Smiths Group plc consists of the following divisions:

Aerospace • Detection • Speciality Engineering • Medical
Smiths Medical is recognised worldwide for the following product brands and trademarks:

Portex • Level 1 • Deltec • Graseby • Pneupac • BCI • DHD • Medex
Bivona • Wallace • Acuvance • Blue Line • Hotline • Cozmo
Gripper Plus • Mini-Trach • Needle-Pro • Pro-Vent • Snuggle Warm
Surgivet • Softseal • Thermovent • Vocalaid

Smiths Medical product range consists of the following healthcare specialities:

Airway Management • Pain Management • Needle Protection
Arterial Blood Sampling • Critical Care Monitoring
Hospital and Ambulatory Infusion • Vascular Access
Assisted Reproduction • Surgical Drainage • Insulin Infusion
Patient Warming • Respiration & Ventilation • Interventional Imaging
Smiths Medical is committed to you

Smiths Medical offers market-leading solutions in two major areas: Critical Care and Medication Delivery & Patient Monitoring.

These two areas cover everything from airway management, pain management, needle protection, arterial blood sampling, temperature management, critical care monitoring, hospital and ambulatory infusion, vascular access, in-vitro fertilisation, surgical drainage and insulin infusion.

Our commitment to you is to consistently deliver on quality, value for money, safety and product performance.

www.smiths-medical.com

Smiths Medical is also committed to the GS1 HUG™ …
GS1 HUG™ Organisation

Project Management Coordination GS1

GS1 HUG™ Co-Chairs
Rich Hollander, Pfizer & Volker Zeinar, B.Braun

Membership
Volker Zeinar (B.Braun)
Jim Willmott (Smiths Medical)

Communication and Coordination
Rich Hollander (Pfizer)
Jim Willmott (Smiths Medical)

Standards Implementation and Regulatory Affairs
Tom Werthwine (J&J MD)
Jackie Elkin (Medtronic)

Standards Development
Peter Tomicki (Baxter)

Business Case
Ed Dzwill (J&J Ph)

Vaccines and Biologicals
Bruce Cohen (GSK)
Steve Hess (Merck)

Instruments & Implants
Volker Zeinar (B.Braun)

GTIN Allocation Rules (Pharma & MD)
Mark Walchak (Pfizer)
Mark Hoyle (Tyco Healthcare)

GS1 HUG™ Local Interest Teams (HUGLITs)

EPC Global HLS BAG
Global

EHI
Europe

GS1 MO’s
Local
Objectives:

Lead and organise internal and external communications of the HUG to establish the HUG as the leading voice in the area of automatic data identification in the Healthcare Industry.

Scope:

• Identify key areas for which we establish recommendations and end-users to address
• Build Communication and Coordination infrastructure

Deliverables:

• Communication strategy
• Press releases
• Newsletters
• Structure and content of website
Communication and Coordination

GS1 Website:

August 15 2005: GS1 US™ announced the completion of the process to unite UCCnet and Transora, two leading providers of data pool services. The new, combined company, called iSYNC, will operate as a not-for-profit subsidiary of GS1 US, formerly the Uniform Code Council, to more effectively help companies realize the value of data synchronization through the Global Data Synchronization Network (GDSN).

- Visit the iSYNC website

July 20 2005: Leading global companies from the pharmaceutical and medical device industry have formed a global GS1 Healthcare User Group (HUG). Its objective is to lead the utilization and development of global standards for the healthcare industry, with the primary focus on automatic product identification to improve patient safety.

- Download the full Press Release (pdf)

Healthcare

GS1 is the leading global standards organisation in the healthcare industry. In 56 countries worldwide, GS1 standards have been chosen to identify pharmaceutical products uniquely. Major regulatory bodies including in the US, Japan and the UK have endorsed them.

GS1 standards improve patient safety and reduce costs in the healthcare supply chain. Automatic product identification at all product levels and full traceability ensure a safe and secure supply chain by providing greater visibility, accuracy and velocity for the benefits of all parties involved.

Preventing medical errors and combating counterfeiting are top-of-mind concerns facing the healthcare sector – GS1 standards help to solve these issues.

The global Healthcare User Group (GS1 HUG), consisting of members from the leading pharmaceutical and medical device companies, leads the healthcare industry in the effective utilization and development of global standards with the primary focus on automatic identification to improve patient safety.

The main focus areas for the HUG are the following: prevention of medical errors, product authentication, tracking and tracing and increasing total supply chain efficiency.

For more information and latest developments in healthcare please contact Ulrike Kreye at ulrike.kreye@gs1.org.
GS1 HUG™ Website:

GS1 Healthcare User Group

Mission and Vision

Our 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.

Our 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.

Join GS1 HUG

To join, please contact Ulrike Krenz at ulrike.krenz@gs1.org.

- Link to list of existing members
- Find out more about HUG members

News

16 March 2005: The most recent HUG newsletter has just been published. Find out about recent developments in the HUG, new work teams and regional activities in South America.

Future Meetings

Next HUG Meeting
21 - 23 March 2006
Rome Marriott Grand Hotel Flora
Rome, Italy
View meeting details

Find out more about the HUG:
Download the HUG brochure

GS1 HUG™ Website: (www.gs1.org/hug/)

©2006 GS1
Join GS1 HUG

To join us, contact Ulrike Kreysa at ulrike.kreysa@gs1.org. Members of the HUG should:

- have a global position in their company
- have the agreement of their management for their engagement
- be actively involved and participate in the work of the HUG
- be able to represent the strategy, opinion and experience of their company regarding product identification and e-commerce in the supply chain
- be business process orientated experts who are well-connected within their organisation
- be familiar with GS1-Standards or at least have an overview about GS1-Standards
- be able to promote the developed global standards throughout their organisation

Members
Communication and Coordination

Members

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<th>Organisation</th>
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<tr>
<td>3M</td>
<td>Affons Rathner, IT-Director Europe &amp; MEENA</td>
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<td>Abbott</td>
<td>Steven Siara, Global IT Director</td>
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<td>Grant Hodgins, Global Product Data Manager</td>
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<td>AstraZeneca</td>
<td>Lewis T. Kontnik, Director, Brand Protection/Business Continuity</td>
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<td>Daniel Black, Director e-Commerce</td>
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<td>CIIU</td>
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<td>EGA (European Generic Medicines Association)</td>
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<td>Tom Wetherwax, Manager, AIIC Technology and Industry Standards</td>
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<td>Johnson &amp; Johnson (Europe)</td>
<td>Edgar Dowling, PEGA Tech Ops - Manager Package development: Pharmaceuticals and Biological Products</td>
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<td>Jeffrey Sevly, Associate Director Distribution Packaging</td>
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<td>Christina Schielke, Supply Chain Management - New Products</td>
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<td>Scott Cameron, Head of GS1N Information NGt</td>
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<td>Olympus Medical Systems</td>
<td>Masakazu Gotanda, General Manager (R&amp;D)</td>
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<td>Kirk McFarland, Senior Director, Global Packaging</td>
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<td>PharmaData E.U.</td>
<td>Mark Watcher, Senior Manager, Global Package Technology and Testing</td>
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<td>Proctor &amp; Gamble</td>
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<td>Public Health Agency of Canada (PHAC)</td>
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<td>Jim Wollnutt, Group Labeling Manager</td>
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Communication and Coordination

GS1 Healthcare User Group

News

Announcements

• **05 December 2005**: The third meeting of the global GS1 Healthcare User Group (HUG) took place in Princeton (US) from 29 November - 1 December 2005. [View meeting summary.]

• **28 September 2005**: Yesterday two industry co-chairs were elected by the HUG work team leaders, one from a pharmaceutical company, one from a medical device company. Rich Hollander (Pfizer) and Volker Zehner (B.Braun) will represent the HUG group towards third parties.

• **16 September 2005**: The most recent HUG meeting took place in Brussels from 13 - 15 September 2005. [View meeting summary.]

Press Releases

• **18 November 2005**: Patient safety is the focus of the healthcare industry and regulatory bodies. The second meeting of the global GS1 Healthcare User Group (HUG) focused on gaining an understanding of global regulatory requirements regarding patient safety as well as reporting progress the group has made since the kick-off meeting in May. [View full press release.]

• **18 July 2005**: Healthcare industry works together to improve patient safety. Leading global companies from the pharmaceutical and medical device industry have formed a global GS1 Healthcare User Group (HUG). Its objective is to lead the utilisation and development of global standards for the healthcare industry, with the primary focus on automatic product identification to improve patient safety. [View full press release.]

Newsletters

• November 2005 / No. 1
Communication and Coordination

GS1 HUG™ "Homepage ":

HITs (HUGs)

October: 412
November: 758
December: 638
January: 758
February: 694
GS1 HUG™ "Total Website":

- HITs (HUGs)
Communication and Coordination
Communication and Coordination
**Communication and Coordination**

**Patient Safety Focus of GS1 HUG 2nd Meeting**

**November 15, 2005**

The second meeting of the global GS1 Healthcare User Group (HUG) took place on November 15, 2005 in London. The meeting focused on the promotion of patient safety. The HUG has made several initiatives to improve patient safety.

GS1 member organizations, medical device manufacturers, and health care professionals joined in the discussion to improve patient safety standards and practices. The meeting included discussions on various topics such as patient identification, medication management, and data exchange.

**Healthcare Industry works together to improve patient safety**

Leading global companies from the pharmaceutical and medical device industry have come together under a global GS1 Healthcare User Group (HUG). The objective is to build the collaboration and development of global standards for the healthcare industry, with the primary focus on an automatic product identification to improve patient safety.

Baxter, Bristol-Myers Squibb, GSK, Johnson & Johnson, Medtronic, Pfizer, and Sanofi-Aventis have participated in the kick-off meeting, which took place on 23 May 2005 in Princeton, New Jersey, and have committed to participate actively in the group. The aim of the HUG is to bring together different healthcare professionals, including medical device manufacturers, hospitals, and other stakeholders, to work towards a common goal of improving patient safety through the implementation of global standards.

The key focus areas for the group are the following:

- Prevention of Medical Errors
- Product Authentication
- Tracking and Tracing
- Improved Supply Chain Efficiency

While evaluating existing standards, the HUG will work on the further development of GS1 standards to optimize their utilization in healthcare applications. The work requires the involvement of participants from the industry who have developed a working plan for the coming 12 months.
Communication and Coordination

Global standards for the healthcare industry

Over the decades, industries have successfully used tried and tested tools like bar-coding with unique and universal standards. Ravi Nathur discusses the benefits of global standards and technologies in improving patient safety.

Institute of Medicine 2001 and Health Grade 2003 report approximately 100,000 deaths annually in USA alone due to medication errors, with the incidence much higher in developing countries. To reduce the incidence of medication errors, regulatory organisations like USFDA, have taken proactive measures to ensure the use of barcodes following international standards in pharmaceutical products, medical devices and implants, and blood bags. Indian hospitals are also implementing best practices in healthcare, in terms of hospital processes, equipment and technology. Patient safety in a hospital is dependent on elimination of medication errors. Error-free work can be facilitated by correct and continuous flow of information, which is possible through automatic capture of accurate data in a standard form. Such a system would prevent confusion over similar sounding or appearing drugs, variety of trade names and concurrent use of chemical names.
Communication and Coordination

WHAT WE NEED IS ...

A Global Auto ID Standard Can Help Solve Counterfeit Issues

by Rich Hollember
Senior Director,
Packaging Services, Global Manufacturing, Pfizer Inc.

There are pressing issues in healthcare today for which automatic identification—linear or two-dimensional bar codes or radio frequency identification (RFID)—is part of the solution. Specifically, I'm talking about dispensing errors, counterfeiting and diversion or fraud.

The Food and Drug Administration believes that part of the solution to counterfeiting, diversion and fraud is to serialize every package, capture that data as the package moves through the supply chain and authenticate the package at each step. The FDA also believes the use of RFID technology is the most promising technology to enable this to happen.

I believe serialization is a very strong solution. Previously, it was difficult to deploy in mass and too many proprietary solutions were available to set any standards.

But when the pharmaceutical industry started hearing about the electronic product code back in 2001, we said, "Oh, now there might be something." The EPC could be that universal number, and the supporting infrastructure, is being developed with open standards.

Global commonality

Dispensing errors, counterfeiting and diversion are business issues facing not only U.S. drug manufacturers. There is a need for a clear understanding of these common issues globally. The European Commission and other individual markets are starting to promulgate regulations, forcing standards in the area of automatic identification. They're all trying to solve the same business issues with different approaches though. That's a problem. It's not efficient. Our global sourcing strategies become difficult to implement if we have to cater to different market needs for this.

To start the process for global standards development, GS1 (previously the Uniform Code Council and EDI International) recently established a new Healthcare User Group.

This idea here is that HUG will help align the healthcare industry to the effective use of global standards for automatic identification. Thus, standards largely exist today; we just need to direct parties on how to effectively use them to address these issues. Where standards still need to be developed, HUG will initiate accordingly with the appropriate group within GS1.

Through an organization like HUG, we can develop technical solutions that will work for everyone.

Generally, the right technical solution will also minimize cost, be scalable at the global level, and have optimal impact on the business issue. By harmonizing around global standards, we can implement solutions faster than if each market would individually mandate their own.

Visit www.gs1.org/hug to learn more about the GS1 HUG™ and to find out how you can participate and benefit. /ADF
Communication and Coordination

HUG Press Releases:

Monday, 18th July 2005

HEALTHCARE INDUSTRY WORKS TOGETHER TO IMPROVE PATIENT SAFETY

Leading global companies from the pharmaceutical and medical device industry have formed a global GS1 Healthcare User Group (HUG). Its objective is to foster the use and development of global standards for the healthcare industry, with the primary focus on automatic product identification to improve patient safety.

Roche, Baxter Scientific, B. Braun, 3M, GSK, Hospira, Johnson & Johnson, Medtronic, Merck, Novartis, Pfizer, Smiths Medical and Tyco have participated in the kick-off meeting, which took place on 23 May 2005 in Princeton, New Jersey and have committed to participate actively in the group. It is the first time that the healthcare industry is aligning around a global solution to enhance automatic product identification for the benefit of patients worldwide. 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 main focus areas for the group are the following:
- Prevention of Medication errors
- Product Authentication
- Tracking and Tracing
- Increase total Supply Chain efficiency

More follows...

November 2005

PATIENT SAFETY IS THE FOCUS OF THE HEALTHCARE INDUSTRY AND REGULATORY BODIES

Assuring patient safety worldwide was the focus of the second meeting of representatives of the world’s leading pharmaceutical and medical device companies and health regulators from the EU and major countries. The participants agreed to drive an industry initiative to develop global barcoding and e-commerce solutions for healthcare products based on GS1 standards.

Speakers from the European Commission (DG Enterprise and DG Sanco), the European Agency for the Evaluation of Medicinal Products (EMEA), the USA Food and Drug Administration (FDA), the Italian Ministry of Health, the National Patient Safety Agency of the NHS, United Kingdom and the Regional Healthcare Service Area of Andalucia, Spain presented their work and views on patient safety. The participants and speakers appreciated the opportunity to have an open discussion and to exchange information and experience and agreed to carry the work of the HUG forward by working together more closely.

Delegates from 26 leading global pharmaceutical and medical device companies and 16 GS1 Member Organisations discussed the HUG work plan and listened to the requirements of regulatory bodies. The HUG is concentrating particularly on ensuring that appropriate data structures are selected in order to meet common business needs, and to help ensure data standardisation in healthcare. If standardisation is applied globally, systems to improve patient safety will be developed and implemented quicker than if individual countries were to pursue
Communication and Coordination

HUG Newsletters:

The Global Healthcare User Group (HUG) - Newsletter No. 1

Welcome to the first edition of the GS1 HUG Newsletter! We are excited to share with you 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 in 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 (manufacturers, wholesalers, hospital and pharmacy) to access the latest and relevant global standards in the healthcare industry.

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 industry-accepted GS1 standards and best practices.

The HUG Leadership Team

The HUG is organized into working teams, which are led by the industry. They have a work plan with milestones for the different groups.

Volkmar Zierler, B Braun is the second HUG Industry Co-Chair.

GS1 HUG Newsletter No. 1 - November 2005

The global Healthcare User Group (GSHUG™) - Newsletter No. 2

Welcome to the second edition of the GS1 HUG Newsletter! We are excited to share with you 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.

The GS1 GLOBAL HEALTHCARE USER GROUP (GSHUG™) – Working together to improve Patient Safety

Our new brochure gives more information about the GS1 HUG™ in a comprehensive manner. Mission, Vision, Values and the objectives and focus areas are explained in the new brochure.

The HUG work teams Communication and Coordination are led by Beth Riehlender, Pfizer, who is also one of the recently elected HUG Industry Co-Chairs, which represents the ‘Growth and Innovation’ team.

Second meeting of global Healthcare User Group (GSHUG™) in Princeton, USA.

For the second time, participants from across the world came together to work on improving patient safety, this time from 29 November to 1 December 2005 in Princeton. More than 80 experts from healthcare manufacturers, wholesalers, hospital groups, regulatory bodies, GS1 member organizations and the GS1 Global Office staff discussed the situation in healthcare today and the development of global GS1 standards.

Although the primary focus of the group is on health care, the GS1 product and service portfolio was discussed and business models from GS1 Barcodes, GS1 and GS1Global attended the meeting.

Paul Pashoff, VP Global Supply Chain solutions at Johnson & Johnson, outlined the importance of the supply chain in the healthcare industry. He emphasized the importance of GS1 standards and their potential in the global Healthcare User Group and supports its goals.

Canadian Pilot Project for Vaccines

Lisa Bellack from the Public Health Agency of Canada (PHAC) informed the GSHUG participants about the Canadian Identification of Vaccines Pilot (CAVP) Project, which was established to test the feasibility of using bar coding technology to track and verify the identity of vaccines. The Pilot Project was initiated to improve the traceability of vaccines and ensure the safety of patients.
WHAT WE NEED IS...

A global auto ID standard can help solve counterfeit issues

by Rich Hallander
Senior Director, Packaging Services, Global Manufacturing, Pfizer Inc.

There are pressing issues in healthcare today for which automatic identification—bar codes or radio frequency identification (RFID)—is part of the solution. Specifically, I’m talking about dispensing errors, counterfeiting, and diversion we find.

The Food and Drug Administration believes that part of the solution to counterfeiting, diversion, and fraud is to serialize every package, capture that data as the package moves through the supply chain and authenticate the

“They’re all trying to solve the same business issues with different approaches, though. That’s a problem. It’s not efficient.”

package at each step. The FDA also believes the use of RFID technology is the most promising technology to enable this to happen. There is a strong momentum to use standards.

Previously, it was difficult to deploy in mass and too many proprietary solutions were available to set any standards. But when the pharmaceutical industry started hearing about the electronic product code back in 2001, we said, “Oh, now there might be something.”

The EPC could be that unique serial number and all the supporting infrastructure is being developed with open standards.

Global communities

Dispensing, errors, counterfeiting, and diversion are business issues facing not only U.S. drug manufacturers. There is a need for a clear understanding of these common issues globally. The European Commission and other individual countries are starting to promulgate regulations, forcing standards in the area of automated identification. They’re all trying to solve the same business issues with different approaches, though. That’s a problem. It’s not efficient. Our global warming strategies become difficult to implement if we have to sort for different market needs.

To start the process for global standards development, GS1 (previously the Uniform Code Council and EAN International) recently established a global Healthcare User Group.

The idea here is that HUG will help align the healthcare industry to the effective use of global standards for automated identification. These standards already exist today; we just need to direct parties on how to effectively use them to address these issues. Where standards still need to be developed, HUG will initiate accordingly with the appropriate group within GS1.

Through an organization like HUG, we can develop technical solutions that will work for everyone.

Currently, the right technical solution will also minimize cost, be scalable at the global level, and have optimal impact on the business issues. By harmonizing around global standards, we can implement solutions faster than if each market would individually mandate their own.

Visit www.gs1.org/hug to learn more about the GS1 HUG™ and to find out how you can participate and benefit. HUG

With Pfizer since 1994, Rich Hallander has responsibility for all areas of global package design and development for Pfizer’s Animal Health, Consumer Health and Human Health businesses. Hallander is an active leader in various standard-setting, user groups and task groups aimed at addressing issues within pharmaceutical packaging. He currently serves on both board and communications chair for the HUG Healthcare User Group (www.gs1.org/hug).
Communication and Cooperation

Benefits of barcoding in the pharmaceutical industry

The use of barcodes on drug labels and medical devices will be an important step to improve patient safety and will allow the tracking of medical products before, during, and after a medical procedure.

Barcodes in the healthcare industry

Barcodes can be used to track and control the diversion of drugs and medical devices, and improve patient safety. The use of barcodes can also help prevent errors, such as incorrect medication administration, and improve efficiency by reducing the time needed to locate and identify medical products. In addition, barcodes can be used to track the movement of medical devices, such as surgical instruments, to ensure that they are properly cleaned and sterilized before being used on patients. This can help prevent the spread of infections and improve patient safety.

References

Communication and Coordination

BAR CODING OF MEDICAL DEVICES
By Ulrike Kreysa

The term 'medical device' is used for a wide range of products, from a syringe to a heart valve to an infusion pump. Medical devices, like pharmaceuticals, are essential in the treatment of patients and play an important role in the healthcare system. The medical device industry is a fast growing one, with the most important markets being the US, Japan and Germany. A high percentage of healthcare costs are generated by medical devices, and through the rapid progress in technical innovation, the global market figure for 2005 is expected to exceed US$26 billion.

At the same time, a number of the issues affecting medical devices are similar to the ones affecting the pharmaceutical industry:

Counterfeiting
There are a few official numbers about the counterfeiting of medical devices but for pharmaceutical products the US Food and Drug Administration (FDA) estimates that 10% of them worldwide are falsified. Medical device manufacturers are also reporting counterfeiting of their products, which causes losses to both the safety of device users and patients, as well as effects on the manufacturers themselves (e.g., by loss of sales and loss of reputation when counterfeited products fail that have been branded with their company's trademark). A safe and secure supply chain is needed which prevents counterfeiting of products and enables proper traceability of medical devices from the manufacturer to the patient. This will prevent illegal re-processing and re-packaging of products as well as the infiltration of falsified and unsafe products. Through the tracking and tracing of the items, effective alerts and product recalls will be possible.

Medical errors
In 2000, the Institute of Medicine (IOM) published its report To Err is Human about the causes of medical errors and how one can prevent them. Automatic identification technology (bar coding) was one of the tools the IOM recommended to help prevent medical errors. As a consequence, in February 2004, the US Department of Health and Human Services issued a final rule requiring electronically-readable bar codes on the packaging of hospital administered pharmaceutical products, biologicals and blood products to be applied by April 2006. To date, no such rule has been released for medical devices, despite pressure from the largest American hospital chains such as Pfizer and the Americas Hospital Association. However, the FDA has organized an official meeting to discuss unique device identification, where stakeholders were given the opportunity to express their opinions.

From April 2006, all US pharmaceutical product packaging must have an electronically-readable bar code

Global medical device market is expected to exceed US$26 billion in 2006

Counterfeiting of products can be prevented with a safe & secure supply chain

Scannable technology
Bar coded pharmaceuticals save lives

Research shows machine-readable product identification is key to preventing medical errors, improving patient safety, helping combat counterfeiting and lowering costs throughout the health sector. But GARY HARTLEY argues New Zealand has fallen behind the rest of the world in mandating bar codes on pharmaceuticals.

BAR codes rest on an unbreakable foundation. They are unique identifiers, which allow a product to be traced throughout its entire life cycle. By linking the product to the patient, a new age of patient safety is possible. The unique identification system may also reduce the cost of counterfeiting.

The key to the success of this system is the ability to read and understand the bar code. The system requires the correct equipment and software to read the bar code, which is why it has been so successful in the pharmaceutical industry. The same technology can be used to identify medical devices, which is why it is so important to make this technology a reality for medical devices.

In conclusion, the unique identification system is a powerful tool for improving patient safety and reducing costs. It is time for New Zealand to follow the rest of the world and mandate bar codes on pharmaceuticals.
Communication and Coordination

HUG Brochure:

The GS1 Global Healthcare User Group - GS1 HUG™
Working together to improve Patient Safety

(www.gs1.org/docs/patient_safety/hug_brochure.pdf)
Communication and Coordination

GS1

GS1 is a global organization dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility in supply and demand chains.

We have more than 30 years of experience in the development and support of global supply chain standards and technologies.

Our portfolio ranges from GS1 BarCodes to GS1 eCom (electronic commerce tools) to next generation technologies, such as GS1 UP Global Trade Item Numbers (GTIN) and solutions such as GS1 GDON (Data Interchange) and GS1 Traceability.

The Global Language of Business

OVERALL BENEFITS: Improving efficiency & visibility in supply and demand chains

GS1 SOLUTIONS & SERVICES USING GS1 STANDARDS

- Solutions for Industry: Inventory Management, Asset Management, Collaborative Planning & Visibility
- Services: Global Network (GSN), Global Trade Item Numbers (GTIN), SmartPractice, Loyalty Certification,Traceability, Training

Integrated system of standards

- Global Standards for automatic identification
- Global standards for electronic business messaging
- GS1 and its Member Organizations: playing a leading role in supply and demand chain management improvement worldwide for large, small, and medium-sized organizations.
- GS1 and its Member Organizations: global presence in over 100 countries driven by more than a million companies that execute over five billion transactions each day using GS1 standards, solutions, and services.

GS1 Around the World

Countries with GS1 Member Organizations

Countries served on a direct basis from GS1 Global Office (Brussels)

(www.gs1.org/docs/patient_safety/hug_brochure.pdf)
Communication and Coordination

What is the GS1 HUG™?

Leading global companies from the pharmaceutical and medical device industry have formed a global GS1 Healthcare User Group (GS1 HUG™). It is the first time that the healthcare industry is aligning around a global solution to enhance automatic product identification for the benefit of patients worldwide.

The work of the HUG will help to improve the efficiency of the healthcare supply chain for pharmaceuticals and medical devices through the collaborative development and implementation of recommended industry GS1 standards and best practices.

Mission and Vision

The mission of the GS1 HUG™ is to lead the healthcare industry to the effective utilization and development of global standards with a primary focus on automated identification to improve patient safety.

The vision of the GS1 HUG™ is to become the single source for regulatory agencies and trade associations (manufacturers, wholesalers, distributors, hospitals and pharmacies) to seek input and direction for global standards in the healthcare industry.

“I’m delighted that GS1 standards will be used to improve the safety of patients worldwide while simultaneously increasing the transparency and efficiency in the healthcare supply chain. GS1 standards are already used in many countries worldwide and for many different products and services in the healthcare sector, but with the industry leadership of the GS1 Global Healthcare User Group (GS1 HUG™) we will see wide implementation and improvement globally.”

Miguel Lopez, President & CEO of GS1.

Objectives

The objectives of the HUG are to:

• Work with key partners in the healthcare supply chain to develop and optimize the use of global standards to ensure accurate and fast movements of goods from manufacturers to distributors, healthcare providers, hospitals or public pharmacies.

• Facilitate awareness in the healthcare sector of new technologies and methods of doing business.

• Provide advice and recommendations to GS1 on issues and opportunities in the healthcare sector.

• Promote best practice implementations in the healthcare area, including the whole product and service portfolio of GS1.

• Promote the implementation of GS1 industry, global business standards throughout the healthcare sector.

“Patient safety has many faces. A standardised 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 harmonised solutions. We engage ourselves in this initiative with the intention to share our expertise, to learn from others and to optimise the product identification in terms of the patients.”

Volker Zelins, B. Braun
Communication and Coordination

Focus Areas

The main focus areas for the group are the following:

1. Prevention of Medical Errors
   - Ensuring that the unit dose or unit of use package to enable automated verification to ensure the right dose for the right patient at the right time.
   - Ensuring that the unit of use package to enable automated verification to ensure the right device for the right patient.

2. Product Authentication
   - Ensuring that the packaging and associated labeling are genuine by utilizing a GS1 data structure, enabling authentication of individual packaging, cases, or pallets.

3. Tracking and Tracing
   - Utilizing a GS1 data structure, working with supply chain trading partners to enable an electronic pedigree for individual packages, such that in the event of a counterfeiting incident, tracing of the suspect product can occur.

4. Increase Total Supply Chain Efficiency
   - Through greater visibility, accuracy and velocity.

"There are pressing issues in healthcare today for which automatic identification - linear or two dimensional bar codes or radio frequency identification (RFID) - is part of the solution for dispensing errors, counterfeiting and diversion or fraud."

Rick Hollander, Pfizer

GS1 HUG™ - Today and Tomorrow

The HUG is concerned particularly on ensuring that appropriate data structures are selected in order to meet common business needs, and its help ensure data standardization in healthcare. If standardization is applied globally, systems to help improve patient safety will be developed and implemented quicker than if individual countries were to pursue separate solutions.

While the main focus is on a global solution for automatic product identification, to help ensure the safety of patients worldwide, GS1 HUG™ will be looking into other aspects of the healthcare supply chain (e.g., Data Synchronization, electronic messaging, and other systems).

"If standardization is applied globally, systems to improve patient safety will be developed and implemented quicker than if individual countries were to pursue separate solutions."

Meeting of GS1 HUG™ in Brussels, 2006
Communication and Coordination

HUG Work Teams:

Communication and Coordination

**Leaders:**
- Pfizer
- Smiths Medical

**Objectives:**
- Lead and organize internal and external communications of the HUG to establish the HUG as the leading voice in the areas of automatic data identification in the healthcare industry.

**Deliverables:**
- Communication strategy
- Press releases
- Newsletters
- Structure and content of website

Scope:
- Identify key areas for which we need recommendations and implement solutions.
- Build communication and coordination infrastructure.

Instruments and Implants Marking

**Leaders:**
- Wolf Medizintechnik
- RBM

**Objectives:**
- Analysis of the necessity of marking instruments and implants, aiming to account for possible application in hospitals and technical feasibility.

**Scope:**
- Level of track and trace (e.g., lot level or instrument level), packaging and/or device marking, data content, data carriers, regulatory compliance.

**Deliverables:**
- Process descriptions, industry baselines, technical framework / database, manufacturer and end user tools, recommendations.

Membership

**Leaders:**
- Volker Zenz
- B. Braun
- Jim Miller: Smiths Medical

**Objectives:**
- Organize HUG enrollment to progressively include all stakeholders.

**Deliverables:**
- List of preferred contact persons.

Scope:
- Identifies and prioritizes the stakeholders.

Standards Development

**Leaders:**
- Pete Tomala
- Baxter

**Objectives:**
- Contribute to supply chain standards development process for adoption by GS1 that is optimized for the healthcare industry.
- Create a standards needs forecasting model of the key supply chain standards required by the healthcare industry in the next 2 to 5 years.

**Scope:**
- In addition to the GSMP, include other global standards setting bodies relevant to the healthcare industry.
- Forecast the need for specific standards to be developed based on industry planning.
- All-HUG members and healthcare industry stakeholders.

**Deliverables:**
- Forecasting model, including a periodic review of strategy documents for future healthcare trends and Auto-ID standards requirements.
- Recommendations and participation in GS1 GSMP optimization for healthcare.

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GTIN Allocation Rules

Leaders
- Mark Watnick
- Pfizer
- Mark House
- Tyco Healthcare

Scope
International in scope, to include all pharmaceutical products (both the Counter (SPC) and Penetration (IPL)) and medical devices (ISIN). Identification is B plus their subtypes and the 4 subject levels - non-vaccine, vaccine, patient sensitive products and ESA classification 1, 2, 3, 4.

Objectives
Provide worldwide guideline for GTIN assignment, built upon and consistent with www.gs1.org/standards for pharmaceuticals and medical devices.

Deliverables
Guidelines Document - whose approval (e.g., because of national legislation) it will include an appendix that will be country specific. It can be expected that HUG will be lobbying for the elimination of country specific divergence in GTIN allocation as these can add significant cost to products and global supply chains.

GS1 Standards Implementation/Regulatory Affairs

Leaders
- Jackie Paik, MDT
- Tom Sheehane
- Johnson & Johnson Medical Devices

Scope
International, in scope to include all GS1 service offerings including RED (RFID tags), identification system (e.g., GTIN, SITIN, STIN, GIN, GIN-G, UDI), business messaging, data synchronization.

Objectives
Identify regulatory, technical, commercial and process barriers to implementing GS1 standards in the global healthcare sector. Develop strategies to overcome barriers for adoption.

Vaccines and Biologicals

Leaders
- Stephanie Hess
- Merck
- GlaxoSmithKline

Scope
One global standard covering all biological and vaccine products and all aspects of the supply chain.

Objectives
Develop a global standard that increases adoption across the supply chain for vaccines and biologicals. This is aimed at improving patient safety and reducing medication errors.

Deliverables
- Maintain database of regulatory agencies and auto identification policies.
- Maintain database of S/G HG/H number and adoption status.
- Develop publication "Global Guidelines for Auto- Identification of Pharmaceuticals and Medical Devices".

Business Case

Leaders
- Ed Dowell
- Johnson & Johnson Pharma

Objectives
Develop a compelling business case to demonstrate the benefits of using a GS1 global standard.

Deliverables
- Executive summary for top management.
- Details on benefits at high level.

[www.gs1.org/docs/patient_safety/hug_brochure.pdf]
Join the GS1 Global Healthcare User Group - GS1 HUG™

For more information or to join, the HUG, contact Liene Krieva at liene.krieva@gs1.org or contact your local GS1 Member Organisation.

The GS1 Member Organisations list is available at http://www.gs1.org

Members of the HUG should:
- have a global position in their company
- have the agreement of their management for their engagement
- be actively involved and participate in the work of the HUG
- be able to represent the strategy, opinions and experience of their company regarding products

The GS1 HUG™ Membership list is attached to this brochure.

Do not hesitate to browse our website for more updates: http://www.gs1.org/hug/about/members.html

http://www.gs1.org/hug/
Contact details:
Jim Willmott
Group Labelling Manager ~ Smiths Medical
T  +44 (0)1303 236874
M  +44 (0)7766441573
E  Jim.Willmott@Smiths-Medical.com