GS1 global Healthcare User Group – GS1 HUG™

TO: HUG Members
FROM: Ulrike Kreysa – GS1 GO
SUBJECT: Meeting held on 13 June to 15 June 2006 in Minneapolis/Minnesota
DATE: 31 July 2006

ATTENDEES

3M – Jill Buss
3M – Monic M. Kryzer
AdvaMed – Jeffrey Secunda
Aesculap AG & Co. KG - Gunther Lamparter
AGA Medical - Mark Rutkiewicz
Amgen – Vladimir Gusev
B. Braun Group - Volker Zeinar
Baxter - Peter Tomicki
Brigham & Women's Hospital – Tom Cooley
DHL - Exel Supply Chain - Mike Meakin
DoD - Kathleen Garvin
FDA – Ilisa Bernstein
FDA/CDRH – David Racine
FDA - Jay Crowley
GlaxoSmithKline - D. Bruce Cohen
GPSG - J&J Pharma - Massimiliano Molinari
GPSG - J&J Pharma - Edward Dzwill
GS1 Austria - Barbara Dorner
GS1 Chile – Eduardo Rodriguez
GS1 France - Valérie Marchand
GS1 GDSN – Peter J. Alvarez
GS1 Germany - Michaela Haehn
GS1 Global Office – Ulrike Kreysa
GS1 Global Office - Scott Gray
GS1 Global Office – Michel van der Heijden
GS1 Global Office – David Buckley
GS1 Japan - Yamato Miyahara
GS1 Japan - Yasuo Kurosawa
GS1 New Zealand – Gary Hartley
GS1 US – John Roberts
GS1 US – Bernard Hogan
Hospira – Brett Novak
Hospira – Eric Strong
Johnson & Johnson - Thomas Werthwine
Johnson & Johnson - Mike Rose
Kimberley-Clark - Gary A. Clement
McKesson - Ron Bone
McKesson – Ted Ng
Medtronic, Inc – Doug Barber
Medtronic, Inc. - Jackie Rae Elkin
Merck - Stephen Hess
Ministry of Health New Zealand – Bruce Anderson
MIT Sloan School of Management – Prof. Masanori Akiyama
Novartis Pharma AG - Diane Arico
Olympus Medical Systems - Masakazu Gotanda
Olympus Medical Systems - Naomi Sekino
Pfizer - Rich Hollander
Pfizer - Mark Walchak
PMP News – Daphne Allen
Premier – Joe Pleasant
Roche Diagnostics – Patsy Johnson
San Raffaele Scientific Institute, Italy – Dr. Alberto Sanna
Smiths Medical - Jim Willmott
St. Jude Medical - Jeffrey McVay
Tyco Healthcare – Mark Hoyle

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

13 June 2006

1. Welcome

Michel van der Heijden, CFO GS1 Global Office, welcomed the participants to Minneapolis for the fourth GS1 HUG™ conference. He gave a short introduction to the mission and vision of GS1 and underlined the strong engagement of GS1 in the healthcare sector.
Dr. Susan Alpert, Senior Vice President at Medtronic, also welcomed the HUG at the Medtronic World Headquarters. She expressed the interest and support of Medtronic for the HUG group and the importance of their work and wished the group a successful conference in Minneapolis.

2. Introduction and Administrative Matters

Ulrike Kreysa opened the meeting as the group's chair and reviewed the anti-trust statement.
A short self-introduction of the meeting participants was followed by a quick look-back into the HUG history one year after the kick-off meeting in May 2005.

3. The HUG – Mission and Vision

Rich Hollander, Pfizer, HUG Co-Chair gave an introduction to the HUG mission, vision and focus areas. He also explained their working principles and coordination mechanism so far with other healthcare working groups e.g. HLS BAG of EPCglobal and GS1 MO's.

4. GS1 BarCodes: A beep can save lives

Scott Gray, BarCodes business manager at GS1 Global Office showed in his presentation the long history of bar codes in use in all parts of our daily lives and that they are reliable and proven over many years. He also explained that bar codes can contribute to improving patient safety. For GS1 healthcare is a new sector with different requirements than the FMCG (Fast Moving Consumer Goods) sector, but GS1 services and solutions are available to fulfil those. Scott confirmed the strong engagement of his business unit in support of the HUG.

5. Status report work team "Communication and Coordination"

Jim Willmott from Smiths Medical showed examples of publications around the HUG throughout the world from New Zealand to India, Russia, Germany and the USA. The HUG brochure has been translated by GS1 France and is now available in French. He reported about the continuously growing numbers of page views on the HUG website – in May about 30.000.
The constantly growing cooperation with Eucomed, the European Association of the Medical Technology Industry was emphasised by him – members of both groups participate in the according activities and exchange information regularly.

6. Status report work team "Standards Implementation/Regulatory Affairs"

Jackie Rae Elkin from Medtronic and Tom Werthwine from Johnson & Johnson MD reported about recent and future regulatory activities. Representatives of the HUG together with AdvaMed had met with the FDA CDRH to discuss the value of medical device serialisation for patient safety. In a meeting at the end of July HUG representatives will meet together with Eucomed and the UK Department of Health to talk about possible coding standards for the NHS.
The HUG is currently in the process of defining their governance, after one year of existence and growing membership, the rules for membership, voting etc. must be clearly defined. The group is also working on a clear roadmap to prioritize the workload.

7. Status report work team "Standards Development"

Peter Tomicki from Baxter reported about the progress in the GSMP (GS1 Global Standard Management Process) review process, where he represents the healthcare industry in the discussions. The new GS1 standard development process is due to 'go live' in August 2006 with the submission of their first change request. The HUG members will need to take an active role in the GSMP. Peter will be further involved in the GSMP process and works on a clear process flow. For the forecast of future standards the group develops a checklist, which takes into account the necessary tools (e.g. data carrier), processes (e.g. identification) and sub-industry classification (e.g. implants).

8. Status report work team “Business Case”

Ed Dzwill from Johnson & Johnson Pharma reported about the progress with the “Business case for Global Data Standards in the Healthcare Supply and Regulatory Chain” project. In discussions with the Michigan State University School of Packaging the deliverables have been defined as a position paper of 100 pages and as well as an executive summary of 10 pages and a conference presentation of 25 pages. The timelines for this are estimated at 15 weeks after the kick-off. At the moment the funding has to be secured, a first sum has been paid by Johnson & Johnson to move ahead. The university plans to collaborate with a number of different faculties and also other universities on this project.

9. Status report work team “Vaccines and Biologicals”

Steve Hess from Merck and Bruce Cohen from GSK presented the findings of the work team, which looks at global data standards for vaccine and biological products. In their work they want to leverage the common elements with the pharmaceutical products as much as possible, but have identified some key differences with regards to cold chain requirements, governments as key customers, a special supply chain and a unique requirement for lifetime patient record keeping. They feel that RFID is not a good short-term solution for these special products, while 2D barcodes could be an efficient solution for item level identification.

10. Status report work team “GTIN Allocation Rules for Pharmaceuticals and Medical Devices”

Mark Walchak from Pfizer and Mark Hoyle from Tyco Healthcare presented the great progress of their group in developing “GTIN allocation rules for the healthcare sector”, which can be applied globally across the healthcare industry. David Buckley from the GS1 GO (Global Office) demonstrated the GTIN allocation website, which doesn’t include medical products yet. The group intends to build a similar website after the standard is ratified as they see big value in this visual realisation. In the rules the sectors pharmaceuticals – OTC and prescription drugs as well as medical devices are included. Especially requirements for kits and complex medical devices are sometimes challenging, but the group is also nearing completion on proposals. The final draft for review will be available at the next HUG conference and then put into the GSMP process.

11. Status report work team “Instruments and Implants”

Volker Zeinar from B.Braun informed about the status of the work team “Instruments and Implants”. In agreement with the members of this group the work is in the first phase concentrating on the marking of instruments and the necessary tracking and tracing processes. The group has developed a questionnaire about the needs for information at the different process steps and levels and for what these are needed. Up to 25 interviews have been carried out in 7 countries (US, FR, CH, DE, IT, AT, JP) and Christian Hay, from GS1 Switzerland, has developed a software tool to capture the data and summarize the results. In parallel, two hospital visits in Paris were organised by GS1 France, which brought interesting additional information as one of them is working with instruments marked with Data Matrix and the other with embedded RFID tags.

12. Risk management, traceability and measuring productivity with POAS (Point of Act System)

Prof. Masanori Akiyama from the Tokyo Medical University and teaching professor at the MIT in Boston talked about the improvement for risk management that were achieved by introducing the Point of Act System (POAS) into the IT system of the hospital. POAS synchronizes and interacts with each department system; this includes finance and accounting as well as pharmacy and imaging and allows immediate information exchange. So business processes and material flows can be handled, but also medical records with electronic prescription are available for the benefit of the patients. The system has shown that it can save significant costs through improved logistics and efficiencies in business processes – over four million US dollars per year. But equally important is the reduction of error rates, down to nearly zero through consequent crosschecking of data when administering medication. Each time there is a safety control ensuring that the right patient is getting the right product at the right time. It is also possible to record the person who is responsible for the administration of the medication or procedure. Another great advantage is the possibility to conduct real time cost analyses by patient and disease – a requirement that is getting more and more

important in healthcare due to budget restrictions in hospitals throughout the world.

13. Stop counterfeit drugs – report and learn more

Ilisa Bernstein from the US Food and Drug Administration, presented the latest FDA Counterfeit Drug Task Force Report published only a few days before the meeting. She stated that the origin of the product can be secured through implementing track and trace relying on unique serial numbers on each drug package, carried in RFID tags or bar codes. Other anti-counterfeiting technologies like overt, covert and forensic methods can contribute also to a safe supply chain.
The FDA has decided recently to no longer delay the effective date of the Prescription Drug marketing Act (PDMA) implementation beyond December 1, 2006 and to issue a Compliance Policy Guide (CPG) that focuses the pedigree-related efforts on those drugs that are mostly vulnerable to counterfeiting and diversion. The FDA will not mandate RFID although they still believe that RFID is the most promising technology, but they look into a feasible timetable and in the meantime a hybrid approach using both - paper and e-pedigree – will be needed.
FDA recommends that the unique identifier for a product should either include an encrypted NDC number or an accessible link to the NDC number should protect privacy. Mass serialisation is a powerful tool to identify individual drug packages.

14. Vertical Integration in the Health Value Chain

Dr. Alberto Sanna from the Scientific Institute and University Hospital San Raffaele, Italy, spoke about his projects to improve patient safety: In the 'DRIVE' project the focus lies in a safer, smarter and trusted healthcare system. In the hospital e-prescription is used by the physicians, the prescription can then be validated by the pharmacist supported by an according system and the administration will only be done after checking the patient and product identification through automatic data capturing and comparison with the prescription. Significant improvements have been registered for patient safety and 30% of the operational costs could be saved by improvement of the logistics in the supply chain. By including unique serial numbers and expiry date in the product data, real time traceability at item level could also be demonstrated. In his recent project Dr. Sanna is now evaluating the benefit of the usage of RFID tags and the related costs.
While the DRIVE project is taking place in the hospital environment, the PIPS project (Personalized Information Platform for Life and Health Services) aims to improve the patient self-care in the daily environment by e.g. enabling continuous self-monitoring of 'at risk' patients.

15. Global Data Synchronisation Network (GDSN)

Peter Alvarez from GS1 GDSN introduced the GS1 business unit to the HUG participants. GDSN is an automated, standards-based global environment that enables secure and continuous data synchronisation, allowing all partners to have consistent item data in their systems at the same time. Thereby through the GS1 Global Registry™ trading partners around the world can exchange standardised data via their selected data pools (SINFOS, 1SYNC and others). Key components for that are items (GTIN), location (GLN) and classification (GPC). GDSN is the foundation for electronic collaborative commerce, which relies on an accurate data exchange and saves costs through efficiencies in logistics, accounting and inventory processes.

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The whole day was dedicated to the Work Teams. Every participant could participate in the work teams Vaccines & Biologicals, Instruments and Implants, GTIN Allocation Rules for Pharmaceuticals and Medical Devices, Standards Implementation/Regulatory Affairs, Standards Development and Business Case.

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16. 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/130606/#presentations on the GS1 HUG™ website.

17. Premier Inc. and the Coalition for Healthcare electronic Standards (CHeS) – an Update on Standards

Joe Pleasant, CIO of Premier, the largest healthcare alliance in the US, where nearly 1.500 hospitals are working together, discussed the advantages of the integrated supply chain and coordinated purchasing. Premier is also a member of the Coalition for Healthcare eStandards (CHeS), a group of large GPO's, the Department of Defence and Veteran Affairs as well as other members from the healthcare industry e.g. the Association for Healthcare Resources & Material Management (AHRMM). They work together to adopt and promote uniform industry data standards in the US with the goal to finally achieve supply chain e-collaboration. Their four major initiatives focus on the following topics:
1. Customer and Supplier Identification through GLN, 2. Product Classification/Taxonomy through the United Nations Standard Products and Services Code (UNSPSC), 3. Universal Product Identification and 4. Product Synchronization (PDU). Joe emphasized that the benefits of technology and improvement of patient safety are tied to the availability of clean, shared and standardized data – the "right" data.

18. EPCglobal – the Healthcare & Life Sciences Business Action Group (HLS BAG) – State of Pedigree and EPC/RFID

Mike Rose, VP RFID/EPC Global Value Chain at Johnson & Johnson and Ron Bone, Senior VP of Distribution Support at McKesson Pharmaceutical gave an update on the work of the HLS BAG, where they each hold the position of tri-chairs. They reported about the constantly growing membership in the different continents and significant progress made in the regulatory infrastructure across the globe. As in Rome they pointed out that there is already some collaboration between the HLS BAG and the GS1 HUG™, but that there are plans to work more closely together on specific work items e.g. serialisation and public policy. With upcoming regulations in some USA States the BAG has in the last few months worked hard on progressing the ePedigree Standards and have made good progress. There is still some more work to be done before industry adoption can take place. In the standard development process for ePedigree the last call for comments on the working document has been published.
Recently also the first meeting of the Medical Device work group took place and the groups for Industry Adoption and Track and Trace have been chartered.

19. Lessons learned with Bar Coding and eMAR

Tom Cooley, Assistant Director Pharmacy Services of the Brigham and Women's hospital in Boston, USA presented their project for significant improvement of patient safety in their 720 bed hospital. The figures of 211,903 patient specific admixtures and 1,382,406 doses prepared in their bar code repackage centre per year shows the significance of this work. To improve patient safety, an Electronic Medication Administration Record (eMAR) and patient bar coding system has been implemented. This system helps to reduce medication errors, which are a result of incorrect transcriptions of orders, and provides a check to ensure the correct medications are given to the correct patients. Additionally, the system links to drug information and real-time clinical laboratory data. The hospital has decided to use Data Matrix to bar code all their drugs, because it can hold information such as; lot number, expiration date and NDC number in a readable, but small format, while being very accurate. To make usage of all these advantages, the hospital has accepted the higher costs of the necessary image scanners. The results have confirmed the value of the project: the overall dispensing errors reduction rate was 85%. Tom pointed out that information and training is necessary for the hospital staff, the best motivation is the experienced reduction of errors and involvement in the decision and implementation processes.

20. Automation and Traceability Pilot in Public Health System - Early Results, Regulation and next Steps

Eduardo Rodriguez Pinot from GS1 Chile reported the status of the activities of GS1 Chile, together with their Ministry of Health, manufacturers, hospitals and a public security agency. The Auge-Plan has the goal to enable process efficiency, cost control and automation in hospitals.
In one work team, a unique standard classification scheme is defined and implemented, while the other one is working on implementation of the GS1 system. After 12 months major progress can be reported. All parties have significantly increased GS1-128 bar code usage and first experiences with a track and trace model, down to the patient bed, have been made. In the project, important improvement in the logistic processes could be shown by reduction in time and manpower needed for the processes and the issue around expired products could be solved. In the second phase, the authorities look now into bar coding of unit-doses, to reduce medication errors and enable correct control of the costs per patient. The Chilean Ministry is also starting a national unique catalogue for health products, which will be hosted by GS1 Chile.
GS1 Chile would like more manufacturers joining their local Healthcare User Group to define common and agreed solutions.

21. Implementation of Bar Code Labelling of Ethical Drugs in Japan

Yasuo Kurosawa of GS1 Japan informed the audience about the new planned rule for the implementation of bar code labelling of ethical drugs by the Japanese government. The vaccines and biologicals work team had already intensively discussed this topic the day before and had used the occasion to send, in the name of the HUG Leadership Team, a letter to the Ministry of Health in alignment with the colleagues of GS1 Japan and Prof. Akiyama. Please see at http://www.gs1.org/hug/meetings/130606/HUG_Letter_MHLW_Japan%202006-03-24.pdf
The Japanese Ministry of Health intends to mandate bar coding with RSS/Composite symbology on the unit-of-use level for ethical drugs (drugs, which are used in hospitals). GTIN, expiry date, lot number and quantity are the required data. The structure of the GTIN in Japan will also change in the future – there will be a transition period determined when the regulation is finalized in July 2006.

22. Advanced Medical Technology Association (AdvaMed)

Jeffrey Secunda, Associate VP of the Technology & Regulatory Affairs Auto-ID Working Group at AdvaMed presented the work of his association. AdvaMed represents more than 1,300 member companies and covers 90% of the domestic USA market. The association is lobbying Congress and represents the industry before legislative committees and regulatory agencies, but also works on international policy collaboration. They're involved in a number of standards organisation as for example ISO and IEC. A special Auto-ID working group supports the development of Auto-ID technology and standards that address specific patient and public health safety problems. The difficulty for medical devices lies in their diversity of size, material, processing, use and criticality. While AdvaMed supports the development of consensus standards for different modes and applications of Auto-ID it demands also that an adoption plan must be included in any solution.

The next GS1 HUG™ conference will be held from 20 to 22 September 2006 at the Tyco Healthcare Elancourt Center of Excellence near Paris, France.

Details can be obtained from the GS1 HUG™ website at: www.gs1.org/hug/meetings/200906/

Participants and Speakers at the GS1 HUG™ Conference hosted by Medtronic