GS1 global Healthcare User Group – GS1 HUG™

TO: HUG Members DATE: 4 December 2006
FROM: Ulrike Kreysa – GS1 GO
SUBJECT: **HUG Conference held on 20 to 22 September 2006 in Paris/France**

ATTENDEES
3M – Alfons Rathmer
ABHI/EUCOMED – Mike Kreuzer
Aesculap AG & Co. KG - Gunther Lamparter
AEXXDIS – Jean-François Fusco
Arthur Inc. – Takahito Asano
Asept in Med – Jean Luc Maurat
Astra Zeneca/EFPIA – Graham Smith
B.Braun Group - Volker Zeinar
B.Braun France – Christine Lacal
Baxter - Peter Tomicki
Baxter World Trade SA – Fredrik Ulrichs
Boston Scientific – Bill Cooley
Boston Scientific – Rene Stistrup Jensen
Cardinal Health – Julie Kuhn
Celesio – Alexandre Poissonnet
CHU Dijon – François Bisch
CHU Rouen – Bernard Dieu
Cladimed – Maurice Ventura
Club Inter Pharmaceutique – Agnes Vabois
Comparatio – Frank Brueggemann
Cook Group Europe – Claes-H. Wallér
Cook Group Europe – Steen Christensen
Cordis – Pascal JL Nieuwland
DHL - Exel Supply Chain - Mike Meakin
Edwards Lifesciences - Dawn
FDA - Jay Crowley
GCS UNI.H.A – Pascal Mariotti
GHX – MJ Wylie
Glaxo Smith Kline – James Hickland
GPSG - J&J Pharma - Massimiliano Molinari
GPSG - J&J Pharma - Edward Dzwill
GS1 Austria - Barbara Dorner
GS1 Canada – Alicia Duval
GS1 – EPCglobal – Gay Whitney
GS1 – EPCglobal – Chris Adcock
GS1 – EPCglobal – Bob Celeste
GS1 – EPCglobal – Bernie Hogan
GS1 France – Pierre Georget
GS1 France - Valérie Marchand
GS1 France – Caroline Raymond
GS1 GDSN – Sally Herbert
GS1 Germany - Michaela Haehn
GS1 Global Office – Ulrike Kreysa
GS1 Global Office - Scott Gray
GS1 Global Office – Mark d'Agostino
GS1 Global Office – Zexia Huang
GS1 Global Office – Eric Decroix
GS1 Global Office – Michel van der Heijden
GS1 Global Office – David Buckley
GS1 Global Office – Eirk Sundermann
GS1 Global Office – Anders Grangard
GS1 Global Office – Tom Heist
GS1 Global Office – Melanie Kudela
GS1 Hungary - Zoltán Krázli
GS1 Ireland – Jim Bracken
GS1 Italy – Stefano Bergamin
GS1 Japan - Yamato Miyahara
GS1 Japan - Yasuo Kurosawa
GS1 Netherlands – Friso van Weelden
GS1 SCG - Miroslav Ilic
GS1 Spain – Carlos Torme
GS1 Spain – Jose Javier Sanchez
GS1 Sweden – Tomas Wennebo
GS1 Switzerland – Christian Hay
GS1 UK – Alice Mukaru
GS1 UK – John Jenkins
GS1 US – John Terwilliger
GS1 US – Bernard Hogan
Hopital Bichat – Damien Talon
Hopital Europeen Georges Pompidou – Florence Vincent
Johnson & Johnson - Thomas Werthwine
Johnson & Johnson – David Howard
Johnson & Johnson – Janice Kite
Johnson & Johnson - Mike Rose
Joint Commission International – Lynda E. Mikalauskas
McKesson - Ron Bone
McKesson – Ted Ng
Medtronic, Inc. - Jackie Rae Elkin
Medtronic – Jordan Montgomery
Medtronic – Jim Domke
Merck - Stephen Hess
Merck KGaA Germany – Christina Schuetze
Merial – Jean Claude Muller
Ministry of Health New Zealand – Bruce Anderson
MIT Sloan School of Management – Prof. Masanori Akiyama
MSU School of Packaging – Prof. Hugh Lockhart
Novartis Pharma AG – Scott Cameron
Olympus Medical Systems - Naomi Sekino
Pastoral – Shotaro Saito
Pfizer - Rich Hollander
Pfizer - Mark Walchak
Pfizer – Tim Marsh
Pfizer – Nelson Camejo
Sanofi-Aventis – Jean-Marc Bobee
Sanofi Pasteur – Jacques Paturel
Sanofi Pasteur - Leteutre
Smiths Medical - Jim Willmott
St. Jude Medical - Bruno De Maeyer
Tyco Healthcare – Mark Hoyle
Tyco Healthcare – Alyette Decieux
Tyco Healthcare – Jean-Pierre Aubard
Vernon Carus – Val O'Brien
Wyeth – Thomas J. Pizzuto

***Note**: This summary focuses on the main subjects discussed and conclusions made at the conference. It is not intended to be a complete record of the conference or discussions that took place.*

20 September 2006

For the first time the HUG conference started with a training on GS1 standards, including GDSN and EPCglobal, for all participants who were interested.

1. Welcome

Michael Linney, VP Logistics EMEA, Tyco Healthcare, welcomed the participants to Paris for the fifth GS1 HUG™ conference. He underlined the strong interest of Tyco in the HUG group and their willingness for strong support as they appreciate the HUG effort to create global standards. He wished the participants a successful and interesting conference.

Pierre Georget, CEO of GS1 France, also welcomed the HUG group in Paris. He explained the mission, vision and organisational structure of GS1. Healthcare is a core sector for GS1 and Pierre confirmed the strong engagement of the whole GS1 organisation in this sector for the benefit of the patients.

2. Introduction and Administrative Matters

Ulrike Kreysa opened the conference as the group's chair and reviewed the anti-trust statement. This was followed by a short self-introduction of the conference participants.

3. The HUG – Mission and Vision/Roadmap

Rich Hollander, Pfizer, HUG Co-Chair, gave an introduction to the HUG mission, vision and focus areas. He explained the new structure of the HUG, where the work teams are directly related to the HUG roadmap for the next two years. Peter Tomicki, Baxter presented the details of this roadmap, with the goals and timelines. The final deliverable will be a packaging/direct marking AIDC Application Standard specific to appropriate product groups or sub-industry requirements, with patient safety as the highest priority.

4. GS1 HUG™ Governance

Michel van der Heijden, CFO GS1 Global Office and responsible for new sectors, introduced the new governance for the group, which has been developed by the HUG Leadership Team. After one year of existence and growing participation the team felt that a governance should be put in place. In the governance charter it is determined, who can become a member, the difference between voting and non-voting members as well as the rights and obligations of the Co-Chairs, the Leadership Team, Work Team Leaders, Work Teams and the voting procedures. The full document is available on the HUG website.

5. Status report “Communication and Coordination”

Jim Willmott from Smiths Medical reported about the different communications of the HUG and related efforts from other GS1 Member Organisations to efficiently spread the HUG message around the world. The HUG website has continuously growing numbers of hits – over 30.000 per month.

6. Status report “Standards Development” Work Team

Peter Tomicki from Baxter presented the new process for healthcare standards in the GSMP (GS1 Global Standard Management Process). The future template for change requests will include a specific healthcare part. The process group in the GSMP, in which Peter is the elected representative of the HUG, is classifying those change requests (CR) as either simple or complex. A simple CR is returned to the Leadership Team for a final vote by the HUG members. A complex CR will be championed by the according Work Team throughout the GSMP process by creating a stakeholder group to discuss further and evaluate possible interactions, also to other industries.

7. Status report “Business Case” Work Team

Ed Dzwill from Johnson & Johnson Pharma gave an update about the status of the “The Business Case for Global Data Standards in the Healthcare Supply Chain”, which is developed in cooperation

with the Michigan State University (MSU) School of Packaging. This is planned to be a fifteen week effort and the experts at the MSU have started to recruit and educate students who will do the literature research under their supervision. The results of the work will be a detailed position paper of approximately 125 pages, an electronic Executive Summary of 10 pages and an electronic conference presentation of 25 pages. These should be ready by the end of January 2007.

8. Status report "Vaccines and Biologics" Work Team

Steven Hess from Merck presented the preliminary results of this Work Team, which will now merge into the Auto-ID Data Work Team, to contribute with their expertise and findings so far. The strategy of the team is to leverage the common elements with the pharmaceutical products as much as possible. Steve outlined the main differences found, which relate to cold chain requirements, governments as key customers, unique requirements for lifelong record keeping for patients, which makes a number of data very important. The finding of the team was that, at present, RFID is not the appropriate solution, but 2D bar codes could be an efficient item level Auto ID solution.

9. Status report "GTIN Allocation Rules for Pharmaceuticals and Medical Devices" Work Team

Mark Walchak from Pfizer and Mark Hoyle from Tyco Healthcare announced that their work team has now nearly finalised their task on developing "GTIN Allocation Rules for the Healthcare Sector", which can be applied globally across the healthcare industry. During the work, 142 comments from over 20 sources were received and discussed in the regular teleconferences. Most of them could be closed – only a small part is still open for discussion. This should happen in the work session at the HUG and then the final document will be put in the form of a change request, into the GSMP process. The Co-Chairs thanked all team members for their contribution, especially GS1 Argentina, which provided the specific healthcare illustrations for the document.

10. Status report "Instruments and Implants" Work Team

Volker Zeinar from B.Braun informed about the status of the Work Team "Instruments and Implants". The team has analysed over 30 interviews, carried out in 7 countries, and visited additionally five hospitals in UK and France. Now the team is working on summarizing the findings. It is important, but difficult, to decide on the right level of tracking and tracing – should it take place on a set or instrument level, directly or "indirectly" marked? The team decided to make the differences, at the different levels, transparent and to describe the business needs for automatic identification for instruments. This will be valuable input into the new work teams Auto-ID Data and Serialisation. This Work Team will now merge and participate in these two new groups.

11. French Hospital Initiative

Pascal Mariotti informed about the latest status of the hospital initiative in France. The group has grown; now 31 University Hospitals and 20 other very large hospitals are also co-operating.
The hospital groups need a system of common references and standards to be able to work together. The board of the group has confirmed the choice of GS1 standards for codification, for classification it decided for ATC, Cladimed and UNSPSC/GPC for all 51 hospitals participating. The strategy of the whole group is to systematically use GS1 Standards, in every hospital, for every new project with tracking, traceability, processes, organization and logistic, on the same as the projects of the hospital of Dijon. The group will need more codification of products for the future.

12. Unique Device Identification – FDA and UDI

Jay Crowley from the US Food and Drug Administration (FDA) presented the recent initiative of the FDA, regarding a unique device identification (UDI) for medical devices. The FDA believes that this could reduce related medical errors and identify compatibility and interoperability issues by ensuring the right device for right patient, the right accessory for the right device, for example MRI compatibility. It would also improve the identification of specific devices in adverse event reports and provide more "denominator" data and facilitate effective device recalls. Additionally, it could facilitate the population of device use information in Electronic Medical Record Systems (HIT) and provide benefits also with regards to supply chain efficiency. After three stakeholder meetings, a federal register notice has been published to which comments can be sent in until the 9th November.
Mainly the following topics are raised:

- At the "unit of use" a unique identifier should combine these device elements and attributes:

- Manufacturer, make, and model;
- Unique attributes (e.g., size, length, quantity, software version); and
- Serial number, identifying lot number, manufacturing or expiration date.

Other questions are, the choice of the best suitable technology and the minimum data set. The FDA is looking at global harmonization and would prefer not to put a US-focused solution forward. After the Public Meeting on the 25 October and the docket closed, the FDA will review and analyze the comments, determine FDA's role and decide about further actions.

13. GS1 HUG™ UDI - Recommendations

Tom Werthwine from Johnson & Johnson welcomed, in the name of the HUG, the FDA activity. He pointed out that the GS1 system is a globally recognized system and the FDA should contribute to harmonizing medical device identification systems around the world. The main UDI data requirements can be fulfilled by the corresponding GS1 Applications Identifiers, the product attribute size should be better held in a database. Tom expressed the opinion, that the data carrier should not be specified by the FDA, but every GS1 data carrier should be acceptable. The HUG will also comment to the FDA docket.

14. EFPIA – Supply Chain Integrity

Graham Smith, Chairman of the EFPIA Distribution Group, explained the view of EFPIA regarding supply chain integrity. The supply chain in Europe is fragment and complex. Main concerns are counterfeiting, issues arising from parallel trade and batch recall capability. Therefore an increased control of transactions is needed and a harmonised EU coding system could offer a more secure, effective and efficient supply chain. The EFPIA recommendation is the adoption of a 2D (Data Matrix) bar code across Europe as the easiest and safer solution for the whole industry. This will enable authentication of products in the pharmacy and increase transparency and security of products for the patients.

15. EUCOMED – The European Medical Technology Industry Association

Mike Kreuzer, Chairman of the eBusiness Task Force (ETF), presented the recent developments at EUCOMED. The group has gone through a recent review, in which they also compared their mission and vision with those of the HUG and decided that the groups are complementary and not competitive. There are overlaps and possible synergies and therefore an official collaboration is in place. The HUG is represented in the ETF and they have chosen official representatives for the HUG, who have agreement and support from their management. The ETF group has launched a research project, with their member base, to find out how the usage of GS1 is being adopted versus other standards and what the trends are. The results will be presented at the next HUG conference in Berlin.

16. Hospital of Rouen - Blood derivate (CFC) supply chain in the hospital

Bernard Dieu, Chief pharmacist at the CHU Rouen, a hospital with 2,500 beds, reported about their recent traceability project. Although traceability is important for them for a number of products for example instruments and implants, they concentrated for this pilot on blood derivates. For that they identified the products (GTIN, SSCC), the staff (GLN, GSRN) and the location (GLN) utilising GS1 standards. In a second step they plan to also include the serialisation of products and, planned for the future is the usage of e-procurement and e-prescribing. The results showed significant improvements with regards to error reduction, stock management, automation of traceability and time spent. The hospital plans to also include now other products in this project.

17. Asept InMed - Wholesaler experience in France

Jean-Luc Maurat reported about the introduction of traceability at the French wholesaler Asept InMed. For them, reliability and the efficiency of traceability depends on the quality of data acquisition all along the logistic process and the rapidity of data treatment/analysis in order to act as soon as a defective device is detected. Already, at the goods receipt, all data is fast, easily and accurately captured in a GS1-128 standard and then consistently followed through all warehouse processes. This enables total control over the goods at any point in time. down to the customer. It is essential that the

supply chain participants use the same bar code standard, to enable this to happen. Asept InMed achieved, within two years, a growth in turnover of 20% per year, a significant improvement of customer service ratio and productivity and could introduce a permanent inventory.

18. Animal Health Products Identification Standard

Jean-Claude Muller, Merial, presented for the International Federation of Animal Health (IFAH), the standard they developed for product identification and traceability. The industry is highly regulated and to fulfil some existing EU regulations, and to prevent further regulation, the industry came together and agreed to implement, worldwide, the GS1 symbology Data Matrix as a stable and affordable solution. Thereby the GS1-128 syntax including GTIN, batch number and expiry date is used. The implementation started in 2005 and is planned to be finalised in Europe in 2007. Regular communications and review of the progress has lead to satisfaction of the regulatory bodies and customers. The solution has proven to be reliable, robust and flexible. All print technologies can be used. EFPIA wants to adopt the same standard for human medicine.

21 September 2006

The whole day was dedicated to the Work Teams. Everyone could participate in the Work Teams; Business Case, GTIN Allocation Rules for Pharmaceuticals and Medical Devices, Instruments and Implants, Auto – ID Data and Serialisation.

The Business Case Team presented in detail the plans in moving ahead to develop the business case for global standards in healthcare and gathered input and feedback from the participants.

The GTIN Allocation Rules Team had conducted a public review of their working document and most comments could already be resolved in teleconferences. The remaining issues were discussed with the participants and closed out.

The Instruments and Implants Team started to define their business requirements, concentrating primarily on the diverse instruments cycle.

In the afternoon two new work teams kicked off. First the Auto-ID Data Team introduced their leading and supporting staff and started to work on the definition of scope and objectives of the team.

Then the Serialisation Team presented their basic topics and also the results of the HLS BAG work team, which has already looked into this. Their input will give a good base for the work in the global Serialisation Work Team.

22 September 2006

19. EPCglobal Overview

Chris Adcock, the president of EPCglobal, gave a broad overview regarding the whole EPCglobal community. The core purpose of his organization is global leadership in developing and promoting multi-industry, user driven standards for collaborative commerce utilising the EPC. The EPC board is multi-sectorial, the membership growing fast, with nearly 1000 members across 36 countries. Recently, more cross industry groups have been formed, the so-called JAG's – Joint Action Groups in which participants from different sectors work together on common topics. So far 7 global standards have been approved – the standard for Gen2 tags is one of them. Gen2 can operate on a global level and has also been recognized by ISO. The spectrum allocation has made good progress worldwide. The work for item level tagging is done in UHF and HF Work Teams as HF, in the healthcare industry, is regarded as necessary.

20. EPCglobal Healthcare and Life Sciences

Ron Bone, Senior VP of Distribution Support at McKesson Pharmaceutical and Tri-Chair of the Health Life Science Business Action Group (HLS BAG) updated the participants on the work of the BAG.

EPC is seen as very important for a safe and secure supply chain and helps to solve critical regulatory issues. Pilots are underway and the learning's are contributing to the standard development process.
The group was formed in 2004 and the US members represent 38 of 40 largest manufacturers, the 3 largest distributors and major retailers. They are focusing on addressing critical needs, for example pedigree management and serialization. The major active Work Teams are Serialisation, which will now amalgamate into a common Work Team with the HUG, item level tagging, pedigree, industry adoption and track & trace.
Ron pointed out that he sees a lot of opportunities for a closer collaboration between the HUG and the HLS BAG in the future. During an integration meeting, in early December, the participants of both teams will discuss this further and for June 2007 the first united meeting is planned.

Ron then reported about the pilot project "Track", which is bringing together trading partners to test and learn how RFID technology can be applied to advance the supply chain with regards to product safety and item serialization. As a result, it will be possible to provide fact-based information to all interested parties.
Manufacturers, wholesalers, associations, the FDA, EPCglobal and solution provider are working together in this project and share their learning's with regards to the critical questions of data sharing, track & trace, tag data, frequency, read ranges and necessary changes in business processes.

21. Master of Business Administration (MBA) - Research Dissertation

Janice Kite from Johnson & Johnson discussed the hypothesis of her MBA dissertation: "Medical Device manufacturer applied/embedded RFID has benefits to Patient Safety over existing Auto-ID technologies, e.g. Bar Codes." To come to conclusions about this, Janice did literature research, conducted interviews with stakeholders and launched a questionnaire to a wider group. In the literature, Janice found zero tangible evidence that tagging medical devices improved patient safety. The interviewed stakeholders saw RFID tags as advantageous in the supply chain and mostly for the groups of assets - e.g. infusion pumps, surgical instruments, orthopaedic implants, stents and other cardiac implants, because of their high value. As main barriers, the following issues were seen: technology/physics, implementation costs, privacy and lack of global standards. With regard to pilots, there is work in progress, but evidence of success is not yet available. Looking also at the results of the questionnaire, at present, the hypothesis has not been definitively proven or disproved.

22. GS1 Spain: Projects for the Healthcare sector

Jose Javier Sanchez from GS1 Spain provided interesting information about the healthcare activities in Spain. The healthcare sector is decentralised in Spain – there are 17 different Healthcare Service Areas, which determine the local requirements.
From the central Ministry of Health a new regulation was put in place in July 2006, which shall enable traceability of pharmaceuticals. An AIDC system must be implemented for all pharmaceutical products in July '07, which shall permit serialization and include information for track & trace (code product, batch number and expiry date). The goal is to have a fast and economic implementation.
The Andalusia Healthcare Service (SAS) has their own project to improve the logistic and purchase processes, enable track & trace and improve patient safety. They request labelling of all products with GS1-128 – the deadline for that has just been extended to January 2007. In the province of Catalonia a project for the traceability of vaccines is in the focus of the authorities. The purpose is to know the exact location of the vaccines and track and trace it in the supply chain. Other projects in Spain concentrate on the traceability of prostheses, EDI implementation and creation of a medical catalogue. A healthcare committee composed of; regulatory authorities, manufacturers, wholesalers and providers is providing direction to GS1 Spain.

23. GDSN and classification – an overview

Sally Herbert, president of GDSN (Global Data Synchronisation Network) introduced this GS1 business unit to the audience.
Data synchronisation is the electronic transfer of standardized item and location information and the continuous harmonization of that data over time. It involves sharing standardized information of the trade items (GTIN) including attributes controlled by the brand owner/data source (e.g. net content, dimensions, weights) as well as location information (GLN) including locations involved in trade (e.g. headquarter, billing, ship to). The GDSN is comprised of a single registry (GS1Global Registry), certified data pools, and trading partners working together to establish technology solutions, business processes, and standards to support data synchronization. Communication is facilitated through standards compliant data and messages – the benefits are clean and accurate data and, as a consequence, reduced out-of stock events and invoice-errors.
GS1 is responsible for two classification systems; one of them is the United Nations Standard Product and Services Code (UNSPSC), the other the Global Product Classification (GPC). Both are complementary, while one is broader, the other one goes more into the depth of product classification. GS1 is working on an integration plan for both.
Sally underlined that for GDSN healthcare is still a new sector, so far they have worked mainly in the retail sector. She offered intensive discussions to evaluate opportunities and the right processes for healthcare involvement in GDSN.

24. Diversity of Classification Systems

Maurice Ventura from the French association Cladimed Association for the Classification of Medical Devices and other health products gave an overview of the existing classification systems. Cladimed has developed a classification for medical devices – in this field not a lot of work has been done yet. In this classification, the devices are divided into different groups, according to the organ or system on which they act, their main use and their validated indications – there are five levels. All modifications are agreed by a scientific committee and are submitted to manufacturers and users for comments or objections. The Cladimed classification has been selected for the e-procurement platform of the French University Hospitals and is already actively used by a number of hospitals in France. In the future it is planned to link it also to GMDN.

25. Report from the Work Team sessions

The Work Team Leaders reported the results of their sessions back to the plenary, the summarizing slides can be found at http://www.gs1.org/hug/meetings/200906/#agenda on the GS1 HUG™ website.

26. GS1 Industry and Sector Strategy

Michel van der Heijden, CFO GS1 Global Office and responsible for new sectors, gave some insight into the GS1 strategy and latest developments. It has been decided that, next to retail, healthcare will be the second core industry with the according priorities. At present, three different GS1 groups are working in this sector: HUG, EHI (European Healthcare Initiative) and HLS BAG. GS1 will lead an integration project to drive towards ONE strategic roadmap.

On Monday **25th September**, GS1 France organised a visit to the University Hospital of Dijon, where the traceability projects of this hospital were explained and demonstrated. It was a very interesting experience and all presentations of this event are also available on the website.

The next GS1 HUG™ Conference will be held from 30 January to 1 February 2007 at the Aesculap Academy in Berlin, Germany and hosted by B.Braun.