to establish a traceability system for all medicines through automatic identification and data capture (AIDC) technologies. Control will be performed through unique automatic identification of products, suppliers and users. The Competent Brazilian Health Authorities (ANVISA) is expected to implement the system over the next three years. ANVISA is currently working on some important requirements, including which code to use, how to manage the database(s) and whether to print the barcode directly on the package or on a special label.



The Brazilian Institute of Ethical Competition (ETCO), a non-profit organisation promoting ethical competition to improve the business environment, has presented to ANVISA a pilot project with Pfizer, Bayer Schering, Sanofi Aventis, Nycomed, Eurofarma, Ache and Mantecorp. The proposed solution incorporates a serialised item number in a GS1 DataMatrix (2D bar code) that will enable



tracing and authenticity in a database. "Considering the risks of counterfeiting, the implementation of a traceability and authentication system is a powerful tool to correct these deviations. However, we think it is essential to be in line with International initiatives and GS1 Standards," concluded Patricia Blanco, Executive Director of ETCO.

UK – GS1 UK submits recommendations to Health Committee's Inquiry into patient safety

For some time, GS1 UK has been involved in submitting standards recommendations to the government that will help make the Healthcare supply chain safer, more efficient and improve patient safety. In November 2008, GS1 UK made a written response to the Health Committee's inquiry into patient safety. In January 2009, Roger Lamb, from GS1 UK, was invited to the House of Commons to provide further information.



The full report is available at: www.gs1uk.org/solutions/health/healthcare.asp

On other occasions, GS1 UK was praised for its efforts to drive the adoption and implementation of GS1 global supply chain standards to improve patient safety. ".. the Department of Health best practice guidance 'Coding for Success' recommended that both industry and the NHS adopt the GS1 System of coding standards and it set out an action plan to support them in achieving this. Since its publication, over 175 hospitals have registered for GS1 UK membership and more are joining all the time.

GS1 UK was praised for its efforts to drive the adoption and implementation of GS1 global supply chain standards.

The Department of Health was initially planning to carry out a formal review of 'Coding for Success' by the end of 2008. However, in view of these achievements, it was decided not to carry out a review but to work with the relevant agencies and stakeholders across the NHS and industry to ensure that the policy is reviewed and updated when the changes have been embedded" said Stephen Atkinson, Customer Service Centre, Department of Health.

GS1 Healthcare Newsletter No. 14 – March/April 2009 Page 4 of 11 pages

Europe - EFPIA project for coding and identification of pharmaceutical products

"In Europe, four countries (Belgium, Italy, Greece and Turkey) are already requesting, for each pack, a serial number (in addition to the national product code). Two other countries (Spain and Serbia) are currently working on new legislation mandating the use of a serial number. Who's next?" said Jean-Marc Bobée, Director, Anti-Counterfeiting Strategy at Sanofi-Aventis and chairman of the EFPIA project on codification and identification of pharmaceuticals in Europe. "EFPIA proposes a standardised coding and identification of pharmaceuticals in Europe, consistent with existing International standards (GS1). Europe has a fragmented supply chain with different coding schemes implemented or proposed by different Member States, which brings the risk of developing 27 (or more) different 'Italian' Bollino's."



EFPIA proposes an end-to-end system consisting of a serialised GS1 DataMatrix on secondary packages, for all products sold in Europe, and the verification of pharmaceuticals at their point of dispensing. This will result in a more efficient and secured medicines supply chain. EFPIA considers an ePedigree more complex and expensive as it

would require either an aggregation process (inference) whereby the manufacturer manages the association of the item's serialisation with the code of the container into which they are packed, or adding RFID tags on every pack (in addition to GS1 DataMatrix) to read and analyse which unit packs are contained in the various cases/pallets.

EFPIA has planned a pilot project in Sweden to prove its end-to-end concept, where 30 to 50 pharmacies will be involved in a 3 to 4 month pilot, at the end of this year, to verify about 100,000 serialised item numbers in a GS1 DataMatrix.

Wait and see is not an option.

"Considering the European Directive of 10 December 2008, mass serialisation of pharmaceuticals should become a reality over the next 4 to 5 years," concluded Jean-Marc Bobée, "Wait and see is not an option. It provides an opportunity to build new, long term strategic relationships with key stakeholders, particularly pharmacists, to improve patient safety and supply chain management."



Europe, Austria and France - Eucomed eBusiness & Supply Chain Task Force (ETF) perspectives



While Unique Device Identification (UDI) is moving to centre stage, "country-specific requirements on UDI would have a major impact on multiple country device configurations and result in supply chain inefficiencies, higher costs and could impact patient safety," warned Mike Kreuzer, Technical and Regulatory director of ABHI (Association of British Healthcare Industries) and chairman of the Eucomed ETF. The priorities of the ETF are to communicate with European industry and authorities, understand the industry's views and needs and develop a risk-based approach to UDI. There is an extreme diversity of medical devices in size, materials, processing, use and criticality, which demands this risk-based approach. "The industry needs a global standards system. Only global and open standards enable the realisation of all healthcare and economic benefits related to UDI," concluded Mike Kreuzer.

The industry needs a global standards solution.

In Austria, currently there are no clearly defined, general measures for traceability, and thus no specific requirements, as have been developed in some other countries. *"Suppliers and users are interested in patient safety and traceability, but we need a single and harmonised standard to link with their systems,"* said Wolfgang Gross, General Manager of AUSTROMED (Association of medical device companies in Austria).

France will migrate to GS1 DataMatrix on pharmaceuticals from 2011, and *"it is probable that it will also migrate to GS1 DataMatrix for medical devices over the next 5 years,"* said Joël Guillou, Director Regulation Reimbursement at SNITEM (French industry association for medical technologies), *"By organising and/or participating in several work groups, at an International and national level, SNITEM aims at facilitating the development of a unique harmonised classification, for use by its members; Good Distribution Practices and global traceability standards."*

GS1 Healthcare Newsletter No. 14 – March/April 2009 The 2008 SNITEM member survey indicated more than 80% (60% for Implantable Medical Devices) used bar codes for traceability, and also indicated a sustained trend towards GS1 Standards."

Germany - EK UNICO endorses GS1 Standards for Patient safety and process optimisation

EK UNICO, the largest group purchasing organisation in Germany comprised of 13 university hospitals (including 300 special clinics and more than 240 institutes), all together purchasing more than €1 billion, strives for cost savings through joint purchasing and optimised purchasing processes. *"Each supplier has their own method to communicate their products and prices to a hospital; printed catalogues, quotations, tenders, spreadsheet tables, website etc.," said Thomas Klein, Purchasing Manager*

EK UNICO endorses GS1 Standards to enable its eBusiness.



University Hospital Düsseldorf and e-business representative for EK UNICO, "We need consistent item master data. The electronic catalogue is the core of eBusiness and requires a definite item identification number and consistent product descriptions."

The advantages of the usage of machine-readable labelling,

when handling consumables in a hospital, are obvious (patient safety, timely product availability and increased efficiency), but there is insufficient standardisation for bar coding on medical products. *"If our hospital were to label all items in the central warehouse, warehouse staff would have to label more than 28,000 different items and we would be shifting medical responsibilities to non-medical staff." said Thomas Klein, "On the other hand, if our hospital were to rely on supplier labels, at least 80 to 90% would have be labelled according to a general standard with unique bar codes. But there are too many standards..." That is why EK UNICO endorses GS1 Standards to enable its eBusiness; unambiguous product identification, consistent and clear product descriptions, and standardised electronic data exchange.*

For more information, the press release can be found at: www.gs1-germany.de/content/presse/ pressemeldungen/index_ger.html?itemid=235

USA - Survey results confirm progress on data standards



Previous attempts to get hospitals and suppliers to support a common set of data standards, to improve efficiency and patient

safety, produced little lasting success. But now, after

recent intense educational and coalition-building efforts, measurable progress is being made.

The survey conducted by the Center for Innovation in Healthcare Logistics (CIHL) at the University of Arkansas, Fayetteville, and the Association for Healthcare Resource & Materials Management (AHRMM), Chicago shows that Healthcare is achieving a critical mass of support for a common set of data standards. The survey of Healthcare providers found that more than 26% of the 1,381 respondents plan to adopt GS1 Standards. In addition, more than 78% said their organisations are at various stages of readiness to adopt data standards.

Yet, even with the significant successful groundwork that has been laid in seeking support of data standards adoption, much work still remains. When asked what was the most significant barrier to data standards adoption in their organisation, the most common response among Healthcare provider respondents is, limited resources (38%). Cultural barriers (14%), including resistance to change, lack of universal acceptance and low management buy-in, are also mentioned as other significant barriers. Some providers (7%) indicate a lack of knowledge as the most significant barrier, which again reinforces a need for further educational efforts. Furthermore, more than half the survey respondents didn't know if their organisation is moving toward adopting data standards for the supply chain. And while some argue this indicates more educational efforts are needed to convince hospitals and suppliers of the value of implementing data standards, Bill Zimmerman, director of enterprise data governance for Cardinal Health, which is actively involved in developing an adoption strategy for GS1 standards, believes it shows that a strong business case needs to be made before supply chain leaders will commit to employing data standards.

The survey of Healthcare providers found that more than 26% of the 1,381 respondents plan to adopt GS1 Standards.

Source: Survey conducted by the Center for Innovation in Healthcare Logistics at the University of Arkansas, Fayetteville, and the Association for Healthcare Resource & Materials Management, Chicago, November 2008.

USA - SMI provider members announce support for data standards adoption

S M S T R A T E G I C MARKETPLACE I N I T I A T I V E Thirty-two industry provider members of the Strategic Marketplace Initiative (SMI) announced their support to work with trading partners to implement GS1 data standards by the publicly announced sunrise dates in the U.S. (adoption of GLN by December 2010 and adoption of GTIN by December 2012).

Carl Manley, SMI's Chairman of the Board and Vice President of Supply Chain at Sentara Healthcare said "These SMI members are all industry leaders dedicated to seeing our entire industry support data standards adoption, through collaboration. Adopting data standards help all trading partners in the supply chain to ensure that the correct products are delivered to the correct locations at the correct time - creating a safer, more efficient and less expensive Healthcare system."

For more information (including a list of all 32 providers), read the press release at:

www.smisupplychain.com/news_infomation/press_ releases.html?pressid=67

For more information about SMI, visit: www.smisupplychain.com



USA - Major Premier hospitals endorse GS1 Standards

The Strategic Advisory Committee (SAC) of Premier Healthcare Alliance, comprised of 25 of Premier's largest Healthcare systems, issued a joint letter to over 800 suppliers endorsing GS1 supply chain standards to improve patient safety and reduce supply chain costs. To realise these gains, the Premier SAC Alliance members asked suppliers to commit to the industry-supported 2010 and 2012 implementation dates for using GLN and GTIN. For more information, read the letter at: www.gs1us.org/healthcare

France - GS1 Standards enable the AURE@ eProcurement platform

UNIHA, a network of 32 university hospitals and 22 large hospitals in France, currently purchases about $\in 1$ billion, out of a total of $\in 7.5$ billion and targets for $\in 3$ billion in group purchasing by 2012. Already, in 2006, the UNIHA Board endorsed GS1 Standards for product identification. In 2007, the French High Authority of Health followed this approach for its drug traceability programme.

In 2006, 19 hospitals, all member of UNIHA, had established AURE@, an eProcurement platform. Today, the first 10 hospitals are placing 7.000 orders per month through

GS1 Healthcare Newsletter No. 14 – March/April 2009 AURE@. Another 17 suppliers have loaded 7,000 references of medical devices and 100,000 references of biologics into AURE@; and more will follow soon. "The UNIHA Board has now decided to change the common template to comply with the GDSN standards," said Pascal Mariotti, Délégué Général of the GCS UNI.H.A. and coordinator of the National Commission



of Purchasing and Logistic Managers of the French University Hospitals.

USA - Georgia Society for Healthcare Materials Management endorses supply chain standards

The Georgia Society for Healthcare Materials Management (GSHMM), a Georgia Hospital Association (GHA) affiliated society, becomes the first state society or association to

Inefficiencies in the supply chain cost the industry billions of dollars each year.

publicly announce its endorsement of GS1 supply chain standards. "The U.S. Healthcare industry significantly lags grocery and retail industries in the adoption of supply chain standards," said Charles Platt, immediate past president of GSHMM and Director of Contracts and Purchasing at the Medical Center of Central Georgia. "Inefficiencies in the supply chain cost the industry billions of dollars each year and adoption of these standards will bring even more value to patients and hospitals. GSHMM advocates for every manufacturer, distributor, provider and Materials Management Information System (MMIS) vendor to prepare their company to adopt these standards." Platt added.

To view the press release <u>click here</u> or visit: www.gs1us.org/healthcare For more information about GSHMM, visit: www.gha.org/societies/gshmm.html

France - Traceability of sterilised medical devices at Robert Ballenger Hospital



Robert Ballenger Hospital, a 650 bed inter-city hospital of Aulnay-sous-Bois, Villepinte and Sevran in France, has developed a project of Unique Device Identification (UDI) for surgical instruments and clinical services instruments. Since 2005, the traceability of all sterile medical devices is the responsibility of the sterilisation unit. These medical devices can be traced from; the point of return to the unit, through to their distribution to clinical services. Up to December 2008, traceability was at the surgical instrument box level rather than the individual instruments contained within the box. Consequently, if the instruments in the box changed, that change was not traceable. The decision was therefore taken to trace the individual instruments in addition to the surgical instrument boxes.



"Over three years, we will identify 10,000 operating the atreinstruments and 12,000 clinical services instruments, using GS1 DataMatrix (2D bar code)," concluded Georges Nicolaos, CHI Robert Ballenger. "The initial results, using laser technology, to identify small instruments, were very promising. More than 99% were readable in the sterilisation unit. However, the

project also highlighted the necessity for standardisation of the UDI. For this project GS1 DataMatrix 2D bar codes was chosen, but other hospitals in France chose to use their own, non-standardised, codes."

Austria - From the national 'Pharmazentralnummer' to an international product identifier

A study performed by the University of Applied Sciences FH Joanneum in Graz, Austria, concluded that transitioning from the national Austrian 'Pharmazentralnummer' (PZN) to a global product identifier (GS1 Global Trade

Transitioning from the national Austrian 'Pharmazentralnummer' (PZN) to a global product identifier (GS1 Global Trade Item Number - GTIN) has definite advantages.

Item Number - GTIN) has definite advantages: it would increase the capacity of available numbers, it would facilitate international trade and it would increase transparency. The PZN provides a 6+1 digits nationally unique pharmaceutical product identifier. While the PZN system only has a capacity of about 730,000 numbers,



every GS1 company prefix makes up to 100,000 numbers available (and possibly more when using GTIN-14). "During a transition period, concurrent use of PZN and GTIN would allow all stakeholders to adapt and make the necessary administration software changes," concluded Dr. Stefan Sabutsch, FH Joanneum University of Applied Sciences.



Japan - Traceability of medical supplies at Kyoto Second Red Cross Hospital

Kyoto Second Red Cross Hospital, a 640 bed hospital in Kyoto, Japan, has established a traceability system for medical supplies by using GS1 Standards. *"In the hospital wards, nurses check the medications to see if they are correct, and they also mix the medications according to the required time and the usage",* said Dr. Kiyohito Tanaka, Kyoto Second Red Cross Hospital. When nurses



mix the medications, they use mobile terminals or bar code readers to confirm the information on the prescriptions and the bar code labels of the injections and the infusions. Precise history tracking of the medications is possible by utilising the bar code attached on the medication cart or the bar code medications notebook. The scanned information, of the medications and medical devices, will be reflected to the distribution system and purchase orders will be placed automatically, based on the preset quantity of inventory. The list of used medicines will be printed out at the pharmaceutical department and the precise quantity will be replenished on the medicine cart.



Austria - Planning a new hospital: considering identification requirements



The Vienna Hospital Association (VHA), one of Europe's largest Healthcare organisations and Austria's largest training facility for Healthcare professionals, will start building a new 850 bed hospital, the Vienna North Hospital

GS1 Healthcare Newsletter No. 14 – March/April 2009 (VNH), early in 2010. Since the late 1980's, a VHA-wide Hospital Information System (HIS) has been supporting a wide range of medical and administrative processes. Bar codes on forms and labels, identification of the electronic health record and bar codes on patient's wristbands, have enabled VHA to address current identification requirements. However, looking into the future, VHA anticipates an evolution of identification requirements, including:

- Traceability of surgical instruments to improve quality of care
- Personalised identification of medication to enhance patient safety and the efficiency of drug supply
- Location of medical devices to support device pools

• Traceability of garments to reduce inventory and costs VHA plans to achieve this, for example, through an innovative supply chain for drugs, with electronic prescription, automated order entry, delivery in unit dose packages and bedside documentation of the medication. Another example is that garments will be RFID-tagged and automatically linked to the user, when issuing and returning garments.



"It will be critical to manage the increased dependency on automated supply processes and the cost and ease of handling for marking or tagging individual items," concluded Dr. Peter Wölfl, responsible for the Technical Facility Management of all hospitals and geriatric centres (nursing homes) of the city of Vienna and Project Manager of the Vienna North Hospital project responsible

for all facility management issues. "Long term availability of standardised solutions is necessary to protect the investment."

UK - Nurses lose up to 25% of working time looking for medical items

In a recent survey of almost 1,000 nurses, conducted by GS1 UK and Nursing Times, in February 2009, it was revealed that nurses lose up to one quarter of their working day looking for medical items. This is equivalent to 40 hours per month or more than GB£900 million of salary expenditure.

Wasting time looking for portable medical equipment such as IV pumps, beds, mattresses or smaller items, which can be hidden away in cupboards, detracts from patient care. When items such as mattresses are not readily available, the hospital often has to rent others, incurring significant additional expenditure and delays. Finding items that require servicing and maintenance can also cost valuable time.



Being able to track and locate assets that are shared between departments or wards within a hospital, and report on where equipment is and its level of utilisation, will render a number of benefits, including more control and to get the best value out of their assets and from nursing staff spending less time looking for things and being able to devote more time to patient care. Using a GS1 standard key like Identification Key, for example a Global Individual Asset Identifier (GIAI) within an RFID tag or bar code linked to one of the many asset tracking solutions on the market will enable hospitals to identify and track their assets as they move within the hospital and more importantly when the asset is taken to another site or to the patient's home.

The Nursing Times article can be found at: www.nursingtimes.net/nurses-waste-an-hour-a-shiftfinding-equipment/1987381.article

Further details about GS1 Identification Keys can be found at:

www.gs1.org/productssolutions/barcodes/technical/ id_keys.html



16-18 June 2009 - Washington D.C.



GS1 HEALTHCARE UPDATE

Enabling traceability of medical products from production to patient

Approval of the GS1 Global Traceability Standard for Healthcare



The GS1 global Healthcare user group has approved a Global Traceability Standard for Healthcare (GTSH) which will ensure maximum interoperability between traceability systems across the Healthcare supply chain and across borders.

The GTSH provides a foundational framework, which describes the traceability process and defines the minimum

requirements for all stakeholders, independent from technologies, organisation size or operational sophistication. As a global open standard, the GTSH was defined and adopted to counter such costly and suboptimal non-standard solutions.

More than 100 representatives, from all stakeholder groups and more than 30 countries, worked on the GTSH, since the Traceability in Healthcare work team was established in December 2007. The work team was cochaired by Frédérique Frémont (C.H.I. Robert Ballanger Hospital, France) and Tim Marsh (Pfizer) and facilitated

by the GS1 Global Office. Now that the GTSH has been approved via the GS1 Global Standards Management Process (GSMP), the work team is currently developing implementation guidelines to assist users in the implementation of traceability across Healthcare supply chains.

Read the full press release at: www.gs1.org/docs/media_centre/gs1_pr_130309_ global_traceability_healthcare.pdf

The Global Traceability Standard for Healthcare can be downloaded at: www.gs1.org/docs/gsmp/traceability/Global_

Traceability_Standard_Healthcare.pdf

Overview from the GSMP Healthcare Work Teams

- The AIDC Application Standards work team kicked off its standards development work for instruments at the Vienna conference.
- The GDSN Healthcare Extension BRAD (Business Requirements Analysis Document) was motioned into Public Review at the Vienna conference. This concludes the business requirements gathering process. The Healthcare data requirements documented in the BRAD will allow us to close the attributes gap identified in the GDSN analysis last year.
- The Implementation Guideline for the Global Traceability Standard in Healthcare has just been motioned to be published after the public review was closed on 24 March 2009 and comment reviews and resolutions have been completed.

DATES FOR YOUR DIARY

Global GS1 Healthcare Conferences

- 16/18 June 2009 Washington D.C., USA In collaboration with the FDA Register now at: www.gs1.org/sectors/healthcare/news_events/160609/
- 6/8 October 2009 Hong Kong hosted by the Hong Kong Hospital Authority
- February/March 2010 Brazil



- GS1 Healthcare at other international events
 - 21/23 April 2009 LogiPharma Europe, Geneva, Switzerland www.wbresearch.com/logipharmaeurope/
 - 1/4 June 2009 ISPE 2009 Washington Conference, Engineering Regulatory Compliance, Washington D.C.
 www.ispe.org/cs/2009 washington conference/2009 washington conference
 - 1/3 June 2009 GHX Supply Chain Summit Nashville, Tennessee www.ghx.com
 - 9 June 2009 Axway and Systech Conference, Global Serialization & Traceability of Pharmaceutical Products, Brussels, Belgium - www.axway.com/newsandevents/
 - 23/24 June 2009 3. GHX Symposium (for the DACH region), Lösen Sicherheit und Standards die Probleme von Morgen?, Düsseldorf, Germany (German language only) - www.ghxeurope.com/index.php?id=312
 - 19/22 July 2009 AHRMM09 Annual Conference & Exhibition, Tampa Convention Center Tampa, FL The Association for Healthcare Resource & Materials Management (AHRMM) Conference is the premier event for healthcare materials management and supply chain professionals. New for 2009: GS1 Standards track. Visit GS1 Healthcare US at booth #1020. For more information and registration visit: www.ahrmm09.org
 - 7/8 September 2009 4th Annual Pharmaceutical Anti-Counterfeiting Strategies London, UK www.visiongain.com/Conference.aspx?cid=173

GS1 Healthcare newsletters can be downloaded from the 'News & Event' section at: www.gs1.org/healthcare























GS1 HEALTHCARE NEWSLETTER IS A PUBLICATION OF:



GS1 Blue Tower, Avenue Louise 326, b10 BE 1050 Brussels, Belgium T +32 (0)2 788 7800 F +32 (0)2 788 7899

Publisher: Ulrike Kreysa, ulrike.kreysa@gs1.org Editors: Jan Denecker, jan.denecker@gs1.org Jim Willmott, Smiths Medical

For more information, please contact: healthcare@gs1.org or visit: www.gs1.org/healthcare