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Special feature: Safeguarding the pharma supply chain



Pharma security is currently at the forefront of government and industry concerns and in this special feature, we have outlined recent developments.

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Axway and GHX join GS1 Healthcare

As GS1 Healthcare shifts its focus and work efforts towards implementation and adoption activities, it is essential that solution providers become involved and support the drive towards adoption of global standards throughout the Healthcare supply chain. Many solution providers are already engaged in local programmes and initiatives. In 2010, the global Healthcare user group amended its governance charter, allowing solution providers to become members of the user group.

Two leading solution providers, Axway and GHX, were the first to join GS1 Healthcare, and others are considering joining.

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"Houston, we have a problem"

"Drug counterfeiting, diversion, cargo theft and economically motivated adulteration are crimes of opportunity, and the opportunity is flourishing because of the dramatic way our world has changed in a relatively short period of time," said Margaret A. Hamburg, U.S. Commissioner of Food and Drugs at the Partnership for Safe Medicines Interchange 2010 held on the 8 October.

"Countries across the globe suffer the scourge of being flooded with fake and sub-standard medicines and this has become a matter of rising international concern," said Kunio Mikuriya, Secretary General, World Customs Organization (WCO) at last year's WCO Council Session.

Is it really 10%?

According to the World Health Organization (WHO), the extent of counterfeiting is impossible to quantify. The WHO estimates that most industrialised countries with effective regulatory systems and market control have less than 1% of the market value. Many countries in Africa and parts of Asia and Latin America have areas where more than 30% of the medicines on sale can be counterfeit. (Source: www.who.int)

The U.S. based Center for Medicines in the Public Interest estimates that counterfeit drugs generate US\$75 billion in revenues – a 92% increase from 2005.

The International Policy Network estimated that fake medicines, for treating malaria and tuberculosis alone, are responsible for about 700,000 deaths a year.

The Pharmaceutical Security Institute collected data worldwide on counterfeiting, illegal diversion and theft incidents for eight consecutive years – in 2009, 2,003 incidents involving 808 different drug products were reported – up from 196 incidents in 2002.

In any case, it is clear that it is difficult to measure a criminal enterprise. But it is also clear that counterfeit medicines are an important threat, a growing problem, and one that is not confined to developing countries. They are increasingly present, even in the best controlled markets.

Can it be solved?

"We need to jointly comply with strict product quality controls, by improving their traceability and by securing pharmaceutical channels," said Jacques Chirac, Former President of France at last year's WCO Council Session, "The need for transparent pharmaceutical supply chains is crucial. Securing pharmaceutical channels requires cooperation between States to harmonise resources and laws."

"The FDA is working to reduce the risk that counterfeit or other adulterated drug products pose to consumers in the U.S., by developing standards for track and trace and authentication systems," said Margaret A. Hamburg, U.S. Commissioner of Food and Drugs. "Earlier this year [in 2010], FDA established a standard for unique identifiers for packages of drugs. This standard creates a "license plate" for individual packages of drug products as they travel through the supply chain. This is an important first step in developing a track and trace and authentication system in the U.S."

"I also want to underscore that threats to compromise drug integrity and supply chain security is a global problem and FDA cannot work in a vacuum to curtail these threats," added Commissioner Hamburg. "To a large extent, our success or failure in this effort will depend on the relationships we establish and maintain with our foreign partners."

The European Commission also works together with European and International partners to ensure that legal methods for the marketing of medicines are respected and enforced. About two years ago, the Commission adopted a legislative proposal to address the risk of falsified medicines entering the legal supply chain in the EU. After public review, the proposed directive has in the mean time been submitted to the European Parliament and the Council of Europe and the final vote is expected in February 2011.

Many other countries worldwide are looking into this problem, and taking legislative and industry initiatives.

Video of Commissioner Hamburg's remarks

GS1 is member of the Technology Work Group of WHO's International Medical Products Anti-Counterfeiting Taskforce (IMPACT).

GS1 signed a Memorandum of Understanding with WCO in 2007.

The industry prepares for serialisation and traceability

"International legislative and regulatory agencies have concerns about the Pharmaceutical Supply Chain's ability to effectively protect products," said Ron Bone, Senior Vice President Distribution Support, McKesson Corp. "A single weak link in the supply chain means we ALL fail. We need to have our electronic systems capture and validate the information."



"Regulations are being driven by patient safety concerns," said Peggy Staver, Director, Product Integrity, Pfizer, "We share this concern and support enhanced safeguards appropriate for the issue being addressed."

Standards-based solutions are essential, which requires industry wide engagement. Serialisation and authentication are necessary first steps to Traceability."

"The regulatory landscape today is challenging. There is often a lack of regulatory clarity and consistency; regulatory requirements change; new requirements are being issued; aggressive implementation timelines or governments issuing labelling requirements are imposed," added Staver, "Implementing serialisation is a multi-million dollar investment. Standards-based solutions will speed the adoption of serialisation requirements, help to ensure interoperability of solutions, and drive cost out of the process."

"It is expected that in 2011 the 'Safeguarding America's Pharmaceuticals Act' will be re-introduced to provide a uniform federal pedigree standard in the U.S.," added Bone. "The Bill will pre-empt state laws on serialisation and pedigree, and introduce standard pedigree requirements and standardised drug identifiers. In March 2010, the FDA published the guidelines for Serialized Numerical Identifier (SNI) as required by the FDA Amendments Act."

A small number of manufacturers in the U.S. have moved forward with serialisation projects. McKesson is currently working with seven manufacturers to test RFID and bar code reading on pallets and cases, as well as RFID and 2-D bar code reading on individual bottles. Pilots need to test serialisation at the unit, case and pallet levels, inference (serialised units aggregated into a case and cases aggregated into a pallet), and pedigree data exchange."



"We have made progress, but there is still much to do to facilitate traceability," concluded Staver, "We must have serialisation, processes must be modified, standards must be completed and solutions must be tested and deployed. Industry wide engagement and investment is required."

Pfizer and McKesson actively support GS1 working groups developing global standards for serialisation and traceability.

AstraZeneca implements track & trace solution

AstraZeneca has taken a multi-faceted approach to combating counterfeiting and ultimately improve patient safety. Implementing standardised item level serialisation – in combination with tamper evident packaging – was identified early on as a powerful approach to respond to these challenges. Axway's Track & Trace solution was chosen as the unique product number repository to achieve these goals, now handling close to 100 million serialised product data records.



"[This solution] enables us to benefit from moving to the GS1 standards-based system EPC Information Services (EPCIS) that reduces the cost and complexity of complying with regulations," added Christoph Krähenbühl, IS program manager, pack coding and product security at AstraZeneca Global Operations Information. "As part of our global programme, we have staff who are dedicated to monitoring all of these requirements, whether they are legal, regulatory or supply chain driven. Even though we have recently seen a surge of such requirements, we have not yet met a requirement that our adaptable, standards-based solution cannot handle."

[Read more](#)

Serialisation - Return on Investment?



In his RxTrace blog, Dirk Rodgers dedicated an article on how to achieve a Return on Investment (ROI) with serialisation in the pharmaceutical supply chain. Here is his way to look at serialisation ROI: "It seems intuitive that there should be an ROI because serial numbers provide increased data granularity and accuracy, but those characteristics in themselves do not guarantee a positive return. For that, you must figure out a way to take advantage of those things in a way that increases productivity through decreased errors and reduced physical handling... My suggestion is to view the ROI through the lens of the regulatory requirements... Manufacturers could choose to

stop supplying drugs in the markets that mandate them. Of course, that would cause a reduction in their revenues and could allow competitors to gain market share in those markets. So the ROI for manufacturers comes from avoidance. For most companies, that's a return that is not small.

Dirk Rodgers currently works within the U.S. pharmaceutical supply chain as a Sr. Consultant in IT. He is contributing to several GS1 working groups, and served in the past as the co-chair of the GS1 EPCglobal Drug Pedigree Messaging work group.

[Read more](#)

EFPIA updates anti-counterfeiting white paper



EFPIA first issued its White Paper on "The Anti-Counterfeiting of Medicines" in November 2005. In November 2010, EFPIA published an updated white paper to reflect ongoing developments and include conclusions from the Coding Pilot Project in Sweden.

EFPIA supports the principle of applying safety features on the outer packaging. To protect patients from counterfeit medicines, the basic level of security on all prescription only medicines should be a combination of tamper-evident packaging and a unique code for each medicine pack, based on one harmonised coding solution across Europe. A unique serial number would enable pharmacists to verify each pack at the point of dispensing thus making a significant contribution to greater product security and patient safety. Supply chain controls should ideally be harmonised between countries to minimise complexity and cost, for all pharmaceutical manufacturers.

EFPIA recommends encoding a GS1 Standards-based identifier in a 2D DataMatrix bar code.

[Read more](#)

EDQM advances pharma traceability

"EDQM proposes a track & trace solution for pharmaceutical products whereby the manufacturer assigns a Unique Medicine Identifier (UMI) and whereby the UMI can be verified by the pharmacist, the patient, customs or other stakeholders," said Dr. François-Xavier Léry, Scientific Officer, European Directorate for the Quality of Medicines and Healthcare (EDQM), Council of Europe, at last year's GS1 Healthcare Conference in Geneva. "In March 2010, we completed the first phase of collecting user's and business

requirements. UMI will use a GS1 Identification Key and GS1 Application Identifiers for the serial number, expiry date, lot number and possibly for a national code."

At the IQPC Pharma Serialisation and Traceability conference in November 2010, Dr. Léry provided an update: "We are in the process of inviting pharmaceutical manufacturers to participate in the pilot by providing sample packs and possibly interfacing the system with their own IT systems." Meanwhile, there are a number of other uncertainties to consider. "Cost is likely to be a major constraint, as the scale of the project is huge," added Dr. Léry. According to an impact assessment undertaken on behalf of the European Commission, there are around 15,000 pharmaceutical packaging lines in the EU which would have to be upgraded at an estimated cost of €11.5 billion. "Having a harmonised, coordinated and phased approach to serialisation at a European level may allow balancing out of the cost via economies of scale," said Léry.

[Read more](#)



INTERPOL seizes counterfeit medicines

In October 2010, more than 40 countries took part in an international week of action, targeting the online sale of counterfeit and illegal medicines to raise awareness of the associated health risks. This resulted in arrests across the globe and the seizure of thousands of potentially harmful medicines. Over 1 million illicit and counterfeit pills were confiscated valued at US\$2.6 million - including antibiotics, steroids, anti-cancer, anti-depression and anti-epileptic pills, as well as slimming or food supplement pills.

[Read more](#)



GS1 collaborates with EAASM

"The European Alliance for Access to Safe Medicines (EAASM) has been formed by a cross-section of European patient safety stakeholders from a variety of backgrounds," said Jim Thomson, Chair, EAASM. "We are committed to protecting patients from fake medicines and what unites us is the desire to combat the inexorable rise in medicines counterfeiting in Europe. Only a fully integrated approach to combating counterfeits will ultimately protect patients."

Because of their mutual interest in patient safety, GS1 has become a member of EAASM, and EAASM has become a member of our global Healthcare user group.

[More information](#)

Counterfeit medicines week in the Philippines

The Philippine Department of Health (DOH) estimates that 10% of the local drug market today, is counterfeit. The third week of November 2010 was declared the 'National Consciousness Week against Counterfeit Medicines,' which aimed to raise public awareness on the harmful effects of fake drugs. "The public will be made more aware of the harmful effects of fake medicines," said Dr. Maria Minerva P. Calimag, Chair of the Food, Drugs and Cosmetics committee of the Philippine Medical Association, "It will also strengthen efforts to continuously call for action to protect the welfare of Filipino patients".

Managing brand protection as part of global risk

Motivated by patient safety concerns, the pharma and biotech industries have been addressing the issues of counterfeiting for many years. A panel hosted by Cambridge Consultants at BIO 2010 highlighted the regulatory, technical and business responses to these problems. The panellists considered technology to be an integral part of a brand protection system. In the case of medications, three different types of technologies are employed (anti-tamper, serialisation and authentication) to provide a layered protection system. There is now a drive towards regulations, which are technology independent, but with standards applied to key measures, such as serialisation using GS1 Standards for product coding for pharmaceuticals.

"... unlike the format wars between BetaMax and VHS tapes, or more recently with Blu-ray and HD discs, a pharmaceutical or biotech company cannot tolerate investing in one technology, only to have the industry decide that another is the preferred one", added one panellist.

[Read more](#)



Risk-based remedies for pharma supply chain security concerns

BSI, the British Standards Institution, estimates worldwide annual cargo theft loss for 2010 was US\$20.5 billion. BSI consistently rates pharmaceutical theft as the top targeted commodity in the U.S. and in many other countries. A single heist can net big profits for criminals. In March 2010, thieves stole drugs, including painkillers and antidepressants, worth an estimated US\$75 million from an Eli Lilly and Company's distribution centre in Enfield, Connecticut.

"Despite recent advances in security practices throughout the industry, pharmaceutical supply chains across the globe continue to be subject to alarmingly high levels of theft and product counterfeiting", writes Dan Purtell of the BSI Group, in his white paper 'A risk-based remedy for pharma supply chain security concerns'. "Manufacturers and distributors are investing in counter-measures such as improved product tracking technologies, but fail to account for the full breadth of potential risk within the supply chain." The white paper elaborates on how to develop a risk-based, methodical approach to security that provides end-to-end protection against cargo theft and counterfeiting.

[Download the white paper](#)



Looking for more information?



[SecuringPharma.com](#) is a free-to-access information service that covers the issues surrounding supply chain and brand security in the pharmaceutical industry. It is a central source of breaking news, market intelligence and technical information on supply chain integrity.

Other resources include:

[Center for Medicine in the Public Interest](#)
[European Alliance for Access to Safe Medicines](#)
[Fondation Chirac](#)
[Partnership for Safe Medicines](#)
[Pharmaceutical Security Institute](#)

GOVERNMENT AND REGULATORY ACTIVITIES

Australia: The future is eHealth



"Our ultimate goal is working towards a Personally Controlled Electronic Health Record (PCEHR)," said Stephen Johnston, Head of Product & Solutions Development, National E-Health Transition Authority, Australia. "The Federal Government announced in the May 2010 budget funding of AU\$466.7 million for PCEHR which will revolutionise the delivery of Healthcare in Australia. Australians will be able to check their medical history online."



"The National Product Catalogue (NPC) will enable the accurate identification of medical products administered, implanted, used in procedures etc. This information will add to other important information held in a patient's PCEHR," added Ken Nobbs, Program Manager, Medical Products, NEHTA. "NPC is our data synchronisation solution established by NEHTA in March 2006 and hosted by GS1net, using the GS1 GTIN as the standard identifier, with a standard data set. Over 150,000

products from 300 suppliers have already been registered in the NPC."

"The NPC will not only enable the PCEHR programme, but is already used today to improve supply chain management, tendering and eProcurement," concluded Nobbs. "It will also enable improvements of reimbursement processes, product recalls and medications management."

Canada: Major vaccine identification initiative launched

A Cost Benefit Analysis (CBA) indicated that the implementation of GS1 bar codes on vaccines will generate cost-savings of more than CA\$900 million over a 20 year period in Canada. The CBA also found that the implementation of GS1 bar codes on vaccine products would result in significant time savings (bar code scanning vs. manual entry), improved immunisation record completeness and accuracy, reduction in supply shortages and improved supply chain management.

"Studies have shown that between 5 to 15% of immunisation records are missing important information and up to 24% contain errors," said Dr. Monika Naus, Associate Director, Epidemiology Services, British Columbia Centre for Disease Control. "A streamlined vaccine identification system will allow Healthcare workers to better maintain and ensure accurate, up-to-date immunisation records."

Collaboration between the Public Health Agency of Canada (PHAC), vaccine manufacturers, stakeholders and GS1 Canada on the Automated Identification of Vaccine Projects (AIVP) initiative has resulted in a collective endorsement of a Consensus Statement on the use of GS1 Standards for vaccine identification in Canada.

"A national protocol for identifying vaccines using globally standard bar codes will without question improve efficiencies and reduce errors throughout the Canadian Healthcare system," said Dr. Robert Van Exan, Director, Immunization Policy, Sanofi Pasteur Limited.

[Read more](#)



France: GS1 DataMatrix now required

As per the French regulation, all medicines sold in pharmacies must now have a GS1 DataMatrix bar code on the sales box, containing a GS1 code, lot number and expiry date.

The regulation also requires that an electronic Dispatch Advice message will be used to enable product traceability. Logistic units should be identified with the Serial Shipping Container Code (SSCC) and GS1 EANCOM DESADV (dispatch advice message).



Hong Kong: Targeting world class eHealth

"A recent recall of a hip replacement systems impacted eight hospitals and over thirty patients in Hong Kong," said Raymond Wong, Head of the Business Support Services, Hong Kong Hospital Authority, "It took two weeks to track the products and patients; one week for the sales record and another week for the procedure record. We need to enhance traceability to support patient and product recalls. We need to collaborate to make this happen."



"We support the adoption of global standards, including GS1 Standards," added Wong, "Product codification and classification is central to all integration. Our Product Codification & Classification (PCC) model supports global data synchronisation, and we engage suppliers to enable data sharing and ensure item data maintenance by supplier. This will support integration with clinical systems and EHR and facilitate responding and managing product recalls."

Japan: Bar coding of all medical devices required by March 2011



"It is inevitable that defective products are entering the Healthcare supply chain, and we need to accurately identify and retrieve them," said Kazuhiko Mori, Chief Safety Officer, PMDA (Pharmaceuticals and Medical Devices Agency) at the GS1 Japan Seminar on Unique Device Identification held in Tokyo on 5 November 2010. "It is important to uniquely identify each medical device or drug at its smallest unit. Bar coding is very useful for this purpose, however, cost, standardisation and scope and timing of implementation have to be considered to effectively secure patient safety. New technologies, such as RFID, should also be pursued. If

it can be attached on high risk implantable devices, it could contribute much for the traceability of the devices."

"The Japanese Ministry of Health, Labour and Welfare (MHLW) has been promoting bar coding of medical devices to enable an efficient and smart supply of medical devices, to ensure traceability, and to prevent medical errors," said Hideaki Kondo of the Economic Affairs Division of the MHLW Health Policy Bureau. "The MHLW issued the Guideline for Barcode Marking on Medical Devices on 28 March 2008, which requires all medical devices to have bar codes by March 2011. We have been collaborating, and will continue to collaborate, with the Japanese Federation of Medical Device Associations (JFMDA) for a smooth implementation of the guideline by the industry".

"JFMDA has been promoting standard product codes and bar codes based on GS1 Standards since 1999 in close collaboration with MHLW," added Seiji Tsumugi, Information & Technology Promotion Committee, JFMDA. "After the issuance of MHLW Guideline for Bar Code Marking, the rate of bar code marking on medical devices is steadily increasing and now it exceeds 80%."

Singapore: IT in hospitals - Turning ideas into action

"By 2030, one in five Singaporeans will be over sixty five, so the pressure on the Singapore Healthcare system is set to increase," said Colleen Brooks, Principal Standards Information Systems Division, MOH Holdings (MOHH), Singapore, "Our strategic vision is to move patients seamlessly across the Healthcare system enabled by a Electronic Health Record (EHR) system. MOHH Information Systems Division (ISD) provides leadership in setting strategic direction for Singapore's national health informatics strategy."

"The cost-benefit analysis in our 10 year investment strategy indicated that the EHR programme, if implemented as assumed, would cost about SG\$1.3 billion (in present value), but generate SG\$1.9 billion (in present value) in benefits over the next 10 years," added Brooks. "Preliminary analysis of ongoing EHR benefits suggests that about 40% of the benefits are a result of better medication management, predominantly from avoidance of adverse drug events. To ensure clinical data included in the EHR can be shared and exchanged safely and reliably, internationally recognised standards need to ensure interoperability."



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THE **un**SUMMIT for BEDSIDE BARCODING

UK: DoH reviews 'Coding for Success'



"Coding for Success simple technology for safer patient care" was published by the Department of Health in February 2007. The most significant recommendation was that GS1 Standards should be adopted throughout the Healthcare system in England. Connecting for Health has played a key role, contracting with GS1 UK and initiating a range of demonstrator projects, which have highlighted areas where patient safety can be improved. Over 300 trusts are now registered to receive a prefix from GS1 to underpin their coding strategy.

Although considerable progress has been made to introduce a coding culture to the NHS, overall progress has been slower than expected. In some respects, this is not surprising given that coding is a necessarily complex topic that requires considerable investment, effort and co-operation across a variety of sectors

and partner organisations to progress application more widely across Healthcare to benefit patient safety.

[Download the review paper](#)

USA: Hospital pharmacies to get ready for bar code medication administration

"In 2011, the hospital-pharmacy setting will transform not only into a profit centre, but also a key driver of improved clinical outcomes," said Mark Eastham, senior vice president and general manager, Pharmacy Optimisation and PACT at McKesson. One of the five key hospital pharmacy trends for 2011 identified by the McKesson Pharmacy Optimisation Team is the rollout of bar code medication administration systems.

Bar code medication administration at the bedside will loom large. With the 2013 horizon for bedside scanning set by the American Recovery and Reinvestment Act (ARRA), hospitals will need to achieve 100% bar code readiness. Many hospitals are turning to pharmacy experts for bar code readiness evaluations and customised recommendations to attain 100% dispensing of bar coded medications.

[Read more](#)

Australia: CH2 implements logistics labels and eInvoice



CH2, Australia's largest wholesaler and distributor of Healthcare products and services, picks, packs and ships three million units per month. "Our order fill rates are now consistently above 97%," said Ged Halstead, Chief Information Officer, CH2, "Of over 40,000 orders per month 70% are placed electronically. This allows us to take costs out of the supply chain. GS1 Standards have allowed us to improve data quality, and thus improve inventory accuracy and reduce pick errors."

"CH2 has worked with customers to implement the Serial Shipping Container Code (SSCC) and Dispatch Advice," added Halstead, "This has allowed us to speed up the receiving of goods into the receiving locations. For example, it is estimated that Dispatch Advice enables between 25% to 45% faster receipting and put away. We now want to work with the suppliers to get SSCC and Dispatch Advice from them."

In 2009, CH2 won the Australian Supply Chain Logistics Association Award for Information Management and in 2010, the Logistics Magazines Mercury Award.

Canada: Ontario Hospital Association endorses GS1 Standards

"The Ontario Hospital Association (OHA) supports the



adoption of GS1 Standards throughout Ontario's hospitals. Global standards improve efficiency, visibility and safety in supply chains, including; providing the foundation for a central repository of product information for supplies used throughout Ontario hospitals," stated Mr. Tom Closson, President and CEO, OHA. "Access to such timely, accurate and trusted data will contribute significantly to a safer, more patient-focused, sustainable and efficient Healthcare system."

Representing 154 public hospitals across the province, the OHA joins a growing number of organisations in Canada and globally that are supporting the worldwide Healthcare sector movement towards adoption of GS1 Standards.

[Read more](#)

Canada: St. Michael's Hospital pilots EDI

With Phase 2 of the Canadian Healthcare Supply Chain Standards Project, focused on standards implementation, steadily moving forward, the first Electronic Data Interchange (EDI) pilot began with St. Michael's Hospital in Toronto, Ontario. This pilot includes the participation of several vendors/distributors, such as Cardinal Health and Medical Mart Supplies Ltd.

With assistance from their third-party facilitator, Rogue Data Corporation, St. Michael's Hospital is sending electronic purchase orders, which contain incoming Global Standard GS1 GTINs (Global Trade Item Numbers) and GLNs (Global Location Numbers). This pilot project is expected to continue into 2011, with a report on the findings distributed within the first quarter of 2011.





Global: J&J continues GS1 Standards adoption

"Our objective is to print GTINs on packaging of all medical devices by year-end 2012," said Dr. Ajit Shetty, Corporate Vice President Enterprise Supply Chain, Johnson & Johnson, "57,000 GTIN's have been assigned to date to medical devices. For pharmaceutical products, we already use GTINs to meet FDA requirements and requirements in the EU. We have also initiated a GSDN project for medical devices, and are currently piloting EPC/RFID. In Belgium, we are piloting GS1 DataMatrix with one of our customers, AZ St.-Jan Brugge-Oostende."

"In a survey conducted by Johnson & Johnson Health Care Systems Inc. in the U.S., J&J customers showed a strong interest to move towards global data standards", added Dr. Shetty, "Customers rated 'interest in moving towards global data standards' 4.5 (on a scale of 5.0), so they are extremely interested". One customer added: "We're going to have one number for each product, so we're going to be able to find products a lot easier. There will be a safety impact. We're going to be able to do data analysis quicker when we compare products, so all the products are going to match."

Global: Cook Medical implements GS1 Standards



"We started our standardisation process ten years ago and implemented one global system for product identification," said Claes Wallér, Vice President Cook Group Europe and Board Member of Eucomed, "GTINs were used for our Computer Part Numbers and are used to identify our

380,000 catalogue items from order to user. However, today, very few hospitals have the capability to track inventory by GTIN and to trace materials all the way down to the patient chart. We have also assigned Global Location Numbers

(GLNs) to each company, which allows us to transact orders electronically, using GLNs' that our customers provide to us. We can associate each order with a specific location to deliver the product to."

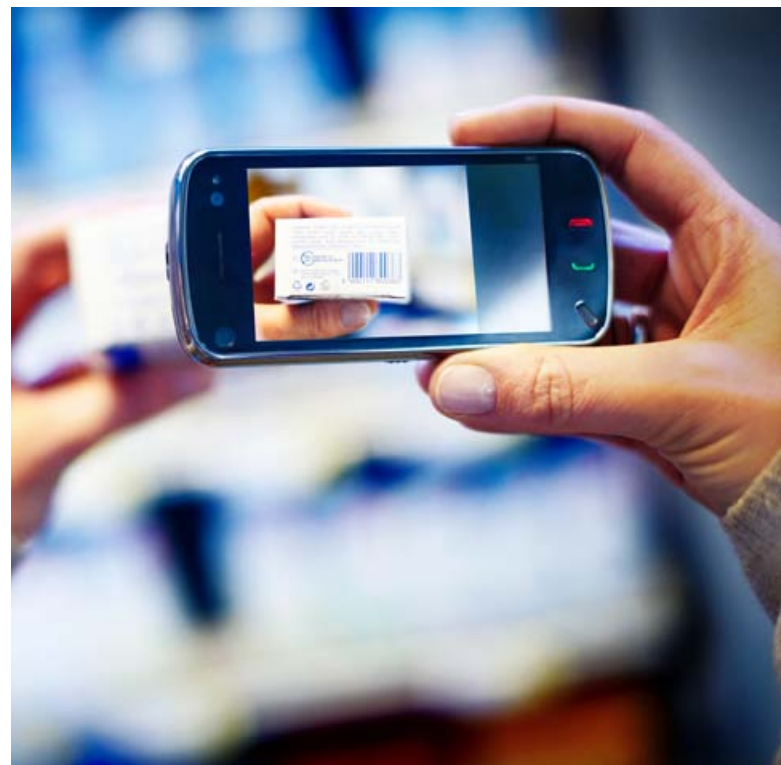
"Sharing medical device information through the GSDN and transferring information seamlessly down to the patient allows us to be more efficient through better inventory control and better visibility of products in the supply chain," added Wallér. "More importantly, it will improve patient care. Cook will be uploading records for its 25,000 products into the GSDN, to identify each product, and make it available to its customers at no extra cost."

Global: 500 million users of Mobile Health Apps by 2015

Within the next five years, about 500 million individuals will be using mobile Healthcare applications (Apps) on their smart phones, according to a new report produced by research2guidance "Global Mobile Health Market Report 2010-2015". The report estimates that there will be 1.4 billion smart phone users by 2015 and that more than one third of them will have a health-related App. Currently, about 43% of mHealth applications are primarily designed for Healthcare professionals.

[Read more](#)

GS1 has a cross-sector work group on how GS1 Standards can enable mobile communications leveraging GS1 Identification Keys and GS1 BarCodes. [Read more](#)



Japan: Innovating the Healthcare supply chain



"In Japan, bar coding of medical products by suppliers is going relatively well, however, using the bar codes in hospitals is still very limited," said Prof. Shigekoto Kaihara, Dean, Graduate School International University of Health and Welfare. "Some pioneering hospitals have been successful in improving patient safety and hospital operations by implementing advanced bar

code and RFID systems. At the National Center for Child Health and Development in Tokyo, all rooms have been equipped with touch screen displays that can be used by caregivers to retrieve patient data and input data using a bar code scanner. They can also be used by the patients as television screens. At Akita University Hospital on the Island of Honshu, RFID tags are embedded into the patient's wristband and in the nurse's nametag. The scanner can read both bar code and RFID. The hospital is currently experimenting with infusion stands equipped with an RFID antenna automatically reading the RFID tag on the infusion bag."

"To ensure wide acceptance in hospitals of such advanced systems and the necessary standards, hospital staff need to recognise that bar codes are useful for patient safety and hospital management needs to invest in these technologies," concluded Prof. Kaihara. "The local GS1 Healthcare user group in Japan drives the adoption of GS1 Standards in the Japanese Healthcare sector."

We deeply regret to announce the sudden death of Prof. Kaihara. The GS1 Healthcare community lost a prominent advocate: Prof. Kaihara was a recognised opinion leader in the Japanese Healthcare sector, and as Chairman of GS1 Healthcare Japan, has contributed significantly to the progress made on supply chain standardisation in Japan. He was Professor Emeritus at the University of Tokyo, Dean of the Graduate School, International University of Health and Welfare, former Chairman of IMIA (International Medical Informatics Association) and of JAMI (Japan Association for Medical Informatics). Our thoughts are with his family at this difficult time.

Japan: Osaka University Hospital traces surgical instruments

"In October 2005, we started to mark two-dimensional DataMatrix bar codes directly on the surgical instruments for laparotomies. For the containers and inner baskets of

sterilisation devices, we have developed heat-resistant metal-compatible RFID tags," said Dr. Seizo Nakata, Director, Itami Municipal Hospital, and Former Director of Surgical Center, Osaka University Hospital, Japan, "We then verified the performance of our surgical instrument traceability system featuring the sterilisation management function using GS1 DataMatrix. The reading verification proved that the laser marked DataMatrix bar codes could be read by our hand-held reader without any problems. Furthermore, the time required to read the DataMatrix bar codes marked on eighty-eight surgical instruments in one instrument set tray was between 5 and 7 minutes, including the time required for human action, which is short enough for practical use."



USA: Mayo Clinic transforms to meet patient expectations

"Now is the time to think about changing the Healthcare supply chain," said Joe Dudas, Director of Accounting and Supply Chain Informatics, Mayo Clinic, USA, "Our patients expect us to provide solutions and hope, and provide trusted and affordable care. This means we need to improve the safety and security of our supply chain, and significantly decrease its cost."

"To improve the quality of our information, and use it to work together, we need to integrate information," added Dudas, "Just two elements (GTIN and GLN) allow us to connect the SCM (Supply Chain Management), the Enterprise and the Industry. Mayo Clinic started its adoption plan for GS1 Standards back in 2008, setting our organisational goals: eliminate custom account numbers and eliminate custom product numbers. We also educated internal and external stakeholders on the requirements of the U.S. GLN 2010 Sunrise. In 2010, we ramped up on GLN with several suppliers, and we have started to educate internal and external stakeholders on the requirements of the U.S. GTIN 2012 Sunrise. Our next steps in 2011 are the launch of Lawson 9.0.1.4 with standard GS1 functionality, establishing GLN as the norm and testing GTIN in a pilot with a supplier."

Mayo Clinic was recently named Top Hospital by the Leapfrog Group. The 2010 Top Hospitals list — 65 from a field of almost 1,200 — is based on the results of The Leapfrog Group's national survey that measures hospitals' performance in crucial areas of patient safety and quality.

[Read more](#)





USA: BJC HealthCare implements GS1 Standards

BJC HealthCare (BJC), one of the largest non-profit Healthcare organisations in the U.S., includes 13 hospitals and multiple community health locations. Like many U.S. Healthcare organisations, BJC has been confronted with a number of economic and operational challenges in recent years - an increase in patients without insurance, reductions in Medicare reimbursement and reform legislation that requires tracking of medical product usage at the point-of-care.

BJC has adopted GS1 Standards to not only address current challenges in operational management and patient care, but also to set the stage to achieve the "Ultimate Solution" - an integrated network of systems through which the Healthcare industry could track product usage and patient outcomes and automate all the supply chain processes to increase operational efficiency, reduce costs and improve patient care.

[Download the BJC Case Study](#)

USA: Survey on standards adoption progress



In a survey conducted by the Center for Innovation in Healthcare Logistics (CIHL), over 68% of respondents indicated that they are moving towards the adoption of a data standards system in the next five years, this is up from 35% in the 2008 survey results with 90% of them are moving towards GS1 adoption. The survey was completed by 678 Healthcare supply chain professionals, of which about 60% were Healthcare providers.

Obstacles to implementing data standards include other higher priority initiatives (37%), Information Technology (IT) system limitations (25%), lack of funding (25%), lack of organisational understanding of the level of effort required (25%), and lack of IT resources (24%).

USA: GPOs announce readiness to adopt standards to identify locations

Moving months ahead of the Healthcare industry's own ambitious schedule, group purchasing organisations announced readiness to adopt standards for Healthcare provider locations in October 2010. The Board of Directors of the Health Industry Group Purchasing Association (HIGPA) have unanimously agreed to a Declaration of Readiness, noting they are prepared to adopt Global Location Numbers (GLNs) to identify precise locations for every Healthcare provider in the United States.

"This is a quiet change that will have an enormous impact," said HIGPA President Curtis Rooney. "Right now, there is no reliable system in place, to know where essential Healthcare providers are located. The adoption of GLNs by GPOs is the first step toward ensuring that the right products are delivered to the right location. It is important all Healthcare supply chain entities also adopt these standards. The next step will be the implementation of Global Trade Item Numbers (GTINs) by 31 December 2012."

[Read more](#)

GS1 HEALTHCARE UPDATE

GLOBAL



Axway and GHX join GS1 Healthcare



(Continued from page 1)



"Extending our U.S. membership to a global level with GS1 Healthcare is something we have wanted to do for some time. Previously software vendors could only apply for national membership in GS1 working groups. When GS1 opened the door to global membership, we embraced the opportunity to start to set the agenda and improve patient safety on an international scale. Axway has invested a lot of time in standardisation efforts, underscoring our deep commitment to international standards," said Dave Bennett, CTO of Axway.

J. Michael Wallace, Director, Global Standards & Serialisation, Abbott Laboratories, and Tri-Chair of GS1 Healthcare, elaborated, "We are at the point where we will have started the process of moving the GS1 Healthcare standards from development to implementation to meet various requirements, traceability in particular. During this process, it is critical that we have the active participation and leadership of solution providers who can bring their systems integration experience to bear. The GS1 Healthcare Leadership Team is excited to have Axway as our first solution provider partner for Healthcare.

The traceability experience they bring to the GS1 Healthcare effort will be extremely valuable as we move our focus towards implementation."

[Axway joins GS1 Healthcare - Read more](#)

[Global User Group Membership - Read more](#)

Other new members include:

- Barema, the trade association for anaesthetic and respiratory equipment suppliers (www.barema.org.uk)
- Becton Dickinson & Co. (www.bd.com)
- EAASM, the European Alliance for Access to Safe Medicines (www.eaasm.eu)

Global Healthcare user group to meet in Washington DC

From 6 to 8 April 2011, GS1 Healthcare will host its 19th global conference, themed "UDI Meets Pharma Security", in the Washington DC Metro Area. Participants from around the world join these conferences to gather the latest on industry and regulatory developments in automatic identification, traceability and electronic product catalogues, leverage a unique neutral and international platform to network and benchmark with other stakeholders from around the world, and learn more about existing supply chain data standards.

[Read more](#)



GS1 interviews key stakeholders



How will GS1 Standards help to meet today's Healthcare supply chain challenges? GS1 has interviewed thirteen key stakeholders from all over the world and representing all different perspectives.

[View the video](#)

GS1 hosts educational session at HL7 International meeting



GS1 has been working with HL7, since 2007, to explore and understand how our standards interoperate and complement each other. HL7 working groups meet three times per year in various locations. The first 2011 International meeting was held in Sydney, Australia from 9 to 14 January. On the Thursday, GS1 hosted an educational session on GS1 Standards

for the HL7 community. This session provided background on GS1 Standards and how these provide benefits in the eHealth environment, leveraging the example of the HL7 CDA implementation guide in Switzerland. The session also illustrated how GS1 works with HL7 and with other Standards Development Organisations.

22 of Gartner Top 25 participate in GS1 user groups

Gartner, a world's leading information technology research and advisory company, has recently published its Healthcare Supply Chain Top 25 ranking organisations striving for supply chain excellence and better patient care. "Leadership in the Healthcare value chain requires a laser focus on enhancing internal supply chain capabilities and a relentless pursuit of joint value with trading partners," said Wayne McDonnell, Research Director at Gartner.

[Read more](#)

Twenty-two out of the top 25 are member of the global or US GS1 Healthcare user group and support the development and adoption of GS1 Standards in the Healthcare sector.

GS1 welcomes any stakeholder to help shape the future of the Healthcare supply chain leveraging global standards. Join the global or a local user group

Public Policy Work Group publishes Traceability White Paper

The Public Policy Work Group has developed a white paper on Healthcare supply chain traceability to provide more information to entities considering or planning the implementation of traceability systems. The benefits and limitations of the different traceability models are considered, and more information is provided about the GS1 process and technical standards that enable such traceability systems. The white paper concludes with GS1 Healthcare's recommendation to implement "contextually appropriate" traceability systems.



[Download the white paper](#)

Public Policy Database - New features added

Initially created in May 2010, the database compiles country specific information on regulations and requirements for different product types. The database currently contains over 110 dossiers from 83 countries.

Among the new features is the possibility for all users to submit a change request, which is automatically sent to the administrators. The home page now clearly lists all the dossiers that have recently been created or updated. To enhance the search function, additional query options, including "data carrier" and "data requested", have been added, or you can browse the library with all documents listed per country. More information can be added to the dossiers, including for example information on e-Commerce impact areas such as GLN or EDI.

The Public Policy Database is accessible to global GS1 Healthcare members and GS1 Member Organisations. [Access the database](#)

For more information, contact: emilie.danel@gs1.org

COUNTRIES

Argentina: First Healthcare Traceability Seminar

On 14 October 2010, GS1 Argentina hosted the first Healthcare Traceability Seminar presenting the latest developments on traceability in the Healthcare sector. The seminar featured local and regional industry benchmarks, including speakers from Eurofarma, ANAHP (the Brazilian association of private hospitals), Axxa Pharma, SSMOCC (the Western Metropolitan Health Service of Chile), and more.

Belgium: First Healthcare Day

On 18 October 2010, GS1 Belgium & Luxembourg organised its first 'Healthcare Day' hosted by the Military Hospital of Neder-Over-Heembeek. Over 200 delegates participated in this seminar themed "Improving patient safety and patient care using GS1 Standards" and chaired by Dr. Ajit Shetty, Corporate Vice President Enterprise Supply Chain, Johnson & Johnson. Speakers included representatives from pharma.be (the Belgian association of pharmaceutical suppliers), APB (the Belgian association of pharmacies), EAHP (European Association of Hospital Pharmacists), and more.

Canada: Second National Healthcare Industry Meeting

GS1 Canada's second annual National Healthcare Industry Meeting was held on 27 October 2010 at the Toronto Convention Centre, where Canadian Healthcare sector representatives convened to learn about next steps for modernising the Healthcare supply chain. With over 140 Healthcare supply chain professionals in attendance they were provided with pointers and direction on implementing Global Trade Item Numbers (GTINs) and Global Location Numbers (GLNs) by the fast-approaching industry-established timelines.

France: Hospitals meet solution providers

On 18 January 2011, GS1 France hosted a meeting bringing together the Commission Logistique Hospitalière (the French hospital logistics committee) and solution providers to discuss how GS1 Standards can be leveraged to improve hospital logistics and enable traceability solutions. The objective was to develop a charter of best practices for hospital warehouse management systems.

Germany: Healthcare Live!

On 28 and 29 October 2010, GHX Europe and GS1 Germany co-hosted a two-day conference in Cologne on process optimisation and cost efficiency in the hospital. Visions and best practices from various stakeholders were presented, including EK-UNICO (German Group Purchasing Organisation), B.Braun, the university hospitals of Freiburg, Heidelberg, Münster, Düsseldorf and Dresden, and many more.

Japan: UDI seminar

On 5 November 2010, over 160 stakeholders participated in GS1 Japan's seminar on Unique Device Identification, held in Tokyo. Kazuo Ogino, Chairman of the Japan Federation of Medical Devices Associations (JFMDA) opened the seminar and welcomed Jay Crowley from the US FDA; other speakers included representatives from the Ministry of Health, Labour and Welfare, and the Japanese Pharmaceuticals and Medical Devices Agency.



New Zealand: Australasia user group meets in March

Following successful meetings in Australia, the GS1 Healthcare User Group - Australasia (HUGA) are holding their next conference on the 2 March 2011 in Wellington, the first time it has been held in New Zealand. GS1 New Zealand and GS1 Australia will bring together key Healthcare sector representatives.

[Read more](#)

Switzerland: Third Healthcare Forum

On the 3 November 2010, GS1 Switzerland hosted its third Healthcare Forum, focusing on how to improve efficiency in Healthcare. Switzerland has excellent Healthcare, but that comes at a cost: 55 billion Swiss francs. About 1.5 billion Swiss francs are being invested in Healthcare IT. The Forum covered how GS1 Standards enable the automatic capture of product information to facilitate Diagnosis-Related Group (DRG)-based financing.

UK: ABHI and GS1 UK host UDI Conference in February

In recognition of the huge importance of developments with Unique Device Identification (UDI), the Association of British Healthcare Industries (ABHI) and GS1 UK are running a joint event on the 15 February 2011 in London. The conference will cover developments in Europe and the USA along with an assessment of their impact on industry. Also on the programme is UDI in Patient Safety, the Clinical Environment and the Hospital Supply Chain. Finally, there will be a look at industry implementation as well as a case study from the retail sector.

[Read more](#)

USA: Workgroup Forum

From 4 to 6 April 2011, GS1 Healthcare US will host its Workgroup Forum in the Washington DC Metro Area, co-located with the Global GS1 Healthcare Conference. This forum provides the opportunity to collaborate face-to-face in workgroup sessions on product identification, location identification, GDSN, traceability adoption & 2015 Readiness Program, and application & implementation.

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