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Special feature: 24th GS1 Global Healthcare Conference

San Francisco welcomes the 24th Global GS1 Healthcare Conference

The 24th global GS1 Healthcare Conference took place in San Francisco during the first week of October and brought together over 280 participants from over 40 countries. During the three-day conference, healthcare professionals demonstrated the benefits and essential role that GS1 Standards play in today's healthcare supply chains.

This year's conference was particularly exciting as it took place just a couple of days after the U.S. Food and Drug Administration (FDA) issued the final rule on Unique Device Identification (UDI), which was the main topic of the first conference day. Leading healthcare supply chain stakeholders gave their perspective on UDI and the expected impact on their organisations: Premier (Joe Pleasant), McKesson Corp (Ron Bone), Johnson & Johnson (Tom Werthwine).

Traceability was a very important topic during the second day of the conference. It is presently the focus of many regulatory bodies and pharmaceutical companies who want to limit the proliferation of counterfeit drugs on the market. The floor was first given to regulatory bodies who presented their latest proposals or measures, such as the U.S. FDA, the California Board of Pharmacy and the National Administration of Drugs, Foods and Medical Devices of Argentina.



Benoit Goyens from the World Customs Organisation demonstrated its global anti-counterfeit tool, Interface Public Members (IPM), whilst Grant Courtney representing the European Stakeholder Model gave an update on the status of the European Medicines Verification System. Finally, Brian Johnson from Pfizer presented RX360, a consortium that brings together pharmaceutical and biotech industries in the U.S., with the objective to enhance the security of the pharmaceutical supply chain and to ensure the quality and authenticity of the products moving through the supply chain.

On the third day, participants heard about hospital implementations from around the world: Mercy hospitals from the U.S., Hospital Aléman from Argentina, and others. Presentations also included the implementation pilot of GS1 DataMatrix for vaccines in the U.S., and the work of the World Health Organization's (WHO) Vaccines Presentation and Packaging Advisory Group on aligning the identification and bar coding of vaccines with a proof-of-concept project planned in Tanzania.

For more information on the conference, and to view all the presentations, [click here](#).



Special feature: 24th GS1 Global Healthcare Conference

Are you ready for UDI?



The U.S. Food and Drug Administration (FDA) released a final rule on a Unique Device Identification (UDI) system that, once implemented, will provide a robust identification system for medical devices in the U.S. market.

The UDI system has the potential to improve medical device adverse events reports, which will help the FDA identify product problems more quickly, better target recalls, and improve patient safety. The FDA has worked closely with the U.S. healthcare industry, healthcare providers and patient groups in the development of this rule.

The UDI system consists of the following three core elements:

- The first is a unique number assigned by the device manufacturer to each version or model of a device, called a **unique device identifier**.
- The second component is the **capture of this UDI both in human readable and in AutoID format**. By default, this information will be applied on the label of each device uniquely identified.
- The third component is an online database administered by the FDA, the **Global UDI Database (GUDID)**, which will serve as a reference catalogue for every device with an identifier. The FDA UDI Final Rule includes the list of core data attribute to be stored in the GUDID.

The FDA is setting up a gradual implementation plan based on a risk-based approach.

- The first compliance deadline will be on 24 September 2014, focusing on high-risk devices (Class III devices under the FDA classification).
- The second compliance deadline will be on 24 September 2015 for life supporting and life sustaining devices, followed by 24 September 2016 for the rest of Class II devices.
- Class I devices will have to be labelled and registered with a UDI by 24 September 2018. The FDA will allow some case-by-case exemptions.

The FDA based its medical device terminology on the Global Medical Device Nomenclature (GMDN) in order to ensure global alignment and understanding by all the healthcare stakeholders. As the GMDN is accepted by all the main organisations (such as the International Medical Device Regulators Forum and 65 national medical device regulators) and thousands of manufacturers worldwide, it guarantees international acceptance.

Once fully implemented, the UDI system is expected to beneficially affect patients, the healthcare system and the medical device industry. It will enhance the ability to quickly and efficiently identify devices when recalled, improve the accuracy and specificity of adverse event reports and provide a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion. It will also offer a clear way of documenting device use in electronic health records and clinical information systems.

For more information,
[click here.](#)



Special feature: 24th GS1 Global Healthcare Conference

IMDRF approves final draft guidance proposal on UDI

The International Medical Device Regulators Forum (IMDRF) is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonisation Task Force on Medical Devices, and to accelerate international medical device regulatory harmonisation and convergence. The current member countries of the IMDRF Management Committee are: Australia, Brazil, Canada, Europe, Japan, and the U.S. The World Health Organization (WHO) is an official observer.

One of the Forum's active work items is the "Roadmap for implementation of Unique Device Identification (UDI) system", currently chaired by Laurent Sellés from the European Commission. This initiative seeks to define the path to implementing a globally-harmonised approach to a UDI system. The objective is for the system to be implemented without regional diversions by different jurisdictions in the world.

The IMDRF work group focusing on this initiative finalised the Draft Guidance Proposal last September, which was then sent to the IMDRF Management Committee for approval. The Committee met in Brussels, and will hopefully come to an agreement and release a final recommendation.

In the quest to improve patient safety worldwide, global traceability is a key contributor making it essential today to implement global solutions.

"It is important that we have harmonised regulations," said Sellés in his video presentation for the Global GS1 Healthcare Conference in San Francisco.

"It will be disastrous for the industry to have to comply with different UDI systems; also for regulators, it would be much more difficult to develop an international traceability strategy without an internationally agreed UDI system and global standards."

For more information, [click here](#).

To watch the video of Laurent Sellés presented at the GS1 Global Healthcare Conference in San Francisco, [click here](#).

Japan's successful UDI implementation

In 2008, the Japanese Ministry of Health developed official guidelines for the placement of standard bar codes on medical devices. The guidelines were established to promote efficient and sophisticated distribution systems, secure traceability, and prevent medical accidents by refining distribution management - from licensed marketing approval holders and manufacturers to medical institutions.



The Ministry requires that companies mark their medical devices secondary packaging with a Global Trade Item Number (GTIN) and also recommends adding a two-dimensional bar code on the primary packaging. The Ministry also highly recommends adding various GS1 Application Identifiers, such as the expiration date, the lot number or the serial number. In order to continuously analyse the current situation, the Ministry has regularly sent out surveys to evaluate the status on the identification of medical devices since 2001.



With that the Ministry can clearly analyse and measure the progress. After more than 10 years, the Ministry can claim that their programme has been very successful: **more than 80% of medical devices are marked on the primary packaging level with a GTIN and up to 98% on the secondary level.** Furthermore, 80% of medical devices are registered in the Japanese MEDIS-DC database, which contains product data about more than 840.000 medical devices.

For more information, [click here](#).



Special feature: 24th GS1 Global Healthcare Conference

Mercy hospitals: getting the most out of UDI

Mercy hospitals, one of the largest healthcare networks in the U.S., wanted to define specific actions to strengthen the post market surveillance of devices through the implementation of UDI. Dr. Joseph Drozda, director of outcomes research at Mercy Health Systems, pointed out that it is crucial to first establish a unique device identification (UDI) system, and then incorporate UDI into the Electronic Health Information (EHI).

In order to link to other data sources, Mercy promotes the development of national and international device registries for selected products. Finally, to improve the adverse event reports and analysis, the reporting method was modernised to simplify evidence generation, synthesis, and appraisal. Mercy is also part of the Medical Device Epidemiology Network Initiative, which aims to develop innovative methods in the area of medical devices to improve and enhance the understanding of device performance. The initiative will provide national/international infrastructure and innovative methodological approaches for conducting robust studies and surveillance. Thus, with a better understanding of the medical device life cycle, through public/private partnerships, medical devices safety and effectiveness will be improved.

Mercy is part of an FDA led initiative which has the following objectives:

1. To integrate UDI in its Electronic Health Records
2. To create data sets containing clinical and device information
3. To link to other health systems and national registries

The initiative consists of gathering all the information received through the U.S. FDA Global Database, the Electronic Health Recodes (EHR), as well as the Integrated Patient Dataset (IPD) to permit Mercy and other healthcare providers to deliver complete post-market device surveillance.

To achieve this, it is indispensable to create partnerships with health systems to establish a harmonised UDI database, in this case with the Healthcare Transformation Group professional societies, national registries, manufacturers and, of course, the FDA.

The initiative started in April 2012, and the working group is currently in the process of optimising the UDI Research Database and analysing its first results from the tests made following various coronary artery operations.

The next step will then be to create a robust system of medical device surveillance and research to support the FDA and physicians to keep patients safe and enhance research on innovative technologies.

For more information,
[click here.](#)

Traceability: an international concern

Traceability and the need to track-and-trace all healthcare products is a high priority for all the stakeholders in the supply chain. In response, many traceability initiatives are underway – not only led by regulators, but also by industry and the healthcare providers.

In Europe, since 2010, the **Turkish Ministry of Health** has set up a Pharmaceutical Track & Trace System, named **ITS** which is able to track and trace all pharmaceutical products in the country. Products are identified with a GS1 DataMatrix, which contains product information such as the Global Trade Item Number (GTIN), serial number, lot number, and the expiration date.

The ability to track each drug unit is achieved by gathering the information of each pack at each point in the pharmaceutical supply chain. The information on the flow of products in the supply chain is then sent and stored in the Ministry's central database, which enables the tracking of every single pharmaceutical product in the supply chain.

Turkey's Pharmaceutical Track & Trace System has proven to be very efficient. Containing more than 7 million drug units and managing over 45 million operations a day, it has clearly prevented reimbursement fraud, limited the number of counterfeit and smuggled drugs in Turkey, and helped to prevent the repackaging of drugs in unknown places.

Last but not least, it allows the pharmaceutical industry to take immediate action as soon as a product recall is needed. Ultimately all stakeholders benefit from the system, with the patient assured that they receive a correct and safe drug, and are billed correctly for it.

For more information,
[click here.](#)



Special feature: 24th GS1 Global Healthcare Conference

In **Latin America**, many initiatives are being set up to fight the increasing numbers of falsified medicines that are brought into the region.

Argentina has, for instance, developed a successful supply chain traceability system to ensure the legitimacy, quality, efficacy and safety of medicines. In 2011, ANMAT introduced a catalogue of drugs covered by its national drug traceability scheme, listing more than 3,000 medicines that require the use of Global Trade Item Numbers (GTINs), as well as unique serial numbers and tamper-evident features on the secondary packaging. The drugs listed are recorded in real-time in a central database managed by the National Administration of Drugs, Foods and Medical Devices of Argentina (ANMAT), which uses Global Location Numbers to locate the various players in the supply chain.

The purpose of this strategy is to actively limit the use of illegal drugs. To this end, ANMAT has shown that the implementation of the system has delivered more than favourable results:

from December 2011 to today, more than 25 million individual packages of medicine (GTIN + Serial Number) have been recorded in the ANMAT Database.

ANMAT is ready to broaden the scope to new drugs and other products, such as medical devices and pharmaceutical raw materials. At this year's GS1 Healthcare Conference, Dra. Heidi Wimmers, chief of pharmacy at Hospital Alemán in Buenos Aires, demonstrated how her hospital carried out the ANMAT traceability system. To implement the traceability system, Hospital Alemán developed a four-step process based on GS1 Standards to manage drug administration. The first step occurs upon receipt of the drug, the hospital staff verifies the origin of the drug and ensures that it is not counterfeit. To do so, the staff scans the GTIN encoded on the drug's secondary packaging and verifies the GLN associated with it in the ANMAT database. The following steps go beyond the ANMAT's regulations: the second step consists of fractioning the drug into single dose units at the pharmacy in the inpatient ward, and then individually repackaging them. In order to identify their content accurately and to simplify its usage, every unit dose is relabelled with a GS1 DataMatrix. The third step involves administering the drug following the five patient rights (right patient, right drug, right route, right time and right dose). To ensure that the patient rights are respected, Hospital Alemán's nurses will scan the drug and verify its legitimacy in the electronic system before administration. The final step is in the patient's hands: he can check whether the drugs he bought are valid. All he needs to do is type the GTIN written on the bill given by the pharmacist, in ANMAT's online portal to verify the drug. Dra. Wimmers concluded that their traceability system is very efficient and has enabled her hospital to create a climate of trust and confidence among all.

For more information,
[click here.](#)



The fight against counterfeit drugs continues

Counterfeit products are a crucial issue that all healthcare takeholders wish to see resolved. In 2010, the World Customs Organisation (WCO) introduced the **Interface Public-**

Members (IPM), an online tool serving as an interface between frontline customs officers and the private sector. IPM is a global anti-counterfeiting tool that allows operational data concerning products to be communicated directly to customs officers on the ground, facilitating the identification of counterfeit goods.

The latest version of IPM offers the possibility to use mobile devices to scan GS1 BarCodes on products, enabling users to search the products database in a more time-efficient manner.

The GS1 BarCode offers three main benefits:

1. a universal pointer to access product data with the Global Trade Item Number,
2. company-related information available on two million registered businesses in 150 countries thanks to the Global Electronic Party Information Registry
3. in the future, it will provide access to the Global Data Synchronisation Network to verify product identity through its registered master data.

The information contained helps the customs agents to distinguish genuine from fake products. The WCO organises five large initiatives to fight counterfeiting a year within different regions. In July 2012, using the IPM tool, the WCO discovered 82 million counterfeit pharmaceuticals goods, which represents a 70% increase in comparison to previous operations without the IPM tool.

For more information,
[click here.](#)



Special feature: 24th GS1 Global Healthcare Conference

On the private sector side, **Rx360**, a not-for-profit consortium led by volunteers from the pharmaceutical and biotech industry, was created. Its purpose is to enhance the security of the pharmaceutical supply chain and to assure the quality and authenticity of the products moving through the supply chain. The consortium's mission is to protect patient safety by sharing information and developing processes related to the integrity of the healthcare supply chain and the quality of materials within the supply chain.

Today, the consortium is made up of 80 top organisations, such as manufacturers, suppliers, auditors and healthcare associations.

For more information,
[click here.](#)

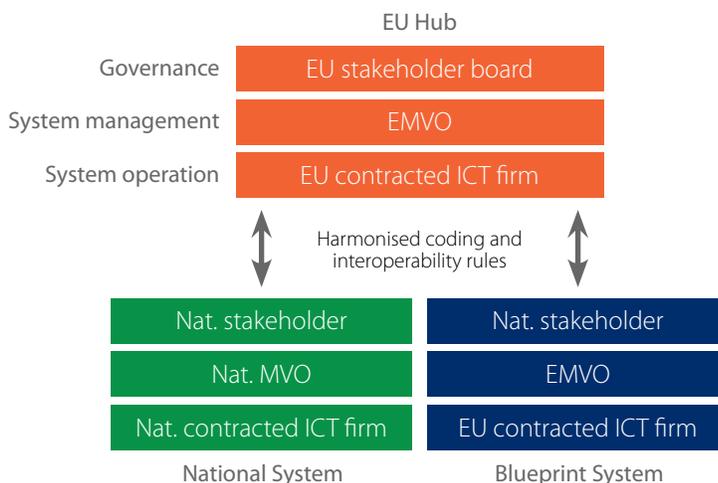
The **European Stakeholder Model** (ESM) was created in 2010 in reaction to the European Commission's Falsified Medical Directive (FMD). It is a partnership of major EU associations which aims to develop a safe, cost-effective and partnership-based pan-European medicines verification system to combat falsified medicines and ensure patient safety.

In 2013, the ESM developed a pan-European system called the European Medicines Verification System (EMVS) that will meet the requirements of the FMD enabling medicines to be verified at the point of dispensing.

The ESM will be operated by a not-for-profit, independent organisation called the European Medicines Verification Organisation (EMVO), governed by representatives from the stakeholder organisations in the EU Stakeholder Board.

The EMVO will:

- develop and control EMVS policies and processes;
- communicate with authorities and broader public;
- establish relationships with national stakeholder organisations;
- oversee development of the European Hub and Blueprint Template;
- provide reports to stakeholders; and
- manage the operation of the Hub and national Blueprint Systems.



The founding principle of the ESM approach is that each pack of medicine is checked individually before it is dispensed to the patient, ensuring that the patient receives a genuine and safe product.

This is achieved through the use of two-dimensional bar codes containing internationally recognised standards, such as the GS1 Standards (GS1 Data Matrix containing the Global Trade Item Number, expiration date, batch or lot number and serial number). By simply scanning the bar code, any unregistered or duplicated code will immediately alert the pharmacist on the possibility of a falsified product.

For more information,
[click here.](#)



Special feature: 24th GS1 Global Healthcare Conference

Product catalogue for procurement in hospitals: an Australian experience



HealthShare New South Wales (HSS), an Australian state-wide organisation, is designed to provide common shared

services while achieving economies of scale and cost savings. HSS is the largest Australian healthcare buyer, averaging around 62,584 purchase orders per month and its central state catalogue include over 200,000 product lines.

For HSS the use of the National Product Catalogue (NPC), which is GDSN® compliant, is essential for an efficient procurement process. It is a way for suppliers to provide standardised, accurate and up-to-date product and price data electronically to the Australian health departments and private hospital through the synchronisation of its data via the Global Data Synchronisation Network. As soon as the NPC data is published, it is received through a system called the Master Catalogue Information System.

The next step will be to establish new connections between the NPC and other specialised data management systems, such as iPharmacy, used for pharmaceutical procurement, dispensing, patient charging, and SurgiNet, used for operating theatre procurement and patient charging.

For more information,
[click here.](#)

GS1 presents HPAC's new awards

Early in 2013, the GS1 Healthcare Provider Advisory Council (HPAC) introduced two types of awards:

- **The Provider Recognition Award**, for an individual who has contributed highly to the GS1 Healthcare work efforts over the years.
- **The Provider Implementation Best Case Study Award**, for provider organisations or individuals who have implemented GS1 Standards for at least one process in their healthcare department or provider (e.g., hospital, clinic, care home, pharmacy) with clear and demonstrable return on investment.

These two awards were presented at the last GS1 Global Healthcare Conference in San Francisco to two exceptional contributors.

Feargal McGroarty received the **Provider Recognition Award** for his long-standing involvement in the promotion and implementation of GS1 Standards. Feargal has a long history with GS1, starting in 2005 with his involvement in the St. James's Haemophilia traceability project. He is also part of the global GS1 Healthcare leadership team.

The **Provider Implementation Best Case Study Award** was given to Michael Innes from Kaiser Permanente who was the first winner of this award. The Kaiser Permanente case study clearly demonstrated the long-term vision of the hospital group in the implementation of GS1 Standards: they use the Global Trade Item Number in the Electronic Health Record to identify products used during a procedure and compared their effectiveness against other similar products relative to patient outcomes.

Congratulations to Feargal and Michael on their well-deserved awards!

Submit your case study or your candidature for the next awards before 31 December by contacting Janice Kite (janice.kite@gs1.org)

For more information,
[click here.](#)



Government & regulatory news

GS1 Accredited as Issuing Agency for Unique Device Identification by the U.S. Food and Drug Administration

GS1 received on 17 December, 2013 accreditation by the U.S. Food and Drug Administration (FDA) as issuing agency for unique device identifiers (UDIs). Global GS1 Standards meet the government's criteria for UDIs and will help manufacturers comply with the requirements of the new FDA UDI regulation, which was published in September 2013 to support patient safety and supply chain security.

The Unique Device Identification system aims at creating a common worldwide system for product identification that will improve healthcare business processes and patient safety. The US FDA UDI rule is the first to be released but is expected to be followed by other similar regulations worldwide.

"GS1's single, global system of standards across the entire healthcare supply chain is fundamental to enable an efficient and effective implementation of UDI by all healthcare stakeholders worldwide and to assist them in complying with the new regulation," said Miguel Lopera, President and CEO of GS1.

Present in 111 countries, GS1 can help manufacturers worldwide to fulfil the requirements of this new regulation.

"Global GS1 Standards support the FDA's vision for a harmonised global supply chain, which is increasingly important as healthcare products are manufactured, shipped and sold across borders," says Siobhan O'Bara, senior vice president, industry engagement, GS1 US. "Using GS1 Standards, healthcare organisations around the world are able to uniquely identify and locate medical devices from product conception through every step of the supply chain lifecycle, improving product movement visibility and patient safety."

For more information, [click here](#).

U.S. Drug Quality and Security Act adopted

President Barack Obama signed on 26 November 2013 into law the H.R. 3204 Drug Quality and Security Act (DQSA) passed by the Senate the week before (18 November). This was the final step for the U.S. national pharmaceutical serialisation and track & trace regulation to become applicable and to pre-empt all existing state law, in particular Californian e-pedigree requirements. The new law gives the U.S. Food and Drug Administration (FDA) a national system for tracking prescription medicines from manufacturers to pharmacy. It is designed to secure the pharmaceutical supply chain.

The requirements will be phased in over a period of 10 years by providing a migratory path from lot traceability to serialisation to item-level traceability and split into three main phases:

- 1 January 2015: paper or electronic pedigree
- November 2017: serialisation
- November 2023: full track & trace down to item level

A product that fails to bear the required product identifier will be withdrawn from the U.S. market or not allowed to be marketed in the U.S.

The FDA has 12 months from the release date to draft the guidance for implementation.

During the GS1 Global Healthcare Conference last October, Dr. Connie Jung, Associate Director of Policy & Communications for the Office of Drug Security, Integrity, and Recalls at the FDA, discussed the developments and intentions of the proposed U.S. federal system for drug traceability to the audience.

For more information, [click here](#).
To read the summary of the bill, [visit the GS1 Public Policy Website](#).



Government & regulatory news

Jordan - JFDA mandates GS1 DataMatrix for pharmaceuticals

The Jordan Food & Drug Administration (JFDA) officially announced in July 2013 **that the identification with the GS1 DataMatrix should be implemented on pharmaceutical products by 2017**. The JFDA also required that all secondary packaging of pharmaceutical products should be identified with a Global Trade Item Number, batch/lot number, expiration date and serial number. The JFDA stated that they have adopted the GS1 Standards “for the purpose of improving Jordan healthcare supply chain efficiency, inventory management, combat counterfeiting as well as cost savings by means of capture technology, electronic storage and transmission of data”.

Furthermore, the Jordan Ministry of Health and the JFDA are working on a database that will enable drug verification and control stock management, as well as control and manage prices of pharmaceutical products.

The JFDA’s final aim is to build a modern infrastructure adequate to new technologies and compliant with new global healthcare developments to improve patient safety and reduce costs.

For more information, [click here](#).

SFDA and GS1 Saudi Arabia sign MOU to regulate pharmaceutical market

Following a new regulation from the Saudi Food & Drug Authority (SFDA) that mandates that all pharmaceuticals products must print a GS1 DataMatrix by the 1st quarter 2015, a Memorandum Of Understanding (MOU) was signed on 20 November, 2013 by the SFDA and the Council of Saudi Chambers representing GS1 Saudi Arabia.

Khalid bin Mohammed Al-Otaibi, Secretary-General of the Council of Saudi Chambers, noted that the MOU is a key step towards more coordination between SFDA and the business sector in Saudi Arabia to regulate the pharmaceutical market in the country. The deal aims at enhancing cooperation between the two parties in implementing GS1 Standards and System in the healthcare sector to improve patient safety, limit counterfeit issues in the pharmaceutical market and improve the traceability of medicines from the market in case of recalls.

The MOU also entails constant exchange of information and provides the latest information concerning Global GS1 Standards, in addition to holding awareness programs for manufacturers and importers to inform them of GS1 Standards’ benefits, successful case studies, and best practices used by other countries.

For more information, [click here](#).



Government & regulatory news

NHS report mandates GS1 Standards

The UK Department of Health published a report that aims to improve the UK National Health Service (NHS) procurement system through a three-year plan. The report, "Better Procurement, Better Value, Better Care: a Procurement Development Programme for the NHS", unveiled last August by the Health Minister, Dr. Dan Poulter, shows how the NHS can save more money, and support economic growth, by changing the way it buys supplies and does business.

The goal of this new programme is to help the NHS save up to £1.5 billion by 2015-16.

The availability of quality information is essential for the delivery of safe and effective healthcare services by the NHS. The plan expects that more effective processes and better relationships will provide a higher-quality supply chain. To enable the effective delivery of high-quality information to organisations on the buy and supply sides of the healthcare network, the NHS must be able to share accurate data. In order to achieve this, common data standards are required. That is the reason why one of the programme's four key initiatives is "to improve data information and transparency".

The report states that "A common language, backed by a common messaging standard, enables trusts and their suppliers to capture and share procurement data using the same bar code driven technology that is used by retailers and industry to eliminate errors and waste in the supply chain. (...)"

The essential building block for improving data for the longer term is the adoption of GS1 as the supply chain coding standard, by both the NHS and its supplier base."

The choice to use GS1 Standards was based upon the [McKinsey report, "Strength in Unity"](#), which identified that the NHS could save between £3 and £5 million for a 600 bed acute trust, based on the full implementation of global GS1 Standards.

The NHS will support the implementation of GS1 Standards with the following procedures:

- mandating through contracts the use of the GS1 BarCode for the NHS;
- creating a single NHS GS1 data pool for the NHS to use in its systems;
- enabling Product Information Management and Messaging technologies;

- creating a single "data warehouse" for NHS procurement data;
- defining standards to ensure interoperability between e-Procurement systems;
- establishing standards for datasets and classification.

The implementation of common standards across the procurement and commercial systems by NHS organisations and its suppliers should enable information to be easily transferred, allowing for better interoperability between systems, reducing errors, and increasing compliance.

For more information, [click here](#).

EU - MD and IVD regulations still under discussions

On 26 September 2012, the European Commission released a proposal for a regulation on Medical Devices (MD) and a proposal for a regulation on In Vitro Diagnostic medical devices (IVD) that will, once adopted by the European Parliament and the Council, replace the existing three medical devices directives. Since then, the texts of the proposals and other related documents have been discussed.

The European Parliament has adopted in its plenary session on 22 October 2013 the amended proposals on the MD and on the IVD regulations.

The final vote was postponed in order to try to achieve an agreement with the Council, but is still expected before the European Union (EU) election in June 2014.

The EU Council met in Brussels on Tuesday 10 December to discuss the proposals on MD and IVDs Regulations. It seems that the Council is not yet ready to start the discussions with the EU Parliament and the Commission as critical remaining points have to be addressed on system of market approval and reprocessing.

This was the last discussion in this regulatory package time under the Lithuanian Presidency. As from 1 January 2014, the Greek Presidency will take over.

On Thursday 12 December, the Greek Presidency presented its health policy priorities which confirmed the high priority of adopting those regulations before the EU elections.



News from around the world

This delay does not impact the EU Unique Device Identification (UDI) requirements yet. If this timeline is respected, as soon as the regulations will be finally adopted, the European Commission will still have time to start the Delegated Acts and complete it as expected by mid-2014. The Delegated Acts will provide the industry with the requirements on the EU UDI system.

For more information on the European Parliament Press Release, [click here](#) and on the Eucomed Press Release, [click here](#).

Tanzania leading the way with GS1 BarCodes on vaccine packaging

A project is planned in Tanzania, proving the benefits of Automatic Identification and Data Capture (AIDC) technology for the vaccines supply chain. In cooperation with the pharmaceutical industry, packages with GS1 BarCodes will be received and distributed in the country, ensuring optimised inventory management and traceability.

In March 2013, the Vaccine Presentation and Packaging Advisory Group (VPPAG) barcode subgroup met in Brussels, Belgium to identify the challenges associated with this project and set out a long-term vision and roadmap for the adoption of bar code technology in the supply chain. The objective of the VPPAG was to identify a bar code standard that met both public and private sectors needs and requirements, as well as define the minimum set of data elements that should be included into a bar code at each packaging level.

Collaborating manufacturers will add bar codes to tertiary and secondary packaging to enable staff to keep track of vaccines as they move down the supply chain from the national to the regional and then to the district level. Encoded in these bar codes will be the product's Global Trade Item Number (GTIN), as well as the lot number and expiration date of the vaccines.

This will enable all stakeholders to keep better track of vaccine stock movements.

For more information, [click here](#).



News from around the world

GS1 Australia and NEHTA launch GS1 Recallnet Healthcare



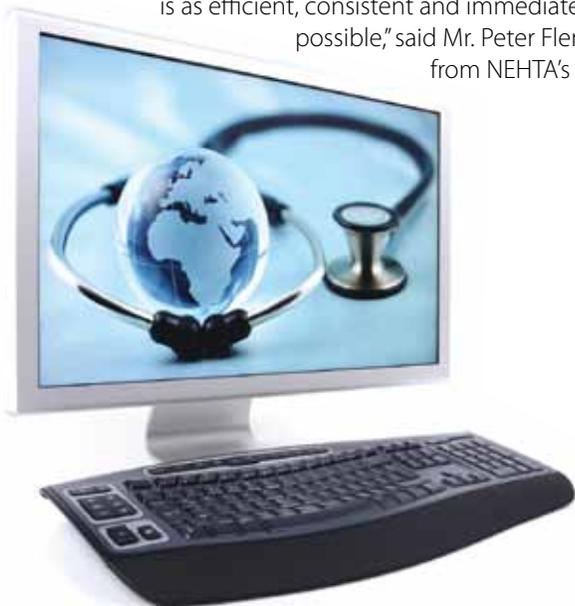
In September 2013, GS1 Australia, with the support of the National E-Health Transition Authority (NEHTA), officially launched GS1 Recallnet Healthcare, an electronic product recall notification management system for therapeutic goods.

GS1 Recallnet Healthcare is an online portal designed to improve patient safety by streamlining the management of product recall notifications. It is designed to provide an electronic product recall notification management system in the Australian healthcare sector to improve patient safety by enhancing the speed, efficiency and accuracy of the recall process for therapeutic goods.

"Therapeutic product recalls always present a significant challenge to the Australian healthcare industry and this portal will improve the therapeutic product recall notification process for the benefit and safety of all Australians," added Ms. Maria Palazzolo CEO of GS1 Australia.

In addition to the support provided by NEHTA, the service was also developed in association with the Therapeutic Goods Administration (TGA), state and territory health departments and a number of medical device and pharmaceutical suppliers.

"By committing to one standardised program, Australian healthcare organisations will ensure the recall of products is as efficient, consistent and immediate as possible," said Mr. Peter Fleming from NEHTA's CEO.



Manufacturers, suppliers, pharmaceutical wholesalers, distributors, health departments, pharmacies, hospitals and government agencies will be able to rely on GS1 Recallnet Healthcare to:

- improve patient and healthcare provider safety and quality of care;
- reduce the costs for issuing and enacting product recalls;
- reduce errors, confusion and re-work;
- decrease the time and effort to respond to recalls;
- increase visibility of recall progress and effectiveness across the chain;
- improve the traceability of therapeutic goods;
- streamline recall progress reporting to the TGA; and
- decrease the risks and costs associated with product recalls.

A similar service called GS1 Recallnet was launched for the food industry in 2011 in Australia, with grocery, food and liquor products able to be withdrawn or recalled quickly and easily.

For more information, [click here](#).

Swiss delegation visits Dutch hospitals to learn more about GS1 Standards

Over the summer, a Swiss delegation went to the Netherlands to see how the implementation of GS1 Standards contributed to making the Dutch healthcare supply chain safer and more efficient. The delegation included representatives from the purchase departments of Swiss hospitals and pharmacies, as well as representatives from GS1 Switzerland, major companies and implementation partners. The objective of the visit was to allow the delegation to witness first-hand how using bar codes combats waste in the healthcare system and improves patient safety.

They visited two hospital members of GS1 Netherlands: the Deventer Hospital, which has implemented a paperless environment across the hospital, and the Erasmus Medical Center (EMC) in Rotterdam, one of the largest hospitals in the Netherlands. The Deventer Hospital has managed to limit the use of paper: virtually all the stages in the patient care are digitised and almost entirely paperless. That not only adds data to electronic patient records, but also has benefits in the area of stock control and finance.



News from around the world

The Erasmus Medical Center has demonstrated high innovation and progress by implementing a traceability scheme that can serve as a source of instruction and inspiration to other hospitals. The EMC makes intensive use of GS1 Standards for identification in various processes, such as blood transfusions: patients are identified via their wristbands with the Global Service Relationship Number (GSRN), and the lab orders for blood products are managed with a Global Document Type Identifier (GDTI). Furthermore, the medical devices' GTINs used in cardiac catheterisation rooms are recorded in the EMC's database which makes them traceable.

The tour was very productive and has led to a positive response. Reinhard Kuster, head of purchasing logistics at St. Gallen Hospital in the Swiss town of the same name, was very positive about the examples presented.

"Our healthcare funding system has changed in recent years. We used to be given a total budget that was topped up at the end of the year. Now we have to keep track of the procedures that have been performed on each patient. That requires a more efficient approach, and we need to develop better cost-awareness and ways of working and buying... This provides a lot of inspirational food for thought and arguments that we can employ in the debate back home," said Kuster.



Thomas Sidler, responsible for customer relations at Johnson & Johnson Switzerland, also said he was highly convinced by the integrated partnership that bar coding can facilitate between suppliers and buyers in the health service.

"This is state of the art, a unique system controlling the entire process," said Sidler. "Standardising and sharing information on pharmaceuticals and medical devices enables a better performance and puts an end to the "out of stock" problem. I am convinced that a good deal of value can be created by optimising the supply chain process."

For more information (in Dutch),
[click here.](#)



GS1 Denmark participates at the 2013 MedInfo

MedInfo 2013, an international medical informatics conference organised every three years by the International Medical Informatics Association, took place in Copenhagen this August. MedInfo 2013 gathered more than 1,200 participants, researchers and practitioners from 64 countries. Over 30 exhibitors were present, including GS1 Denmark who represented the GS1 community, gathering knowledge about health informatics and how IT can support treatment of patients today and in the future.

The theme of the conference was "conducting health informatics by converging technologies, conveying sciences and connecting people". Approximately 2/3 of the Electronic Health Record systems presented at the conference had a ready-to-use Bar Coded Medication Administration (BCMA) module compliant with GS1 Standards, and a part of the remainder systems had intentions of developing a GS1-compliant BCMA module.



For more information,
[click here.](#)



GS1 Healthcare update

New standard to address missing link in hospital supply chain processes



Point-of-care verification and traceability systems rely on the effective capture of healthcare product data at all packaging levels, whenever dispensed, administered, distributed or

used. But until today, hospitals were confronted with the lack of globally-harmonised standards on how to identify products at lower levels of packaging, such as a single-packed catheter or the individual blister cell from a multi-cell blister card. A GS1 Healthcare work group, consisting of over 80 supply chain experts, accepted the challenge to clarify and update the GS1 Standards to provide clear and consistent guidance on how to identify healthcare products at the single unit level, also referred to as "Level Below the Each".

Commenting on the need to use one single global standard, Frédérique Fremont, Organisation Engineer at Robert Ballanger Hospital (France) and co-chair of the Level Below The Each Work Group said that "it is essential that healthcare providers work with manufacturers to implement Level Below the Each marking, as this will enable us to reach the critical mass adoption of standardised and automated processes that will reduce medication errors and ensure safe use of medical devices".

Updates have been made to the [GS1 Healthcare GTIN Allocation Rules](#) that incorporate guidance on how a "responsible entity" in the healthcare supply chain should identify a Level Below The Each trade item, which may include, for example: single unpackaged pills, pills packaged in blister cells, unpackaged liquids, single-use non-sterile devices such as screws and pins, or multi-use non-sterile devices such as a blood pressure cuff.

Recognising the impact on patient safety of this accomplishment, Peter Tomicki, Director of Global Standards at Zimmer and co-chair of the Level Below The Each Work Group, stated, "in healthcare, lower levels of packaging exist that require identification. This new standard will provide clear and consistent guidance on how and who identifies items at these levels."

For more information,
[click here.](#)

HL7 and 54 other global healthcare companies endorse GS1 Standards

Healthcare stakeholders have expressed their strong support for GS1 Standards –the global standard best suited for their industry.

55 global healthcare leaders representing hospitals, manufacturers and distributors from around the world have endorsed the GS1 System of Standards for healthcare.

Health Level Seven International® (HL7®) is one of the organisations who has signed the position paper expressing the endorsement.

During the GS1 Healthcare Conference in San Francisco last October, the two organisations renewed their Memorandum of Understanding (MOU) to work together to reduce medical errors and to increase the effectiveness of the healthcare supply chain by having GS1 President and CEO Miguel Lopera, and HL7 CEO Dr. Charles Jaffe sign an extension of the agreement to join forces to achieve these goals.

"GS1 is pleased to continue joining forces with HL7® to combine the development and adoption of GS1's global supply chain standards with HL7®'s standards for the interoperability of health information technology first and foremost to improve patient safety around the world," said Lopera.



"The integration of GS1 supply chain standards and HL7® standards used in healthcare data exchange, storage, and retrieval have been and will continue to be critical in lowering healthcare costs from manufacturers to patients as well as improving patient safety," said Dr. Jaffe.



GS1 Healthcare update

This event marks an important milestone in global healthcare cooperation between the world's two leading global standards organisations: GS1 develops the most widely-used supply chain standards system in the world and HL7® develops international healthcare informatics interoperability standards and is regarded as the world's most important player in the interoperability of healthcare.

If you also wish to support the adoption of the GS1 System of Standards for healthcare on a global basis, please contact Ulrike Kreysa (ulrike.kreysa@gs1.org).

For more information,
[click here.](#)

Fifth edition of the GS1 Healthcare Reference Book now available



GS1 Global has recently published the fifth edition of the GS1 Healthcare Reference Book (Edition 2013/2014), a compendium of case studies containing examples of the many success stories and promising projects that are advancing the implementation of GS1 Standards in the healthcare supply chain worldwide.

In recent years, traceability has become a hot topic in a number of sectors, due in part to notable failures occurring across the supply chain. In response to this public health concern, there have been an increasing number of traceability pilots undertaken and several regulations emerging around the world, for both pharmaceuticals and medical devices, aimed at minimising failures and ultimately improving patient safety.

The case studies demonstrate the wide range of efforts taking place around the world by different stakeholders – all intended to achieving visibility in the healthcare supply chain by implementing traceability systems and solutions based on GS1 Standards. Although the case studies may have different drivers, they all ultimately have the same goal: improve patient safety.

This edition shares many examples of traceability implementations from different stakeholders.

The Irish Health Service Executive now requires that all surgical instrument trays are identified using GS1 Standards to enable all stakeholders to track and trace them throughout the supply chain. On the other side of the ocean, the U.S. **Centers for Disease Control and Prevention** launched two projects using GS1 Standards to automate the information management processes on the vaccine itself and Vaccine Information Statement in patients medical records. Many more examples are available in the Reference Book.

For more information,
[click here.](#)

With gratitude, happy retirement Ron!

The entire GS1 Healthcare team extends its sincere gratitude to Ron Bone of McKesson for his immense engagement since 2005 in GS1 Healthcare.



After having been part of the creation of GS1 Healthcare and the Global Healthcare Leadership Team, Ron was also a member of the Process Oversight Committee for over three years, part of the Automatic Identification and Data Capture updates Mission Specific Working Group and was a key player in the development of the Level Below the Each standard.

He has been a major contributor to the development of GS1, especially in the healthcare sector, and has actively contributed to the improvement of patient safety through Global Standards! We wish Ron our best wishes for a healthy and happy retirement!



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