GS1 Healthcare Newsletter

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SPECIAL FEATURE:
GS1 HEALTHCARE CONFERENCE GATHERS IN LISBON

GS1 Healthcare takes the stage in Lisbon

Hosted by GS1 Portugal and supported by Johnson & Johnson, the 22nd GS1 Global Healthcare conference was held in Lisbon for the first time and brought together 270 delegates representing over 40 countries.

Prof Helder Mota Filipe from INFARMED (National Authority of Medicines and Health Products) opened the conference by confirming the government's commitment to protect the sustainability of the healthcare system and guarantee affordable and effective care and, for that reason, support innovative and harmonised solutions.

During the three-day conference, healthcare professionals demonstrated the benefits and essential role that GS1 Standards play in today's healthcare supply chains, from manufacturing to patient, including hospitals, wholesalers, pharmacies and other healthcare stakeholders.

Katy George, Director at McKinsey & Company revealed the findings of their latest report on Healthcare supply chains, which highlights the cost savings and patient safety benefits of adopting a single global supply chain standard in Healthcare.

Other topics were high on the agenda, such as the recent proposed regulations of the FDA and EU Commission on a Unique Device Identification (UDI) System for medical devices, as well as the activities of the European Commission and other European stakeholders with regards to the Falsified Medicines Directive. These directives will have a major and direct impact in improving patient safety whilst also securing and improving the healthcare supply chain.

The conference combined plenary sessions, expert sessions and working lunches to respond to the unique needs and issues of the different healthcare actors participating. In parallel to the conference, regulatory bodies met during a Think Tank, which addressed specific matters from government's perspectives.

"Be the change you want to see in the world"

Mahatma Ghandi

Finally, the conference demonstrated that standards adoption and implementation is a joint effort by all Healthcare stakeholders who have the power to improve patient lives and enable the healthcare systems to be more efficient worldwide. Change is already well underway as today GS1 Member Organisations (MOs) facilitate 31 local Healthcare User Groups around the globe, fostering ideas, best practices and bringing together all stakeholders for the benefits of all individual patients.

McKinsey & Company reports on the benefits a single global standard brings to Healthcare

During the conference, McKinsey & Company released a much awaited report highlighting the cost savings and patient safety benefits of adopting a single global supply chain standard in Healthcare. McKinsey interviewed more than 80 Healthcare leaders across the world and examined more than 25 cases of standards-enabled improvement.

This report, called: "*Strength in unity: The promise of global standards in healthcare*" is the first of its kind to quantify the benefits of a single global standard for Healthcare supply chains which have shown to be huge.

Report findings :

- The research has revealed **"that implementing global standards across the entire healthcare supply chain could save 22,000-43,000 lives and avert 0.7 to 1.4 million patient disabilities."**

- Addressing counterfeit drugs, a major and ever growing problem for public health and industry; the report concludes that **"rolling-out standards based systems could prevent tens of billions of dollars' worth of counterfeit drugs from entering the legitimate supply chain".**

- At the same time, it states that **"global standards could enable substantial safety benefits and enable healthcare cost reduction of $40-100 billion"**. Once adopted, global standards benefits will span over all supply chain stakeholders from manufacturers to patients.

- "The healthcare industry faces a potentially costly patchwork of requirements. Over the long term this patchwork could become unworkable. **The adoption of a single set of global standards will cost significantly less than two and far less than three or more"**.

- The report concludes that the potential benefits enabled by global standards in Healthcare supply chains "could be significantly larger than anticipated, as proven by the lessons learned from the CPG/retail industry, when GS1 standards were widely adopted". End-to-end supply chain visibility could create new opportunities in mobile health, improve treatment compliance, avoid adverse drug interactions and more.
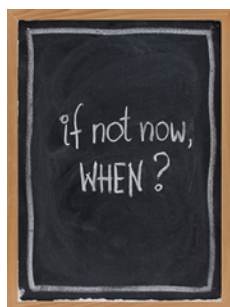
Katy George, Director at McKinsey & Company further emphasised that now was the time to act: "Healthcare is at a crossroads, the technology is in place, the standards exist. Global standards will make the difference, and the only way we can deliver those benefits is if the industry collaborates and aligns to drive adoption."

Dr Ajit Shetty, former Vice President, Enterprise Supply Chain Johnson & Johnson, supported the report by stating that Johnson & Johnson sees benefits in using GS1 Standards worldwide. He concluded by saying: "All patients owe GS1 a word of gratitude for a truly integrated, standardised and global approach to the supply chain of healthcare products".

Download the McKinsey report

EU: Acting against falsified medicines

"International Standards are really important. We need one standard that we can use in any country and globally. GS1 Standards decrease the costs of implementation, increase certainty and also reduce the risk of errors – because multiple systems, multiple standards introduce high risk."

Grant Courtney, EFPIA

Falsified medicines are a growing threat to public health and safety in Europe. Counterfeit medicines seized at the outer border of the EU have tripled between 2006 and 2009, reaching approximately 7.5 million items. Over the last five years, Customs at EU borders have seized 30 million counterfeit medicines alone. Adopted in June 2011, the EU Falsified Medicines Directive (FMD) is an important step in protecting patients from counterfeit medicines. Mrs Agnès Mathieu, from the Directorate-General "Health and Consumers" at the European Commission explained that the European Commission will be drafting the technical aspects in a "delegated act" which is expected to be released by end 2014.

As a result, European pharmaceutical supply chain actors are developing different systems with the objective to meet the requirements of the FMD. These systems will combine the use of a unique serial number with tamper-evident packaging.

The first one, the **ESM (European Stakeholder Model)** has been developed by The European Federation of Pharmaceutical Industry Associations (EFPIA) and is supported by pharmaceutical supply chain actors like GIRP (Pharmaceutical full-line wholesalers

in Europe), PGEU (Pharmaceutical Group of the European Union) and EAEPC (European Association of Euro-Pharmaceutical Companies). It will provide a high level of security for patients, be cost-effective and integrate effectively into existing supply chain practises. The ESM is a pan-European point-of-dispensing verification system that, at the time product is dispensed to the patient, allows pharmacists to check the unique identification code on each individual pack.

The repository system uses a 2D barcode (GS1 DataMatrix) that contains 4 key data elements: product number (Global Trade Item Number or GTIN), randomised unique serial number, expiry date and batch number. The tender process for the first phase of the European Medicines Verification System (EMVS) continues with the objective of delivering an effective and secure system on time with mandatory compliance across Europe expected in 2017.

The **German securPharm** consortium is carrying out another pilot project using a DataMatrix code that will include the product number, batch number, expiry date and serial number. In January 2013 the pilot project is expected to start and will be running for 3 months, until April 2013. The field test is the start of the rollout, with further developments planned from April to the end of 2013. It is also planned to connect to the ESM, with a first pilot test starting in April.

Another pan-European system currently being developed to support the verification of medicines is **eTACT**, which is maintained by the European Directorate for the Quality of Medicines & Healthcare (EDQM). Point-of Dispense verification is also its focus, using a Unique Medicine Identifier (UMI). In this case, the UMI will also be encoded in a GS1 DataMatrix including GS1 Standards (GTIN, Serial Number, Batch number, Expiry date).

At the conference, talking about the ESM, Grant Courtney, EFPIA representative said: "The EU has 27 member states, so the more we can do to minimise the diversity of national systems the cheaper the overall cost will be".

For more information about these systems, download the presentations

Australia: Continued progress for the supply chain reform agenda

Australia has made great progress since the inception of the National E-Health Transition Authority (NEHTA) in 2005. This independent organisation was established to develop better ways of electronically collecting and securely exchanging health information.

The lack of standardised **product identification**, **location identification** and maintenance of multiple product data catalogues per hospital, per hospital network and per state made the reform necessary.

The National Product Catalogue and eProcurement process are at the heart of this eHealth supply chain reform, providing a way for suppliers to communicate standardised and accurate product and price data electronically to Australian health departments and private hospital providers by using and sharing one key identifier across all parties, the GS1 Global Trade Identification Number (GTIN).

Aligned with GS1's Global Data Synchronisation Network (GDSN) standards, NEHTA's National Product Catalogue (NPC) uses the standard Global Trade Item Number (GTIN), as the globally unique primary product identifier for every NPC record. The NPC has today topped a quarter of a million GTINs and is continuing to grow strongly.

With more suppliers coming on board and more GTINs added, their number now totals 276,121 from more than 390 suppliers. This equates to an 80% increase in the past two years.

Read the NPC Press Release

Portugal: Implementing GS1 Standards at Novartis

Novartis Pharma is looking very carefully at the California ePedigree law and EU directive on falsified medicines (FMD) and taking actions to ensure traceability of products up to the patient. By applying and registering a unique identifier to the packaging of their drug Ranibizumab, Novartis Portugal can follow the product across the supply chain from packaging to a third party distribution centre and ultimately to the hospital and pharmacy.

Each product pack contains a GS1 DataMatrix incorporating a Global Trade Item Number (GTIN) , unique serial number, expiry date and batch number and follows the specifications provided in EFPIA's "European Pack Coding Guidelines".

The frontend hospital application is web based, making it very simple and allowing each hospital to have access with as many users as necessary:

- Upon prescription, the pharmacist scans the packs. Serial number, date and time of dispensing are recorded

- The product is then sent from the hospital pharmacy into the surgery room with an internal shipping document containing the serial number, batch number and shelf life

- After administration the pack is again scanned and the internal patient code is introduced manually or by scanning the patient barcode if available

- The patient data remains confidential during the entire process through a complex encryption system

- In the hospital, reports are available by "Date of scanning", by "Date of treatment", by "Batch number" and by "Patient number"

The pilot started in one hospital in October 2010, and in 2011 expanded to four other public hospitals. To date 979 treatments have been tracked and traced. The project has been very well perceived, with great potential to expand to other products in areas where a more restricted control over medication is needed, such as in oncology.

Global: The Healthcare Provider Advisory Council (HPAC) calls to action

During the conference, The GS1 Healthcare Provider Advisory Council (HPAC) – consisting of thought leaders from a broad clinical provider environment – who have been exploring the opportunities and challenges of implementing GS1 Standards to improve various care-giving processes and ultimately, patient safety, launched two calls to action. The first call to action was to solution providers to address IT/IS interoperability issues taking place in hospitals. This remains one of the major and recurring challenges for healthcare providers, slowing down the implementation of GS1 Standards and its positive impact on the reduction of medical errors and supply chain efficiency.

The second raises issues with bar codes on received products and requests suppliers to apply one single standard, readable barcode, on both pharmaceutical and medical device packs.

Receiving pharmaceuticals and medical devices that carry GS1 Standards-based, quality barcodes on the packaging or as Direct Part Marking (DPM) is fundamental to patient safety and foundational to enable and improve key processes such as procurement, inventory management, internal deliveries,

dispensing, tracking, tracing, recalls and many more.

Dr Roberto Frontini, President of the European Association of Hospital Pharmacists (EAHP) supports the initiative and further emphasised the need for traceability of medicines in hospitals down to the single unit. "Barcodes on single units* are essential in hospitals, as barcode technology reduces medication errors by 41%". Each single unit package should be individually identified and fully labelled using GS1 GTIN, expiry date and batch number.

*Single unit package = GS1 primary package, is the one that contains one discrete pharmaceutical dosage form, i.e. a tablet, a certain volume of a liquid or that is the immediate package for a medical device like a syringe

Read the HPAC position statements on barcoding issues and interoperability

GOVERNMENT & REGULATORY

US: FDA reveals details on their Unique Device Identification (UDI) rule

On the 10th of July 2012, the United States Federal Drug Administration released the UDI proposed rule, establishing a Unique Device Identification (UDI) system, which will allow to unambiguously identify a manufacturer's specific medical device.

The ultimate goal of the UDI system is to enhance patient safety and global traceability of devices through a globally Unique Device Identifier that will be applied to a device or its label, will be documented in the UDI database and will be employed consistently throughout distribution and use.

A UDI system can provide multiple benefits, including:

*   Allow for more accurate reporting, reviewing and analysing of adverse event reports so that problem devices can be identified and corrected more quickly

*   Reduce medical errors by enabling healthcare professionals and others to more rapidly and precisely identify a device and obtain important information concerning the characteristics of the device.

*   Provide a consistent way to enter information about devices in electronic health records and clinical information systems

*   Provide a standardised identifier that will allow manufacturers, distributors and healthcare facilities to more effectively manage medical device recalls

*   Provide a foundation for a secure global distribution chain, to help address counterfeiting and diversion and prepare for medical emergencies

Based on the proposed rule, stakeholders have been invited to submit comments to the FDA. The deadline for comments expired early November and the FDA is now working on including those comments and finalising the UDI rule. The final rule is expected to be released by summer 2013, with a first implementation deadline for Class III devices one year after publication.

Read more about the FDA proposed rule

US: GS1 Healthcare submits comments to US FDA proposed rule for Unique Device Identification

GS1 US and GS1 Global Office submitted comments to the proposed FDA rule on time, before the deadline of 7th of November. The FDA received over 300 submissions. The main points raised by the stakeholders, and of relevance for GS1, are around the need to clarify the rule, the use of Data Matrix only and the use of globally harmonised standards systems for Automatic Identification and Data Capture. Additional comments are related to the implementation timelines.

An amendment to the proposed rule has been introduced on 19th November by the FDA with comments requested by 19th of December.

Read comments submitted by GS1 Healthcare

EU releases the draft of the new Medical Devices Regulation

On the 26th of September, the European Commission published its proposal for a revised regulatory framework for medical devices, comprised of the following:

• A proposal for a Regulation on medical devices (to replace: Directive 90/385/EEC regarding active implantable medical devices and Directive 93/42/EEC regarding medical devices)

• A proposal for a Regulation on in vitro diagnostic medical devices (to replace Directive 98/79/EC regarding in vitro diagnostic medical devices)

The main elements of the proposals include:

• Wider and clearer scope of EU legislation

• Stronger supervision of independent assessment bodies by national authorities

• Extended database on medical devices, providing comprehensive and public information on products available on the EU market

• Better traceability of devices throughout the supply chain with introduction of a Unique Device Identification system

• Stricter requirements for clinical evidence

• Alignment to international guidelines, to facilitate international trade

The Commission's proposal is now under discussion in the European Parliament and the Council and a political agreement could be reached during the Irish Presidency possibly in June 2013. In parallel, the European Commission will start working on the Delegated Acts.

In the meantime, the European Commission is working on a Recommendation to the EU Member States on UDI in order to avoid the development of non-harmonised national UDI systems.

The GS1 Healthcare Public Policy Work Team will be following this important regulatory development.

To join the GS1 Healthcare Public Policy team, contact Geraldine.Lissalde.Bonnet@gs1.org

NEWS FROM AROUND THE WORLD

Australia : Victorian Product Catalogue System goes live!

Health Purchasing Victoria (HPV) has released Stream I of the Victorian Product Catalogue System (VPCS) - an essential enabler of future supply chain and quality improvements across Victoria's public health system.

The VPCS facilitates automated receipt of supplier data loaded to the National Product Catalogue (NPC) which is a key part of the National E-Health Transition Authority's (NEHTA's) reform program that GS1 Australia hosts on GS1net.

The Victorian Product Catalogue (VPC) provides reporting, workflow management, email alerts, data translation and data synchronisation. Starting in 2013, progress roll out to all Victorian public hospitals and health services will continue. This rollout will provide hospitals and health services with VPCS functionality and access to common product and pricing information.

For more information, contact GS1 Australia at gs1aust@gs1au.org

Spain: Efficiency model in the Andalusian Health Service supply chain

The Andalusian Health Service, composed of 29 hospitals, 1514 Health centres and 9 management areas has been working towards the implementation of an Integral System of Logistic Management (SIGLO) to ensure patient safety and enhanced supply chain efficiency.

The objective of the Andalusian Health Service was to establish a sustainable model to increase patient safety, logistic service levels and reduce supply chain costs. By implementing Global Trade Item Numbers (GTINs), Global Location Numbers (GLNs) and all Electronic Data Interchange (EDI) messages, this new system was able to provide better purchasing prices and general conditions, modernisation of warehouses and overall reduction of bureaucracy.

Switzerland: Use of GS1 Standards to avoid pharmaceutical product confusion

Strongly supporting patient safety, Swiss hospital pharmacists association GSASA and manufacturers' associations unanimously adopted joint recommendations to implement GS1 Standards on pharmaceutical product labelling to avoid medical errors for, respectively:

• The avoidance of confusion concerning the primary packaging and labelling of solid pharmaceuticals dosage forms

• The avoidance of confusion concerning the primary packaging and labelling of liquid pharmaceuticals dosage forms

• The avoidance of confusion caused by pharmaceutical packaging and labelling which look similar ("look alike")

• The avoidance of confusion caused by similar sounding designations of pharmaceuticals ("sound alike")

Read these recommendations

UK: NHS Trusts take action to implement GS1 in NHS procurement

Sir David Nicholson, NHS Chief Executive, demanded that the NHS Trusts take action to implement GS1 in NHS Procurement. In the latest document released "NHS procurement: Raising our game", a number of recommendations are made to improve NHS procurement, including a 'requirement for trusts and suppliers to adopt standard barcoding (GS1), to improve procurement data and enable price comparisons while improving stock control and patient safety'.

For more information on the guidance, go to the UK Department of Health website

Global: IHTSDO/GS1 – position statement

The International Health Terminology Standards Development Organisation (IHTSDO) and GS1 have issued a joint position statement that sets out how the standards of both organisations can be strategically applied, in relation to each other, within healthcare systems across the world. IHTSDO, along with its members, seeks to improve the health of humankind by fostering the development and use of suitable standardised clinical terminologies, notably SNOMED Clinical Terms (CT), in order to support the safe, accurate and effective exchange of health information. Applications of both standards in collaboration are currently ongoing in Australia, Canada, New Zealand, and the UK. The CEO of IHTSDO, Jan-Eric Slot will be presenting at the next global GS1 Healthcare conference in Buenos Aires.

GS1 HEALTHCARE UPDATE

GS1 Healthcare in China

The 2012 Chinese Congress of Clinical Engineering & Information Technology (CEIT) was held in Ningbo, China on 9th to 10th November 2012. Mrs Ulrike Kreysa (Vice-President, GS1 Healthcare) and Mr Zhang Chenghai (President and CEO of GS1 China) who were invited to speak at the conference called for the Healthcare industry to use the GS1 Standards and systems to increase the efficiency of the supply chain and secure patient safety, to the more than 1000 participants from the local and global healthcare industry.

The sub-forum "Hospital Logistics Engineering and Medical Consumable Procurement Management" proved to be one of the most popular forums, with ~300 participants. Ulrike Kreysa re-emphasized that users of GS1 Standards ensure visibility for the benefits of patients worldwide. Mrs. Jiang Xiuzhu, Senior Pharmacist of Chief Pharmacist's Office, Hong Kong Hospital Authority, further demonstrated the value and role of the GS1 system in their public hospitals' current and future projects.

Many experts from local and international hospitals discussed how GS1 Product Identification standards can be used in critical hospital supply chain processes, like purchasing management, medical consumable management or hospital logistics management.

In connection with the Congress, GS1 China held the National Healthcare Promotion Working Group Meeting, which reviewed the key achievements of 2012 and set the priorities for 2013.

UPCOMING EVENTS

GS1 Healthcare speaking at events

The Cold Supply Chain Conference
7-8 March 2013 in Brussels, Belgium

Fleming Europe 3rd Annual Pharma Packaging and Labelling Conference
19-20 March 2013 in Berlin, Germany

3rd IVD Performance Evaluation & Regulatory Conference
25-26 February 2013 in Frankfurt, Germany

2nd EU Medical Device Regulation Conference :
18 - 19 April 2013 in Brussels, Belgium

Are you ready for the EU Falsified Medicines Directive?
24 January 2013 in Barcelona, Spain

Parallel Trade
6-7 February in London, UK

Temperature maintenance of pharmaceuticals in distribution
26-27 February 2013, Berlin, Germany

GS1 Healthcare wishes you a very happy and healthy new year 2013

23rd Global GS1 Healthcare Conference 23-25 April 2013 - Buenos Aires, Argentina

Invitation to Buenos Aires, Argentina

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