

Welcome to the third edition of the **GS1 HUG™ Newsletter!** This newsletter aims to inform you regularly about our activities and progress in the global Healthcare User Group, GS1 HUG™.

We look forward to receiving your comments, feedback and questions, possibly for inclusion in future newsletters.

More information can be found on our website <http://www.gs1.org/hug/>

### Third meeting of GS1 HUG™ global Healthcare User Group in Rome, Italy.

The GS1 Healthcare User Group, GS1 HUG™ met from 21 to 23 March 2006 for the third time, discussing and developing global healthcare business requirements to improve patient safety.



The 3-day conference provided valuable perspectives, from various parties in the healthcare supply chain, into a wide range of business issues requiring GS1 standards in support of their resolution. The issues discussed ranged from prevention of dispensing errors, visibility into healthcare costs, e-commerce to serialization. Work teams had the opportunity to meet and have more in depth discussions about how to begin aligning towards existing global standards for each area or conversely, to identify standards that do not yet exist and need developing.

This time the meeting took place in Rome and was hosted by GS1 Italy, supported by sponsorship through Pfizer. Alvaro Fusetti, the CEO of GS1 Italy, and Dr. Bergamaschi, from the Italian Ministry of Health, welcomed the 80 delegates from global manufacturers, wholesalers, hospitals, associations, regulatory bodies, GS1 member organisations and GS1 Global Office.



**Alvaro Fusetti, GS1 Italy** gave a short introduction into the GS1 organisation and explained the broad GS1 product and service portfolio with BarCode, eCom, GDSN and EPCglobal. He also underlined the importance of the work in the healthcare industry for GS1.

**Dr. Bergamaschi** introduced the traceability project of the **Italian Ministry of Health** and the current status. The second phase of the project has now started. The first promising results can be seen and a technical working group has been formed, to which GS1 is invited to participate.



**Rich Hollander, HUG Co-Chair, Pfizer** provided an overview of the HUG, including its formation, mission and vision, present focus areas, guiding principles and work teams.

Afterwards the HUG work team leaders from **Smiths Medical, Medtronic, Johnson & Johnson Medical Devices and Pharmaceuticals, Baxter, GSK, Merck and B. Braun** broadened this understanding by providing more information about the objectives, actions and status of their work teams.

**“Our target was to use international and most shared systems of reference. For the codification system the choice is GS1.”**

Pascal Mariotti, University Hospital of Lyon

**Mark d’Agostino, VP of GS1 Standard Development**, expressed the commitment of GS1 to develop the standards the healthcare industry needs and appreciated the commitment of the HUG to the GSMP, the GS1 Standard Development process.

## Track and Trace in Swiss Healthcare Clinical Settings

**Christian Lovis, Head of the Clinical Informatics Unit at the University Hospitals of Geneva, Switzerland** gave an interesting insight into the usage of RFID technology to improve patient care processes and efficiencies in these healthcare facilities. The technology is used in the logistics to support care, such as



access control, clothes distribution, reception and distribution of merchandise, but also for authentication of care providers to insure patient privacy. Recently, these technologies have also been used to improve patient safety: by using labels including RFID tags in the preparation of chemotherapy in the pharmacy, to tracing the medication down to the patient level and ensure that the right person administered the right medication to the right patient at the right time. The data is automatically registered in the electronic patient record, so that it is possible to keep track of all actions around administration of medicines to the patients.

This all happens in combination with an e-prescription system, which additionally increases the patient safety by helping the doctors with alerts and warnings.

To consolidate the flow of information is important and the hospital plans further expansion of the usage of the GS1 keys.

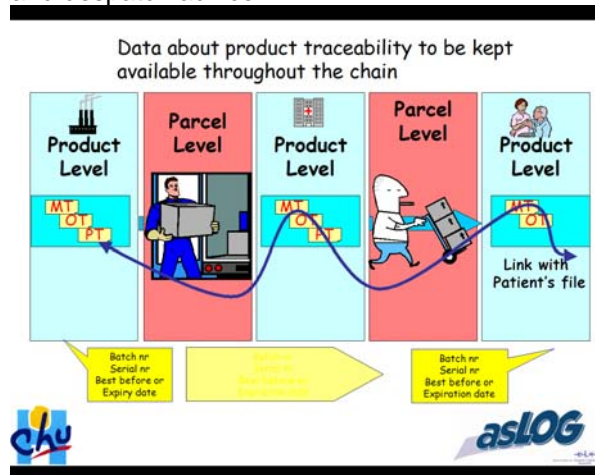
## Traceability in a French hospital

**Francois Bisch, Director Logistic of the University hospital of Dijon** has established traceability in the supply chain in this very large hospital (1,683 beds). The hospital care unit is the last step in the supply chain, before delivering to the patient. The data about product traceability must be



kept available throughout the whole supply chain and the original product data remain unchanged. It is important that the solution is simple and safe.

Dijon has chosen the GS1 keys for identification of all the participants from the GSRN<sup>1</sup> for the identification of the patient to the GLN<sup>2</sup> for the identification of dispatch and receiving point, GRAI<sup>3</sup> for identification of the transport container and the GTIN<sup>4</sup> for product identification. All the transport information, including product details (e.g. batch/serial number, best before or expiry date) are kept and interchanged through SSCC<sup>5</sup> and despatch advice.



The project has been very successful and well received, also by the staff and further rollout is planned. It has also raised great attention with other hospitals and healthcare specialists in France and Europe.

## The new French e-Procurement platform

**Pascal Mariotti** from the **University hospital in Lyon** informed the interested audience about the new French e-procurement platform. 17 university hospitals in France have created a common platform for purchasing of drugs, medical devices, laboratory material and supply for



homecare. They have chosen the provider 'Achat-Pro' as their partner for hosting the platform. The

<sup>1</sup> GSRN= Global Service Relation Number

<sup>2</sup> GLN = Global Location Number

<sup>3</sup> GRAI = Global Returnable Asset Identifier

<sup>4</sup> GTIN = Global Trade Item Number

<sup>5</sup> SSCC = Serial Shipping Container Code

pilot with the first three hospitals has been successfully finished and now the implementation will continue. In the meantime there are a number of other hospitals, which want to join the group. With the creation of a common purchase organisation in January 2006, which is linked to the platform, the need for a common identification system was obvious and the GS1 system was chosen.

The suppliers will be asked to provide their e-catalogues to the marketplace with a number of required fields. The hospitals have decided to use international and most used systems of reference. All products have to be identified with GTIN (GS1/EAN13), all places and medical units with GLN and for all deliveries a despatch advice (DESADV) is requested as well as for parcels a SSCC. With regard to the classification, ATC<sup>6</sup> will be used for drugs, Cladimed<sup>7</sup> for medical devices and UNSPSC<sup>8</sup> or GPC<sup>9</sup> for the other product fields.

## The view of the Wholesaler in Europe



**Monique Derecque-Pois, secretary general of the European Association of Pharmaceutical Full-line Wholesalers (GIRP)**

talked about the view and position of GIRP with regard to automatic product identification and patient safety. GIRP has full members from

national wholesaler associations and direct members, including the four largest companies in the EU/EFTA. For better identification and traceability of products, GIRP and its members aim at harmonizing product identification for pharmaceutical products by agreeing, within the pharmaceutical industry and all supply chain partners, on standards with cost efficiency for all participants. Thereby it is important for them to have the national product identification, expiry date and batch number available in a machine-readable format. GIRP chose GS1-128 or Data Matrix as the most suitable data carriers for today and RFID as a future technology after having examined the different technical possibilities. Members of GIRP are active in different HUG work teams.

<sup>6</sup> ATC = Anatomical Therapeutic Chemical (WHO)

<sup>7</sup> Cladimed = Classification des Dispositifs Medicaux (France)

<sup>8</sup> UNSPSC = United Nations Standard Products and Services Code (UN)

<sup>9</sup> GPC = Global Product Classification (GS1)

The second day of the HUG meeting, during the morning session, was dedicated to the present environment in the **Italian healthcare supply chain** and representatives from all associations, which play a role there represented their view from the retail pharmacists, to the hospital pharmacists, wholesaler and manufacturer, to the Italian government.



## The role of DAFNE in the enhancement of medicine provision

**Dr. Stefano Novaresi** from **DAFNE**, a consortium between Pharmaceutical Companies and Wholesalers introduced the aim of his organisation to involve the pharmaceutical partners through the development of electronic connections with international standard (EDI<sup>10</sup>) and the Internet.



The objective is to work with all players of the pharmaceutical supply chain for an effective collaboration. DAFNE was created in 1991 by some leading pharmaceutical companies. Today DAFNE's users cover 95% of the Italian market with regards of suppliers and 99% regarding wholesalers. An intensive exchange of EDI messages between suppliers and wholesalers has been developed and the next goal is to now involve the hospitals. The target for 2006 is to connect 100 hospitals with 25 suppliers using the electronic messages for order, order confirmation, invoice and tracking. For DAFNE the first step towards any improvement of product and information flow is to enable a fast and accurate Automatic Data Capture. DAFNE is also part of GIRP and supports the conclusions of the European Association.

<sup>10</sup> EDI = Electronic Data Interchange

## The drug tracking system in Italy



**Dr. Walter Bergamaschi** from the **Italian Ministry of Health** explained the traceability project of the Italian healthcare authorities and showed the initial results achieved. As public health expenditure has been increasing in Italy, the scope of the project has been enlarged from countering

existing fraud, safeguarding Public Health and the Treasury, to leveraging the potential of the Central Data Base for improved visibility into the expenditure and consumption of drugs at the regional level within Italy. All movements of drugs will be reported in the future to the central database and from that significant data for all the players involved in the tracking system will be provided. Additionally a control over the appropriateness of prescriptions and drugs consumption can be achieved. The Central Data Base is fundamental within the new NHIS (National Health Information System), which aims at the implementation of a System of Individual Health Records. From June to December 2005 350 million movements have been tracked and analysed in reports, in average 1,7 million per day. In the first phase only out movements, the transmission of data related to the supply of Bollini by the IPZS (the national mint) and the transmission of the value of all drugs supplied were monitored. For the completion phase it is now necessary to find an agreed solution to standardize the ID system and to propose technical solutions for traceability in agreement with all supply chain participants – GS1 is invited to contribute to that. A technical committee will be created and the application of international standard and safeguard of enterprise investments ensured. In this team – including GS1 Italy – all obstacles for a further successful roll-out shall be discussed and eliminated.

## Farindustria: The Vision of Track & Trace

**Dr. Sergio Liberatore, Vice-President of Farindustria** presented the approach held by the manufacturers in



supporting the requirements of the first phase in implementing the dataflow to the central database. He highlighted the large impact in terms of process change introduced on the production lines of the manufacturers by the 'Bollino' and the unresolved issues related to the reading of each single label before distribution. The serial number is on the box but nobody is enabled to read it. Farindustria therefore has some concerns related to phase 2 of the project and is committed to participate actively with the technical committee which will be set-up directly by the Ministry of Health, in order to drive as firmly as possible towards a practical solution. In this, the industry confirms its primary commitment to the public health as a fundamental driver to the decision making process.

## Track & Trace of Drugs: The view of the wholesalers

**Dr. Sergio Sparacio, General Director of ADF**

(Associazione Distributori Farmaci) presented the structure of the secondary distribution channel throughout Europe and Italy, remarking that the role of the wholesalers is to guarantee high-level quality of service to pharmacies and hospitals and make available the pharma products as many as 2-3 times a day, in the high turnover selling points. He highlighted the risk of the dramatic decrease in productivity, possibly related to the obligation to read (scan) every single unit at the end of the picking process.



## Track & Trace of Drugs: The Italian Way



**Giuseppe Perroni, General Manager of Federfarma**, the Italian association of pharmacies, reviewed the process set up in Italy for tracking and tracing of pharmaceuticals, driven by the control of expenses and the objective to manage correct reimbursement of drugs and avoid fraud. Although today there is a serial number on the bar code labels it is not possible to read them

at present. The creation of a network to exchange information and track drugs through the supply chain is important. While RFID is on the horizon it could already be used today for the information stored in 2D bar codes. Standardizations and automation in alignment of all supply chain parties will help to move to more productivity and better data accuracy while reducing lead times in distribution.

## FIASO – the Italian Hospital Association: The new Logistics in the Hospitals

**Dr. Nicola Pinelli** from **FIASO** represented his organisation with more than 140 members from large and smaller hospitals. The objective of the association is to create a 'virtual' environment for sharing best practices and to bundle purchasing power. More and more hospitals come together to combine their demands for products and create a central purchasing organisation, which delivers better economic results with common tenders and agreements with the suppliers. This can take place on different levels; national, regional or local. The central management brings efficiencies in supply chain management and logistic handling of the goods, but reduces of course the negotiation power on other levels. The role of IT in moving forward with the process simplification is significant. The hospitals are interested in electronic communication with their suppliers to also improve the processes. While budget control is a constraint in the daily business, the main concern is on patient safety and quality of care. The afternoon, of the second day, was dedicated to the **work teams**; Standards Implementation/



Regulatory Affairs, Standards Development, GTIN Allocation Rules for Pharmaceuticals and Medical Devices, Instruments and Implant, Vaccines & Biologicals and Business Case. Every delegate could participate in two sessions. The leaders of

the work teams reported their results back to the plenary on the next day. The summarizing slides can be found on the GS1 HUG™ website <http://www.gs1.org/hug/meetings/210306/-presentations>

In the HUG work team Instruments and Implants a



new Co-Chair, **Herve Ney** from the **University hospital of Geneva** was elected. He will share the team leadership with **Volker Zeinar**

from B.Braun and contribute with his practical experience and knowledge from his daily work in the sterilization department of the hospital.



## The Voice of the Medical Technology Industry in Europe and Beyond

EUCOMED is the Association representing the Medical Technologies Industry in Europe. The membership of Eucomed consists of 60 companies and 26 associations, which represent 80% of the business turnover of this industry in Europe. **Claes Wallér** from **Cook Group Europe** explained that Eucomed's key objectives are to secure a balanced and predictable regulatory framework and a competitive and coherent health policy as well as the good reputation of the



medical technology sector. Eucomed is working closely with the American association Advamed to exploit their potential synergies around the world and is also a cooperation partner of the HUG. Eucomed has a number of work groups; one is the ETF (eBusiness Task Force) dealing mainly with issues and business processes around bar codes. It becomes increasingly clear that identification, tracking and traceability of medical devices are key issues in the hospitals not least because of patient safety considerations, but it is not clear what the concrete requirements of the customers are. ETF and HUG will work together to define solutions to improve patient safety. They will participate regularly in each other's meetings and work teams.

## GS1 Traceability Standard

GS1 has recently released a new Traceability Standard, which was developed by a large group of industry experts, under the leadership of GS1. **Miodrag Mitic** from **GS1 Global Office** explained that it is a business process standard describing the traceability process independently from the choice of enabling technologies. It defines minimum requirements for companies of all sizes across industry sectors and corresponding GS1 Standards used within information management tools.



According to the ISO definition, traceability is the ability to trace the history, application or location of that which is under consideration. It is mainly in the focus of the industry to meet regulatory requirements, or business requirements, for efficient product recalls and withdrawals within the context of quality, safety and security assurance and supply chain visibility.

Implementing a traceability system within a supply chain requires all parties involved to systematically associate the physical flow of materials, intermediate and finished products with the flow of information about them. More and detailed information about the GS1 Traceability Standard can be found at <http://www.gs1.org/productssolutions/traceability/>

## Traceability in the Crop Protection Industry in Europe



**Hans Kraft** from **Syngenta** showed the traceability solution that the crop protection industry in Europe has created, following the standards of GS1. Product tracking means the capability to follow the path of a specified unit of a product through the supply chain as it moves from point to point between organisations.

Products are tracked routinely for stock management and logistical purposes. Product tracing means the capability to identify the precise identity of a particular unit, or batch of product, located within the supply chain, by reference to records held upstream in the supply chain. Products are traced for purposes such as product

recall and investigating complaints. For products in the CP industry it has been defined that the traceable item is the product plus batch number, depending on the level in the supply chain. Although companies in Europe have developed this solution it is aligned with North America.

## EPCglobal Healthcare & Life Sciences Business Action Group (HLS BAG): State of Pedigree and EPC/RFID Standards

**Ron Bone** from **McKesson Pharmaceutical Supply** represented, as one of the EPC<sup>11</sup> tri-chairs, the work and progress made in the HLS BAG<sup>12</sup>.



The group was formed in 2004 and the USA membership represents 38 of the 40 largest manufacturers, the 3 largest distributors and major retailers. It was formed in association with HDMA, NACDS and other associations and the FDA is involved in the standard development. The focus lies in addressing critical needs e.g. pedigree management, air interface sStandard for item level tagging, serialization (the format of the EPC on the tag), decommissioning of tags and network security. The key drivers for the BAG are patient safety, requirements of the FDA and the pedigree laws from different States in the USA. While currently pilots are underway (see Viagra pilot of Pfizer), the price for tags and reader is coming down and physical and standards challenges are being addressed.

**Mike Rose** from **Johnson & Johnson**, who is also one of the EPC tri-chairs, explained the organisation of the



11 EPC = Electronic Product Code™ see <http://www.epcglobalinc.org/>

12 HLS BAG = Healthcare Life Sciences Business Action Group

standard development. The HLS BAG is organised in multiple work groups – some of them are working in cooperation with the FMCG sector. The EPC tri-chairs said that they see a lot of opportunities to work closely together with the HUG. A continuous discussion and alignment between the leaders of the two groups has already taken place.

At present the focus of the work is on e-pedigree with the upcoming laws and time limits in different States in the USA (e.g. California, Florida and Nevada) and clarification of the serialization, where two options have been developed. For 2006 the capabilities of Track & Trace, Reverse Logistics, Authentication and in the future Patient Care Management, are also in the scope. Recently a workgroup for medical devices has been established.

The challenges for the HLS BAG are seen at the moment in policy topics, wider industry adoption and certain aspects of the technology.

## Enhancing Patient Safety - Pfizer RFID Pilot

**Rich Hollander** from **Pfizer** provided insight into Pfizer's RFID pilot with **Viagra®** marketed in the USA. Pfizer announced their intention for this pilot in late 2004, with the objective of learning how RFID technology could be used to authenticate product in the supply chain as a



means to help improve patient safety. Once the supply chain is enabled with this technology, additional benefits of tracking and tracing would help further. Viagra was chosen because it is one of the most counterfeited products in the world. The focus was to enable authentication of all packaging levels for wholesalers and pharmacies. All Viagra produced for sale in the USA now contains an RFID/EPC tag. Objectives for Pfizer were to understand the costs and benefits of the new technology, to learn more about the business processes, the new technology requirements, experience the technical/physical limitations and be aware of the implications and challenges associated with widespread implementation. While HF was chosen for the item tag, UHF was used for the case and pallet level tag. A Data

Matrix bar code containing the EPC number is backing the item level tags, in case of a tag failing to read and linear bar codes are used for case and pallet level, for the same reason. Customers wishing to authenticate are provided authorization to access to the SupplyScape portal. They can receive specific information about the product and other important messages using the portal at the time of reading/scanning. In 2006 Pfizer is focusing on collaborating with trading partners to understand more about how the technology works as the supply chain becomes enabled to read the tags.

\*\*\*

## The GS1 HUG™ Brochure

The HUG brochure was featured in the previous newsletter and provides detailed information, including details about the GS1 structure.

Copies can be downloaded from [http://www.gs1.org/docs/patient\\_safety/hug\\_brochure.pdf](http://www.gs1.org/docs/patient_safety/hug_brochure.pdf)



## Next HUG Conference...

Continued on next page:

---

## Next HUG Conference in Minneapolis, Minnesota, USA



The next **GS1 HUG™** conference will be hosted by **Medtronic, Inc.**, at their World Headquarters in **Minneapolis, Minnesota** and takes place from **13 to 15 June 2006**.

Conference details, agenda and registration can be found on the GS1 HUG™ website:

<http://www.gs1.org/hug/meetings/130606/>  
[http://www.gs1.org/hug/meetings/130606/ - agenda](http://www.gs1.org/hug/meetings/130606/-agenda)  
<http://www.gs1.org/hug/meetings/registration/>

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)



This newsletter was written and produced by the GS1 HUG™ Communication Work Team. Any questions should be addressed to Ulrike Kreysa, GS1 Global Office. [ulrike.kreysa@gs1.org](mailto:ulrike.kreysa@gs1.org)  
T +32 2 778.78.37.

All text, images and graphics © GS1 2006. [www.gs1.org](http://www.gs1.org)



---

**The global language of business.**