



# The Global Healthcare User Group

## GS1 HUG - Newsletter No. 1

Welcome to the first edition of the GS1 HUG Newsletter! We have initiated this newsletter to inform you about our activities and progress in the global Healthcare User Group, GS1 HUG. We look forward to receiving your comments, feedback and questions.

### The GLOBAL HEALTHCARE USER GROUP (HUG) – the Healthcare Industry works together to improve Patient Safety

In May 2005 leading global companies from the pharmaceutical and medical device industry formed the global GS1 Healthcare User Group (HUG). Its mission is to lead the healthcare industry to the effective utilization and development of global standards, with the primary focus on automatic identification to improve patient safety.

The HUG vision is to become the single source for regulatory agencies and trade organizations (manufacturer, wholesaler, hospital and pharmacy) to seek input and direction for global standards in the healthcare industry.

Baxter, Boston Scientific, B.Braun, 3M, GSK, Hospira, Johnson & Johnson, Medtronic, Merck, NACDS, Pfizer, Smiths Medical and Tyco have participated in the kick-off-meeting. In the meantime the group has significantly grown – it currently has 34 members. They are committed to work towards a global solution to enhance automatic product identification for the benefit of patients worldwide.



### HUG - Focus areas and Working Teams

The main focus areas for the group are the following:

- Prevention of Medical errors
- Product Authentication
- Tracking and Tracing
- Increase total Supply Chain efficiency

The work of the HUG will improve the performance of the healthcare supply chain for drugs and medical devices through the collaborative development and endorsement of recommended voluntary GS1 standards and best practices.

### The HUG Leadership Team

The HUG is organized into six working teams, which are lead by the industry. They have developed a work plan with deliverables for the different groups.

The work team **Communication and Coordination** is lead by **Rich Hollander, Pfizer**, who is also one of the recently elected HUG Industry Co-Chairs, which represent the group toward third parties. He is leading and organizing internal and external communication of the HUG to establish the HUG as the leading voice in the area of automatic data identification in the healthcare industry. Working tools for that are the GS1 HUG website <http://www.gs1.org/hug/>, press releases and in the future also a regular newsletter.



**Volker Zeinar, B.Braun** is the second HUG Industry Co-Chairs.



Volker and **Jim Willmott, Smiths Medical** lead the work team **Membership** and take care of an organized HUG enlargement, to progressively include all stakeholders of the healthcare supply chain.

In the **Standards Implementation** group **Tom Werthwine, Johnson & Johnson Medical Devices** leads the efforts to identify and help resolve GS1 standards implementation issues in the healthcare market. The team is currently working on an industry baseline.



**Peter Tomicki, Baxter** reviews, in the **Standards Development** team, the existing relevant standards development processes in healthcare and will develop a proposal for optimization. At the same time the group will work on forecasts of the key supply chain standards required by the healthcare industry in the next 2 to 5

years.

The objective of **Regulatory Affairs**, lead by **Jackie Elkin, Medtronic** is to organize the industry around a single position to influence future standards and regulations. The group has started the work by creating a unique baseline about existing regulations in healthcare worldwide.



**Edward Dzwil, Johnson & Johnson Pharmaceuticals** has already developed the outline for a **Business Case** for Global Standards in the Healthcare Supply and Regulatory Chain. This is important to address and convince all stakeholders (Healthcare manufacturers, wholesalers, hospitals,



pharmacies, regulatory agencies and trade groups) of the benefits of global healthcare standards.

## HUG Meeting, 13<sup>th</sup> – 15<sup>th</sup> September in Brussels

All HUG work team leaders reported on their group and work progress at the last HUG meeting, which took place in Brussels on 13<sup>th</sup> to 15<sup>th</sup> September. The participants from leading global pharmaceutical and medical device companies and GS1 healthcare experts from around the world discussed and approved on the first day the HUG work plan.



## Regulatory bodies – status and requirements

On the second day, the focus was on regulatory bodies, their work and requirements with regards to patient safety.

Speakers from the European Commission (DG SANCO and DG ENTR), the European Agency for the Evaluation of Medicinal Products (EMA), the US Food and Drug Administration (FDA), National Patient Safety Agency of the NHS (UK), the Italian Ministry of Health and Regional Healthcare Service Area of Andalucía (Spain) presented their view and interest in patient safety issues. They appreciated the open discussion and possibility for direct information exchange with global manufacturers and GS1 staff.

**Dr. Hans Georg Wagner** from the **European Medicines Agency (EMA)** pointed out that counterfeiting is a global problem. With unannounced inspections of marketing authorisation holders the European





commission and EMEA try to react to the problem. The EMEA also promotes better information sharing and coordination between the member states. Dr. Wagner emphasized that future solutions need to be technically mature, proportionate to the threat and affordable.

**Sabine Atzor from the European Commission, DG Enterprise and Industry, F2/ Pharmaceuticals**



reported about the actions taken by the European Commission to combat counterfeits. Besides existing regulations and guidelines the regulation (EC) No 2006/2004 of the EP and Council on cooperation between national authorities responsible will enforce the consumer protection.

The Head of Medicines Agencies have also created a new group, the EU Medicines Enforcement Officers (EMEO), with representatives from the member states and observers from the EMEA and European Commission to survey the extent of the counterfeit problem in the EU and develop an EU wide anti-counterfeiting strategy.

**Dr. Marianne Takki from the European Commission, DG SANCO, Patient Health**, talked about her view on the topic of patient safety. In DG SANCO so far work has been done on the sectors blood products, tissues and cells, best practise in health systems and quality projects.



Member States are facing common challenges to their health systems; ensuring quality is one of them. Benefits come from greater cooperation with national responsibility.

**Michelle Limoli from the US Food and Drug Administration (FDA)**



spoke concerning the view of the FDA on counterfeiting. The reported cases in the US have increased in the last years. Therefore an electronic track and trace technology is the favourite solution for

FDA. They see this as feasible by 2007 and look at RFID as the most promising technology for it. While studies are conducted on the impact of this technology on pharmaceutical products, FDA is actively supporting the standards development process. The e-pedigree, with a complete history of drug sales and distribution, is the preferred solution to combat counterfeiting for the FDA. With regards to the authentication technology, the FDA has found that companies are increasing their use of authentication technologies in products and packaging.

**Dr. Walter Bergamaschi from the Italian Ministry of Health**



informed about the project for the drugs tracking system in Italy, which has its origin in a European Directive from 2001 and shall "facilitate the withdrawal of defective products from the market and allow more effective efforts against counterfeit products". As core of the project, a central

database was created and a progressive numeric ID code ("Bollino") introduced. The project has two phases: a phase of first implementation and a phase of completion and is managed by a technical working team including all relevant stakeholders. The central database is essential for the new NHIS (National Health Information System), which will be a system of individual health records. Dr. Bergamaschi said, that he is open for all suggestions and information, which facilitate the Italian project.

**Prof. David Cousins, Head of Safe Medication Practice from the National Patient Safety Agency (NPSA) of the NHS**



shared his findings on patient safety. For the NPSA a patient safety incident is any unintended or unexpected incident, which could have or did lead to harm for one or more patients receiving NHS funded healthcare. Worldwide alarming numbers have been reported in several studies.

The first aim of NPSA is to ensure safety of patients but might potentially offer other improvements in efficiency and effectiveness. Over the next ten years, the National Programme for IT will connect over 30,000 GPs in the UK to almost 300 hospitals and give patients access to

their personal health and care information, transforming the way the NHS works.

A Regulatory Impact Analysis (RIA) will set out the likely costs and benefits of possible solutions from the one of “do nothing” to the most advanced technologies and must be done before a new legislation is progressed.

**Jesús Gavira Sánchez** from the **Regional Healthcare Service Area of Andalucía** presented their organisation, an aggregation of 29 hospital areas with 16,500 beds, 650,000 admissions/year and 4,400,000 treatment days/year. A common platform for the IT support of ‘digital strategy’ in purchasing and logistics has been created. All suppliers of the hospitals are requested to fulfil the requirements with regards to product information and product identification to support a central catalogue with standardized information. The actual deadlines are the following:



31 October 2005: codification and master data alignment (AFM), 30 April 2006: barcode symbology of trade units and 31 October 2006: barcode symbology of consumer units following the norm of S.A.S. Further, a surgical implant register and a project to improve the system in case of recalls is planned.

**“We have chosen the GS1 standards, because they are truly global. ”**

**Jesús Gavira Sánchez, Logistic Manager, Regional Healthcare Service of Andalucía, September 2005**

## GS1 activities in Europe, USA and Japan

In the next section GS1 experts reported on the GS1 activities in Europe, USA and Japan.



**Jim Bracken, CEO of GS1 Ireland and Director of EHI** gave an overview about the European Healthcare Initiative, which was started in 2003 to create external awareness of the GS1 system. In the “Pharma Supply Chain” project (EPSCWG) a Pharma

Voluntary guideline and e-messages (EANCOM) were developed, which have now been given to the HUG as a base for discussion in the development of global guidelines. The recent efforts lie in the planning of three pilots: One in France and Belgium between Baxter, AEXDIS and hospitals in Rouen, Dijon and Lille, based on Product Catalogue exchange and marking at all levels of packaging. The second is the traceability of haemophilia products to the patient’s home in Ireland and the third is an e-pedigree pilot in the UK, with owner and product authentication at each step of the supply chain.

Jim underlined the future collaboration of EHI and HUG, where EHI will play a key role in standards implementation in Europe.

**John Roberts, Director Healthcare GS1 US** provided an overview for the GS1 activities in healthcare in Canada and the USA. In Canada a successful vaccine pilot has been accomplished, where GTIN, lot number and expiry date in a Data Matrix symbology was used. In the next HUG meeting the Canadian government will provide detailed information.



A large project at GS1 US is the GLN Healthcare Registry for Healthcare™, a registry for all healthcare locations in the USA. It is managed by an industry steering group and will enable accurate accounting and accurate shipping across the whole country. 83% of all hospital data is already entered in

the database.

**Yamato Miyahara, General Manager of GS1 Japan** reported that

medical/surgical products in Japan are internationally traded - around 40% are imports. While the fixed information is managed in a database, the flexible product information is carried in a GTIN-128. In medical institutions also a wristband bar code label for the patient is used. In the National Center for Child Health and Development in Tokyo with 500 beds every room has a bedside terminal with a barcode – reader connected to the electronic medical records, the accounting system and the supply, processing, distribution system.



In 2004 a pilot project between manufacturer and distributor has been done in the medical and



pharmaceutical products industry to label vials with RFID labels to maintain sales records. Though the reading rate at a 90-degree angle was poor, the inspection time was shortened by about 91% compared to the current visual or barcode methods.

### **The working teams: Standards Implementation, Standards Development and Regulatory Affairs Work**

Great progress was made on the third day in the three working groups; Standards Implementation (Tom Werthwine, J&J), Standards Development (Peter Tomicki, Baxter) and Regulatory Affairs (Jackie Elkin, Medtronic). The contribution and expertise of the participants was essential in moving the work ahead.



All participants were very committed to the GS1 standards and promoted them as their chosen global solution to the present regulatory bodies and industry associations.

**The next HUG meeting will be hosted by Johnson & Johnson and take place in Princeton, New Jersey, USA on 29/30 November/1 December 2005.** The agenda and other details can be found on the GS1 HUG website.

For more information on the GS1 HUG, please visit the website <http://www.gs1.org/hug/> or contact Ulrike Kreysa at [ulrike.kreysa@gs1.org](mailto:ulrike.kreysa@gs1.org)

**“Patient safety has many faces. A standardized machine-readable product identification can make an essential contribution to it. Where could we discuss and enhance all the related aspects better than in a global working group, which is open for all healthcare supply chain stakeholders. The GS1 HUG offers an excellent platform for working on harmonized solutions. We engage ourselves in this initiative with the intention to share our expertise, to learn from others and to optimize the product identification in terms of the patients.”**

**Volker Zeinar, B.Braun**



**The global language of business.**



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