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SPECIAL FEATURE:

GS1 issues Track and Trace guideline for US Healthcare

GS1 US has just published a guideline for Pharmaceutical Product Serialization, Traceability and Pedigree requirements. The guideline titled "Applying GS1 Standards to U.S. Pharmaceutical Supply Chain Business Processes to Support Serialization, Pedigree and Track and Trace" is a tool to help companies apply traceability standards to their own business processes in order to better trace the movement of their products throughout the distribution network.



The guideline is published in preparation for the California drug pedigree requirements, which will become mandatory in 2015.

"This guideline will help organisations take an active role in the transformation of the Healthcare system, meeting the goals of patient safety and regulatory compliance while making the supply chain more efficient" said Siobhan O'Bara, Senior Vice President Industry Engagement, GS1 US.

The publication focuses on best practices and methodologies as well as on findings from different pilot studies and other collaborative endeavours by GS1 and its pharmaceutical supply chain partners.

"The guideline will help companies leverage their existing technology investment and move forward with effective implementation strategies", said Michael Ventura, Serialisation and Security Manager at GlaxoSmithKline.

The new guideline is available for download at www.gs1us.org/RxGuideline

Future releases are planned and will provide more detailed information on forward and reverse logistics scenarios as well as on exceptions.

[Read more](#)

GOVERNMENT & REGULATORY NEWS

Australia - NEHTA endorses GS1 Standards to identify and mark products

On 17th December 2012, the National E-Health Transition Authority (NEHTA) published an official Supply Chain Reference Group Communiqué promoting the use of GS1 Standards in terms of product identification and marking. The document was developed in order to face rising demands from Australian Healthcare brand owners requesting better guidance and information on product identification. They are realising that more and more international suppliers are implementing bar coding on Healthcare products. The announcement clearly states that all Australian Healthcare companies should "align with global developments by using Global GS1 Standards".

Additionally, NEHTA Supply Chain Reference Group (SCRG) recommends that Australian and International Healthcare brand owners adopt GS1 Automatic Identification and Data Capture (AIDC).

[Read more](#)



Denmark – The Central Denmark Region requires a GS1 compliant system in its hospitals



The Central Denmark Region is aiming to implement automatic identification and traceability of items and people in its hospitals.

In February 2013, it opened a request for projects, demanding for the system and technology proposed to be GS1 compliant as well as HL7 compliant. The Central Denmark Region has already identified 40+ scenarios where automatic identification and traceability will add value to the different processes in hospitals.

The system will then gradually be launched in the hospitals of the Region.

[Read more](#)

Nigeria – Implementation of mobile authentication service for anti-malarial drugs and antibiotics



The Nigerian Ministry of Health has committed to the complete eradication of counterfeit medicines in the country by January 2014. Therefore, the National Agency for Food and Drug Administration and Control (NAFDAC) has imposed that all manufacturers, importers and marketers of anti-malarial drugs had to implement a Mobile Authentication Service (MAS) by 2nd January 2013, and antibiotics manufacturers, importers and marketers by 1st March 2013. Approved MAS Service Providers are: Sproxil, mPedigree Network, PharmaSecure, UBQT.



The GS1 Public Policy Team has developed a discussion paper on the use of MAS for drugs authentication. This paper acknowledges that the use of SMS solutions in healthcare and their potential benefits to increase patient safety can be viewed as promising, in particular for products destined for Low-Medium Income Countries (LMIC). The LMICs have been widely reported to be a major source or recipient of falsified pharmaceuticals. Reducing and/or detecting falsified medicines are therefore a key driver for deployment and use of MAS solutions. The discussion paper also demonstrates and concludes that while these solutions may be suitable for specific drugs in specific countries, they are not scalable on the broader, regional or even global level as they are often proprietary and not standards-based.

The final version of the discussion paper will be published as soon as formally approved by the GS1 Healthcare Leadership Team.

Taiwan – Draft bar code requirements published



Taiwan's Food and Drug Administration (FDA) published a first draft listing the bar codes required on Healthcare products. The draft requirements mention that:

- All tertiary packaging should possess a GS1-128 bar code (containing GTIN, Exp. Date, Batch No., Serial No.)
- All secondary packaging should possess a 2D bar code (containing GTIN, Exp. Date, Batch No., Serial No.)
- All primary packaging should possess a 2D bar code (containing GTIN, Exp. Date, Batch No.)

The final requirements should be published by the end of 2013.

Bar codes should be placed on injectable drugs, antineoplastic agents and specified drugs (narcotics, biologics and vaccines) by **1st January 2015**. All other prescription drugs should possess the necessary bar codes by **1st January 2018**.

Brazil - ANVISA opens public comment on traceability proposals



On 3rd April, ANVISA, Brazilian Health Surveillance Agency, has published a public consultation to improve medicines traceability.

The consultation proposes that all companies registering pharmaceutical products will have to include the following identification information on all secondary level packs and hospital packs:

- 13-digits ANVISA registration number
- serial number
- expiration date
- lot number

This information should be marked in both a DataMatrix and human-readable form.

These new requirements will be applicable 180 days after the publication of the final rule.

ANVISA is accepting comments on the document between 10th April and 9th May, and responses will be published on its [website](#).

GS1 Healthcare plans to submit comments to ANVISA.

UDI requirements update

The International Medical Device Regulators Forum (IMDRF) held its third meeting in Nice from 19th to 21st March 2013, including a stakeholder meeting on 20th March. The meeting was chaired by the European Commission and included presentations of the outcome of their work by the different Working Groups. The draft UDI Guidance from IMDRF (repealing the GHTF Guidance on UDI) will be published end of April with a comment-period until end of July. IMDRF will work on a consolidated version in August and September. A final version should be presented to the IMDRF Board for final adoption in November.

In parallel, the EU decision making process on the adoption of the EU Medical Devices Regulation is moving forward. The proposal from the European Commission is currently being discussed at the European Parliament. Key topics are: a stronger and stricter approach regarding notified bodies, a centralised pre-market authorisation for high risk MD and concerns to be addressed with regards to reprocessing and classification. The draft report from the Environment, Public Health and Food Safety Committee (ENVI Committee) will be published by end of April with a deadline for amendments in May and a vote in July. The aim is to have the text adopted this year, before the EU elections in June 2014.

The EU Commission has just published a Recommendation on a common framework for Unique Device Identification (UDI) system of medical devices.

The Recommendation mentions the three elements of the UDI system:

- UDI number
- UDI Data Carrier
- UDI DataBase

This is a non-mandatory legal text aiming at providing an harmonised framework to Member States when developing UDI systems.

The Delegated Acts on UDI (based on the MD Regulation) will provide mandatory requirements on UDI at a latest stage.

GS1 will work with Eucomed on a detailed analysis.
[Read the Commission Recommendation](#)



NEWS FROM AROUND THE WORLD

North America - GTIN System adopted by Cook Medical



Since January 2013, Cook Medical has implemented the GS1 Global Trade Item Number (GTIN) on all of its medical devices. The process began a decade ago when Cook Medical concluded that they needed to improve their tracking plan in order to simplify their supply chain operations. In addition, US FDA has also been pushing industries to standardise their supply chain systems. The GS1 System seemed the obvious choice as other major industry health systems were already using it.

"We think standards make sense for health care and for our business," said Dave Reed, vice president of the Healthcare Business Solutions division and vice president of operations at Cook Medical. "The lack of a common language for identifying products and the lack of clean data in health care make it difficult and costly to do business. More than manufacturers and health care providers will benefit from using a standard like GS1."

Additionally, the GTIN provides companies with Unique Device Identification (UDI) data which will soon be mandatory for medical devices in the United States.

We've been working with GTIN for about a decade. It wasn't always easy, but it's very positive for health care, right down to the patient level," added Reed. "We feel like all the effort was worth it."

[Read more](#)

New Zealand – Suppliers to District Health Boards urged to provide GS1-standard data on their products



Suppliers to District Health Boards are being urged to provide GS1-standard data on their products to Health Benefits Limited (HBL) for inclusion in a new DHB National Catalogue for purchasing as soon as possible.

Health Benefits Limited (HBL), a Crown-owned company charged with securing efficiencies and cost savings for New Zealand's District Health Boards (DHB) is actively working to build its National Catalogue, which is a key enabler in HBL's Finance, Procurement and Supply Chain Programme.

All data on the catalogue must be provided in compliance with GS1 standards to ensure its quality and its ease of recognition and use by all parties. Suppliers should flow their data to HBL via GS1net as it assists the data to be as accurate as possible.

Mr Nigel Wilkinson, HBL Chief Executive, and Ms Keri Yeo, HBL Programme Manager, point that "the catalogue will allow DHB's to purchase products from a single information system replacing the more than 20 different Catalogues in use today". They also defend that "the Catalogue will benefit suppliers by making their products visible to all DHBs and by making it easier to update data".

Mr Wilkinson also stressed the merits of suppliers engaging with HBL to provide “a single source of truth” about their products as soon as possible, and emphasised the relevance of a GS1 standards-based Catalogue to HBL’s wider mission. “From our perspective it is essential that we have a well-constructed Catalogue with quality data in it for the implementation of an automated and integrated system for DHBs. I can’t really overstate the importance of the Catalogue and your contribution (as suppliers) to the building of the Catalogue.”

[Read more](#)

Denmark – benchmarking the Dutch healthcare efficiency



Denmark is planning to build 5 new hospitals all around the country based on a new model. In order to build a new efficient model, a Danish delegation has decided to tour around The Netherlands, Belgium and France to learn from tested and successful experiences. “We’re looking for the best developed and most advanced practical examples. We want to learn from things that have been tried and tested”, explains Project Manager Lars Jensen. During their tour, the delegation was particularly impressed by the efficiency established by St. Antonius Hospital in Nieuwegein, The Netherlands. They demonstrated all the advantages of implementing the GS1 Standards. The hospital involved its manufacturers and suppliers in the process by making them responsible for entering the data in a central database in line with the GS1 Standard for item data. This has been a proven success model: not only it has improved the supply chain efficiency by reducing stock and simplifying the recall procedure, it has also gained in patient safety as caregivers are scanning and double checking all their medical procedures. Last but not least, the investment has been profitable: Menno Manschot, Procurement Officer at St. Antonius Hospital has demonstrated that the investment was recouped within eighteen months to two years.



However it is important to point out that the key to for a successful business case like this is the full support of all parties. “What we really need, though, is for suppliers, hospitals and pharmacies all to work together. The key to success is the full support of all parties”, points out Esther Peelen of GS1 Netherlands.

Argentina - new traceability programme extended for medicines



In 2011, Argentina introduced a catalogue of drugs covered by its national drug traceability scheme. It lists more than 2.000 medicines that require the placing of unique identification number complying with GS1 Standards such as a Global Trade Item Number (GTIN), 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 (GLNs) to identify the various actors in the supply chain. Last February, the government of Argentina added another 11 substances to the catalogue.

The purpose of this programme is to actively limit the use of illegal drugs. ANMAT has stated that the implementation of the system has shown more than favourable results.

ANMAT will present their work at the next GS1 Global Healthcare Conference taking place in Buenos Aires on 23-25 April 2013. They will be hosting the Public Policy Think Tank, open to regulatory bodies. This will be a great opportunity for participants to ask all their questions concerning the implementation of Argentina's national medicine traceability initiative.

Governments fight back against counterfeit products

Colombian police has recently seized \$3.6 million in bogus prescription drugs coming from India. More and more operations of counterfeit seizures are taking place, but this is one of the largest of its type in the region. The consequences of illicit drugs are tremendous: not only are they dangerous and ineffective but they also affect the countries' economy. Each year up to 100,000 people around the world may die from substandard and counterfeit medications, according to a recent estimate by the University of Ottawa and the American Enterprise Institute.



The Indian government is also finding ways to reduce counterfeit products. It has required that all exported pharmaceuticals and drugs should have a bar code by 1st July 2014.

Many other countries are also planning to enforce regulations to help limit the proliferation of counterfeit drugs which are being supported by pharmaceutical companies. For instance nearly 30 pharmaceutical companies have joined together to support Interpol in the creation of a new Pharmaceutical Crime Programme (PCP). The companies are contributing €4.5 million over the next three years to the PCP to help build Interpol's Medical Product Counterfeiting and Pharmaceutical Crime (MPCPC) unit.

GS1 HEALTHCARE UPDATE

First HPAC recognition awards

For the first time, the GS1 Healthcare Provider Advisory Council (HPAC) has introduced two awards: the Recognition Reward and the Best Provider Implementation Case Study Award.



The Recognition Award is for an individual who has contributed highly to the GS1 Healthcare work efforts over the years. They will win an expense paid trip to the GS1 Healthcare Conference in Buenos Aires on 23-25 April where they will be presented with the Recognition Award.

The Best Provider Implementation Case Study Award rewards a provider organisation/department (i.e. hospital, clinic, care home, retail and hospital pharmacy), or an individual within a provider organisation, that has implemented GS1 Standards for at least one process in their hospital/clinic/care home/pharmacy/department. The implementation case study must demonstrate a clear and measurable Return on Investment (ROI).

Submit a relevant case study now for a chance to win a trip to the next conference.

Application forms can be downloaded [here](#).

For more information, contact Janice.kite@gs1.org.

GS1 New Zealand grants fellowship



GS1 New Zealand has offered the unique opportunity, to a person working in Healthcare in New Zealand, to attend the next GS1 Global Healthcare Conference in Buenos Aires in April. Candidates were required to provide a written application explaining why they thought they should be granted the fellowship, how they would use the information received during the conference and their interest in the use of GS1 Global Standards in New Zealand. Each application was then reviewed and assessed by a judging panel and the award announced.

The lucky winner this year is Dr Andrew Bowers, a Physician and Medical Director of Information Technology for one of New Zealand's District Health Board.

[Read more](#)

GS1 Spain launches GDSN in the Healthcare sector



Since 2011, GS1 Spain and local stakeholders have been driving the adoption and implementation of product data synchronization through "Aecocdata", the GS1 Spain GDSN data pool, to increase supply chain efficiency and save costs. This initiative has the support of leading pharmaceutical distribution companies in Spain (Alliance Healthcare, Cecofar, Cedifa-ofsa, Grupo Cofares, Cruzfarma, Farmanova, Federació Farmacèutica, Hefame) that are starting to receive standardised product data from participating manufacturers. Two of the pharmaceutical distribution companies (Alliance Healthcare and Federació Farmacèutica) have already started to receive standardised product data from participating manufacturers. The others pharmaceutical distribution companies will start in May 2013. "Aecocdata" has been designed to be a single source of agreed and relevant product data (Product Identification, pricing, logistics, technical and clinical data) for manufacturers and distributors in the Healthcare sector, connecting with each other and moving their business forward.

UPCOMING EVENTS

8th Annual unSUMMIT for Bedside Barcoding in Orlando, Florida April 24-26, 2013

The unSUMMIT is the premier educational event for hospitals interested in Barcoding at the Point of Care (BPOC).

No need to muscle your way through — get help from experienced peers at The unSUMMIT.

- Compact schedule delivers everything you need in three days
- 14 continuing education hours available
- Save time evaluating vendors with our one-stop exhibition hall

Download the full brochure [here](#)



23rd Global GS1 Healthcare Conference

23-25 April 2013 - Buenos Aires, Argentina

Invitation to Buenos Aires, Argentina

Improving patient safety through visibility in the supply chain

Join key stakeholders at the **23rd Global GS1 Healthcare Conference** in Buenos Aires, from 23 to 25 April 2013, and find out more about the **latest developments and adoptions** of GS1 Global Standards in the Healthcare supply chain.

This **three-day event** will bring inspiring and informative content, including:

- Plenaries on **UDI** regulations, traceability
- The latest **McKinsey & Company** report findings
- **Hospital realities**, and international collaborations
- Implementation **case studies**
- Ask the **experts** sessions
- Public Policy **Think Tank** hosted by **ANMAT** (on invitation only)
- Working lunches on Public Policy or the Healthcare Provider Advisory Council
- Site visits to manufacturers, wholesalers or hospitals



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