HUG

Global Healthcare User Group
GS1 HUG™ ~ Rome ~ March 2006

Communication and Coordination

Rich Hollander Pfizer *Jim Willmott* smiths

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GS1 HUG

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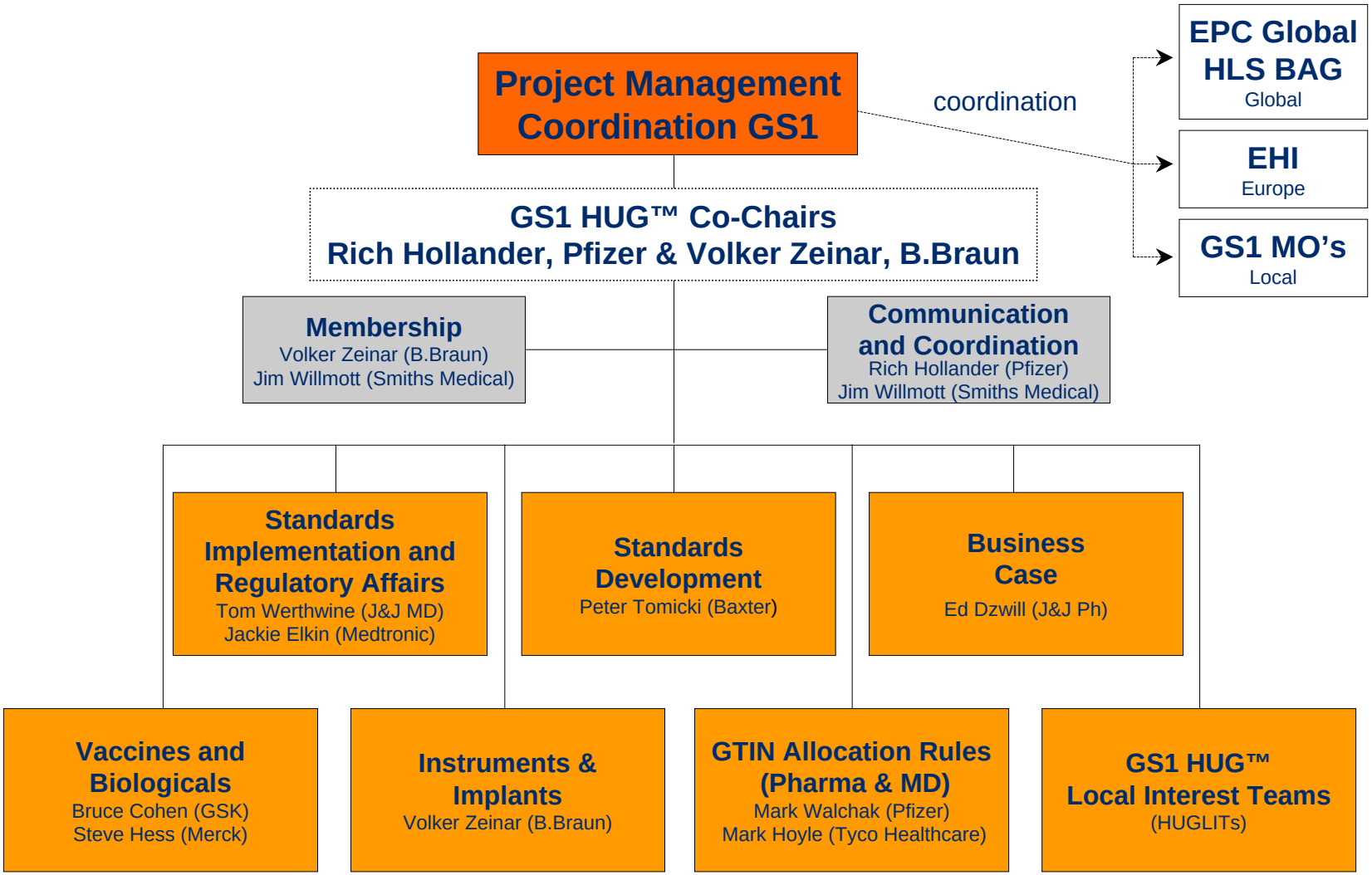

HUG

Communication and Coordination

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

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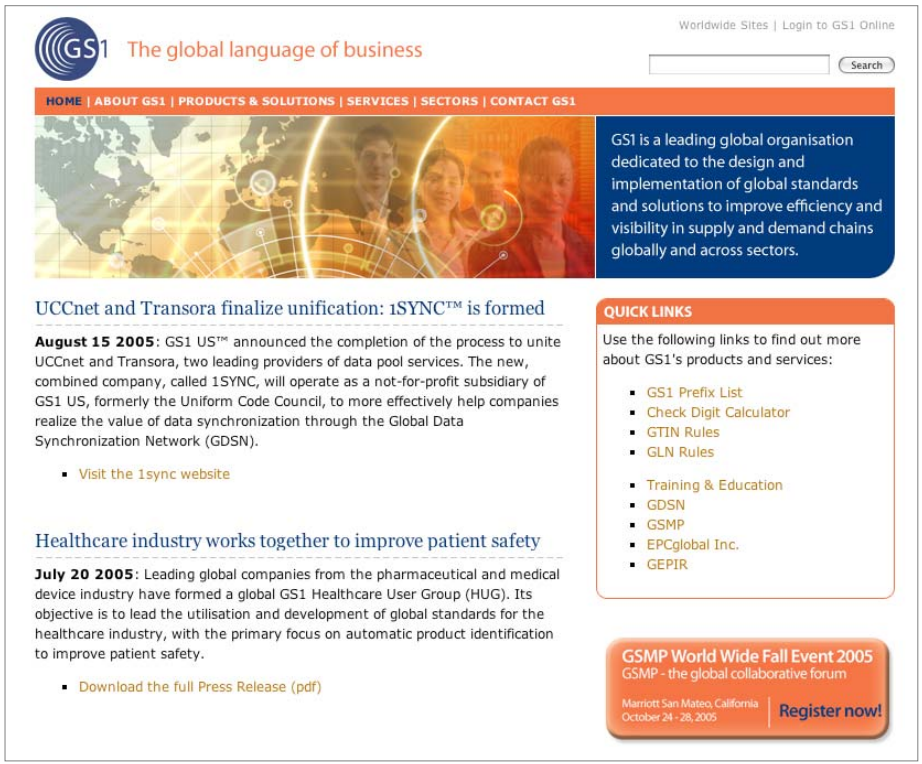
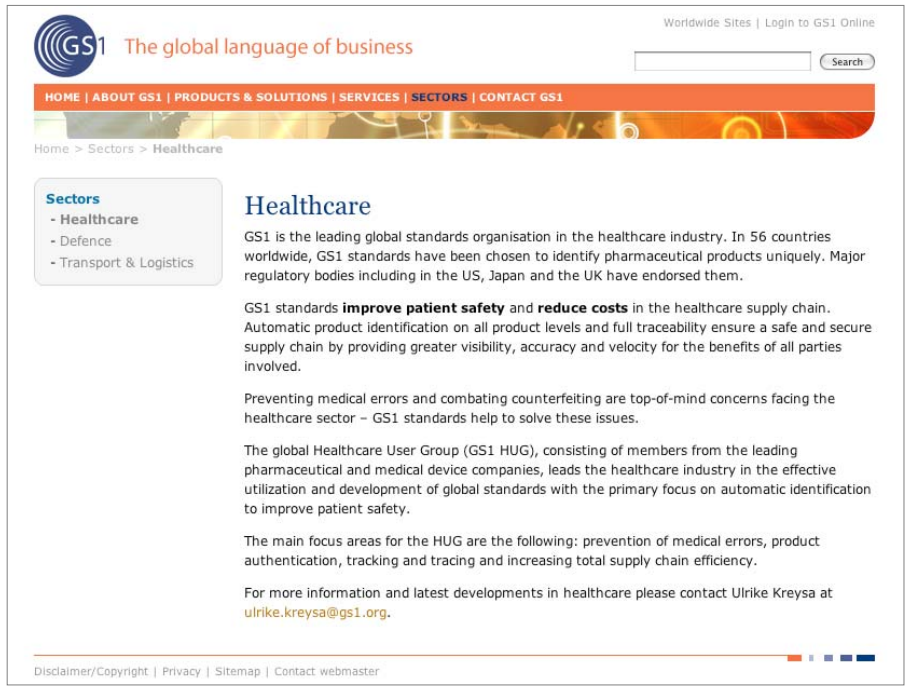
Communication and Coordination

GS1 Website:





(www.gs1.org)

Communication and Coordination

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.

Find out more about the HUG: download the HUG brochure

Join GS1 HUG

To join, please contact Ulrike Kreysa at ulrike.kreysa@gs1.org.

- View list of existing members
- Find out more about the HUG

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 activiites in South America.

Future Meetings

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

View meeting details

(www.gs1.org/hug/)

HUG

Communication and Coordination

GS1 Healthcare

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GS1 Healthcare User Group

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- News
- Charter
- **Members**
- Workplan
- Contact

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

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Members

Organisation	Representative
3M	Alfons Rathmer, IT-Director Europe & MENA
	Bernhard Geissler, Manager European Centers of Excellence Packaging Engineering
Abbott	Steve Siers, Global IT Director
Alcon Laboratories	Grant Hodgkins, Global Product Data Manager
AMGEN	Lewis T. Kontnik , Director, Brand Protection/Business Continuity
Astra Zeneca	John Morgan
B. Braun	Volker Zeinar, Global Supply Chain Expert
Baxter	Peter Tomicki, Global Packaging Engineer
	Jerry White
	Bob Houin
	Uwe Klaener, Global e-commerce director
BD	Dennis Black, Director e-Commerce
	Dirk Damen
Boehringer Ingelheim GmbH	Rainer Kirch, CDept. International Logistics
Boston Scientific	Bill Cooley, Director, Global Supply Chain Programs
Cephalon	Brian Brown, Senior Manager Commercial Operations
Cook	Claes-H. Waller
EGA (European Generic Medicines Association)	Rene Kappers
GSK	Bruce Cohen, US Packaging Services
	Kevin Gagnon
Grupo Cofares	Luz Lewin Orozco, Technical and Quality Director
Hospira	Laurie Hernandez, Vice President of Strategic Marketing.
	Brett Novak, Marketing Manager, Speciality Pharmaceuticals
Johnson & Johnson	Tom Werthwine, Manager, AIDC Technology and Industry Standards
	Edgar Dzwill, PSGA Tech Ops - Manager Package development Pharmaceuticals and Biological Products
Johnson & Johnson (Europe)	Janice Kite
Medtronic	Jackie Rae Elkin, Regulatory Compliance Manager
Merck	Stephen G. Hess
	Jeffrey Seeley, Associate Director Distribution Packaging
Merck Germany	Dr.Thorsten Clajus, Assistant Manager, Central Warehouse Department
	Christina Schuetze, Supply Chain Management - New Products
NACDS	Stephen Perlowski, VP Industry Affairs
NHS	Richard Haigh, Connecting for Health
Novartis Pharma AG	Scott Cameron, Head of GSCM Information Mgmt
Olympus Medical Systems	Masakazu Gotanda, General Manager (R&D)
Pall Medical	Brian Stripp
	Karen Peterson, Sr. Director, Global Labeling and Quality Services
Pfizer	Rich Hollander, Senior Director, Global packaging
	Mark Walchak, Senior Manager, Global Package Technology and Testing
Pharmdata s.r.o.	Josef Simacek
Premier Inc.	Joseph M. Pleasant, CIO
Procter & Gamble	Bob Weston
Public Health Agency of Canada (PHAC)	Camille Madeira
	Liza Belzak
Smiths Medical	Vaughan Hennum, Global Applications Manager
	Jim Willmott, Group Labelling Manager

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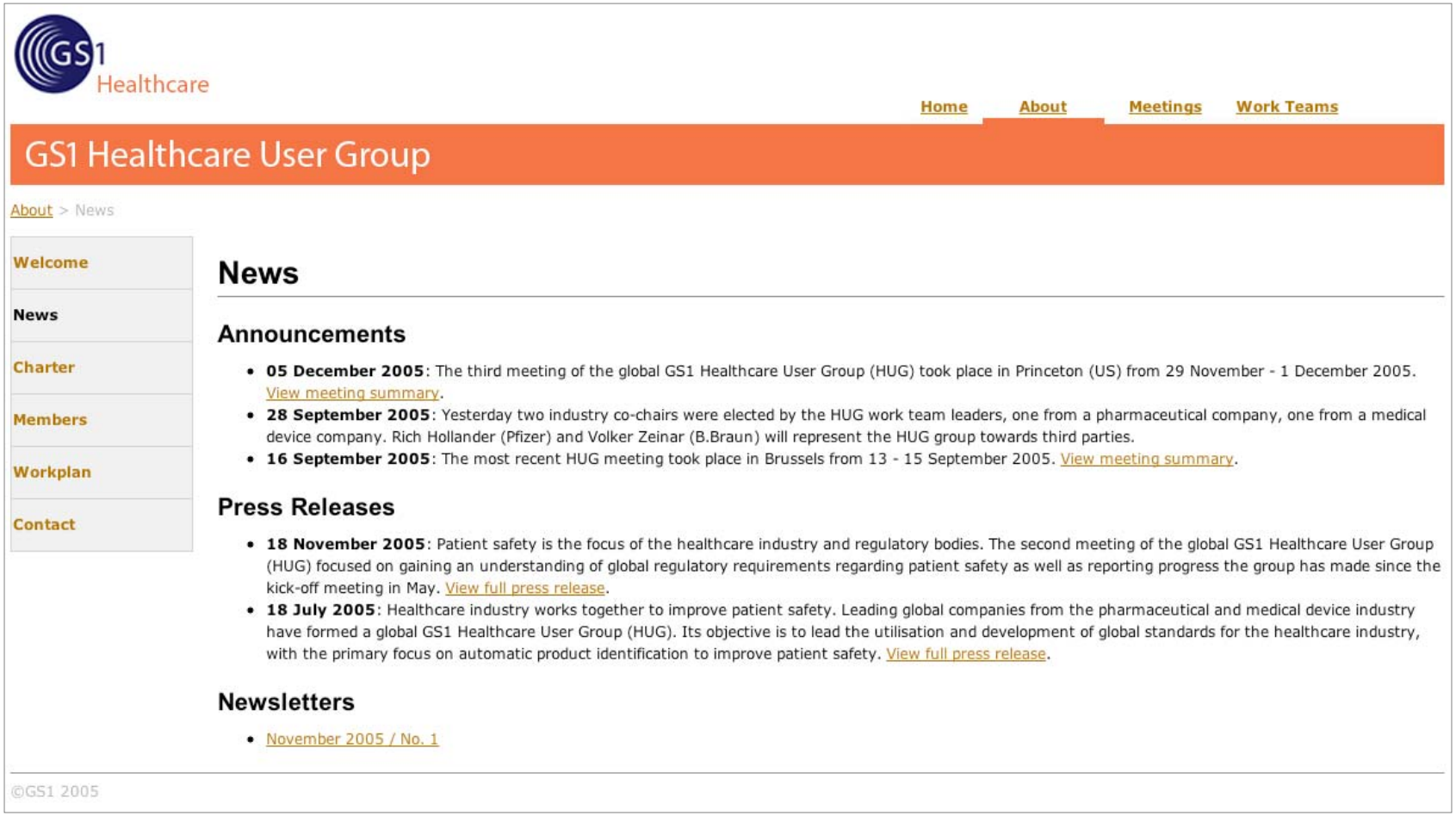

GS1 Healthcare

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GS1 Healthcare User Group

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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 Zeinar (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

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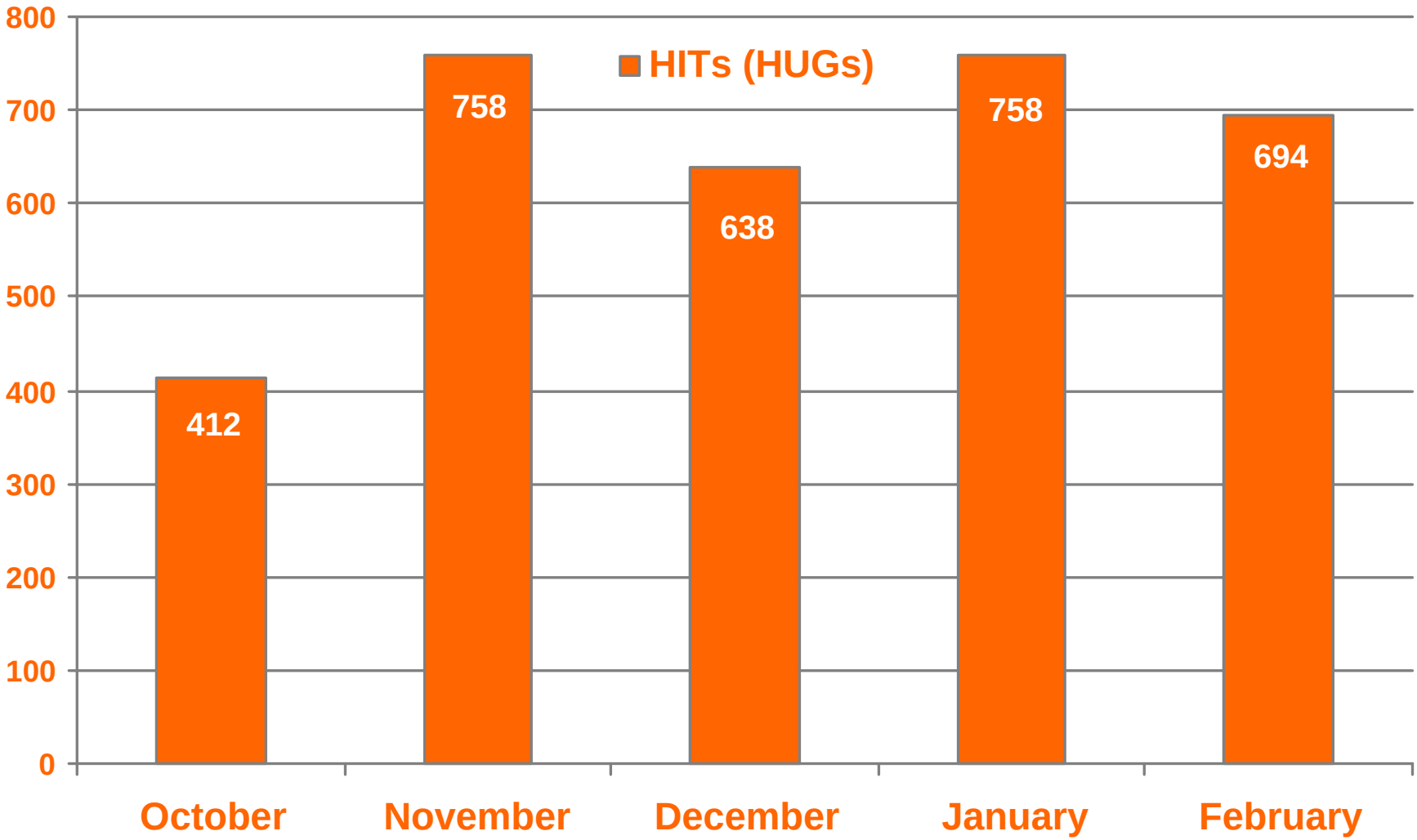
GS1 HUG™ "Homepage ":



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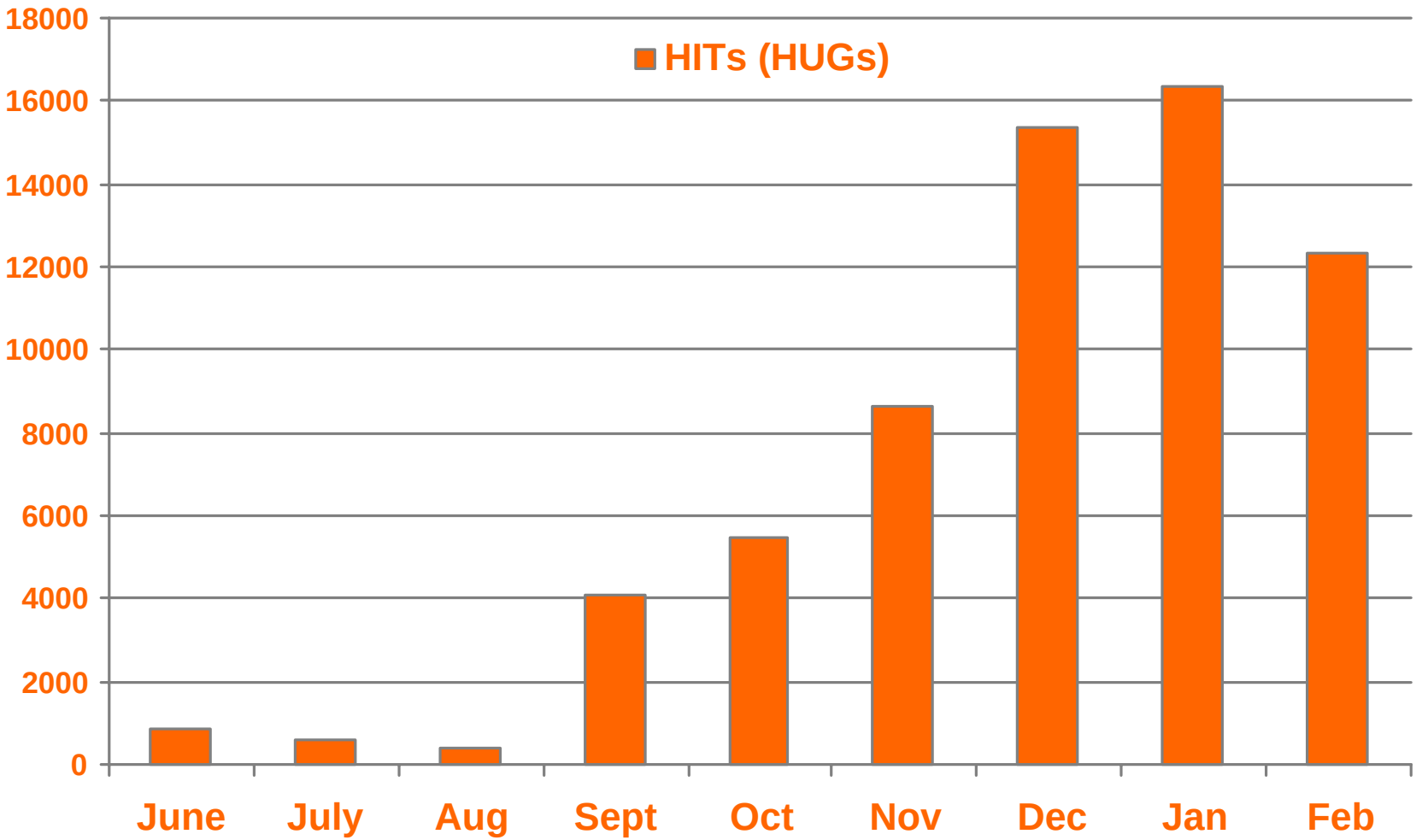
GS1 HUG™ "Total Website":



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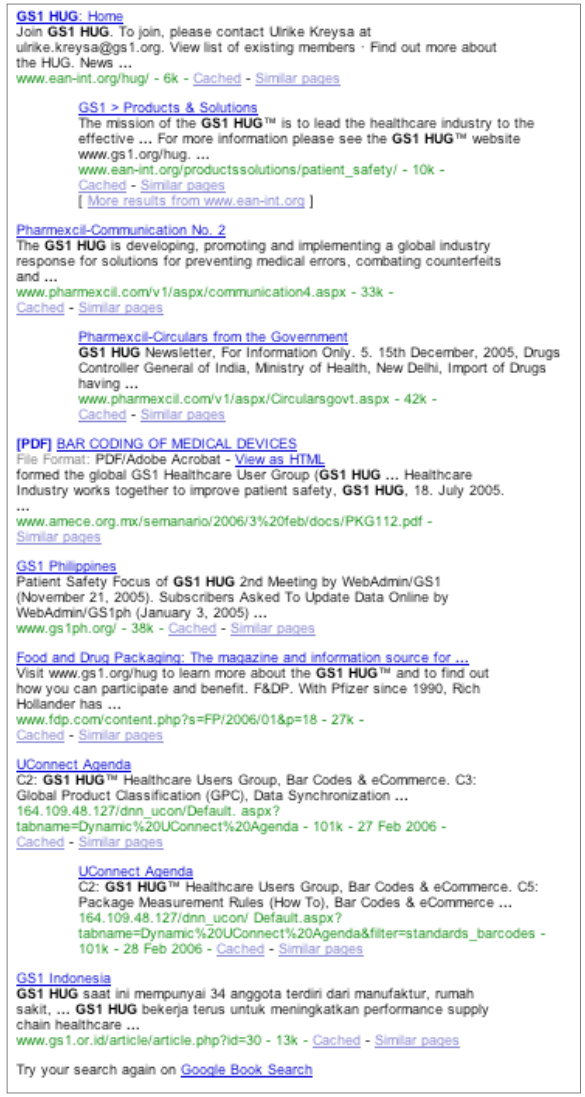
Windows

Safari

Firefox

Internet Explorer

Netscape



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Join **GS1 HUG**. To join, please contact Ulrike Kreysa at ulrike.kreysa@gs1.org. View list of existing members · Find out more about the HUG. News ...
www.ean-int.org/hug/ - 6k - Cached - Similar pages

GS1 > Products & Solutions
The mission of the **GS1 HUG**™ is to lead the healthcare industry to the effective ... For more information please see the **GS1 HUG**™ website www.gs1.org/hug. ...
www.ean-int.org/productssolutions/patient_safety/ - 10k - Cached - Similar pages
[More results from www.ean-int.org]

Pharmexcil-Communication No. 2
The **GS1 HUG** is developing, promoting and implementing a global industry response for solutions for preventing medical errors, combating counterfeits and ...
www.pharmexcil.com/v1/aspx/communication4.aspx - 33k - Cached - Similar pages

Pharmexcil-Circulars from the Government
GS1 HUG Newsletter, For Information Only. 5. 15th December, 2005, Drugs Controller General of India, Ministry of Health, New Delhi, Import of Drugs having ...
www.pharmexcil.com/v1/aspx/Circularsgovt.aspx - 42k - Cached - Similar pages

[PDF] BAR CODING OF MEDICAL DEVICES
File Format: PDF/Adobe Acrobat - View as HTML
formed the global GS1 Healthcare User Group (**GS1 HUG** ... Healthcare Industry works together to improve patient safety, **GS1 HUG**, 18. July 2005. ...
www.amece.org.mx/semanario/2006/3%20feb/docs/PKG112.pdf - Similar pages

GS1 Philippines
Patient Safety Focus of **GS1 HUG** 2nd Meeting by WebAdmin/GS1 (November 21, 2005). Subscribers Asked To Update Data Online by WebAdmin/GS1ph (January 3, 2005) ...
www.gs1ph.org/ - 38k - Cached - Similar pages

Food and Drug Packaging: The magazine and information source for ...
Visit www.gs1.org/hug to learn more about the **GS1 HUG**™ and to find out how you can participate and benefit. F&DP. With Pfizer since 1990, Rich Hollander has ...
www.fdp.com/content.php?s=FP/2006/01&p=18 - 27k - Cached - Similar pages

UConnect Agenda
C2: **GS1 HUG**™ Healthcare Users Group, Bar Codes & eCommerce. C3: Global Product Classification (GPC), Data Synchronization ...
164.109.48.127/dnn_ucon/Default. aspx?tabname=Dynamic%20UConnect%20Agenda - 101k - 27 Feb 2006 - Cached - Similar pages

UConnect Agenda
C2: **GS1 HUG**™ Healthcare Users Group, Bar Codes & eCommerce. C5: Package Measurement Rules (How To), Bar Codes & eCommerce ...
164.109.48.127/dnn_ucon/ Default.aspx?tabname=Dynamic%20UConnect%20Agenda&filter=standards_barcodes - 101k - 28 Feb 2006 - Cached - Similar pages

GS1 Indonesia
GS1 HUG saat ini mempunyai 34 anggota terdiri dari manufaktur, rumah sakit, ... **GS1 HUG** bekerja terus untuk meningkatkan performance supply chain healthcare ...
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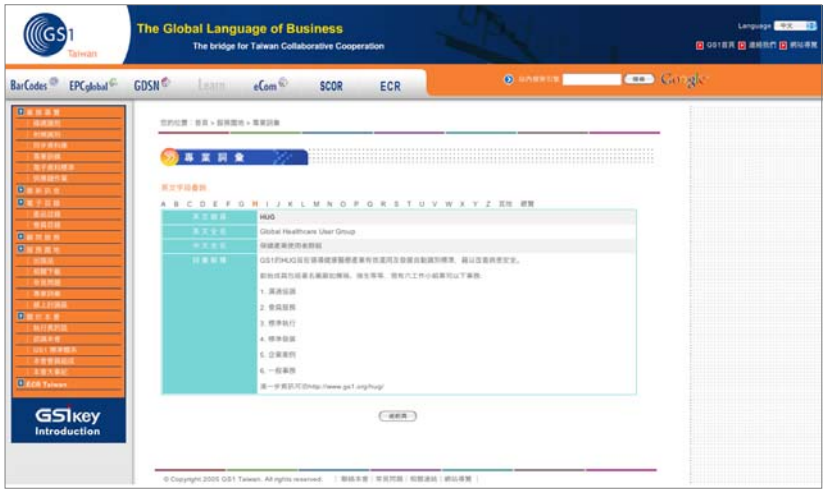

HUG - Healthcare User Grou

Les principales multinationales de l'industrie pharmaceutique et des dispositifs médicaux ont formé au sein de GS1 un groupe d'utilisateurs à l'échelle internationale. L'objectif de ce groupe est de pousser l'utilisation des standards internationaux GS1 dans les industries de produits de santé, avec comme première étape l'identification automatique des produits pour améliorer la sécurité du patient.
C'est la première fois que les majors de la santé se regroupent autour d'une solution globale d'identification automatique des produits au bénéfice du patient.
Parmi les autres axes de travail qui sont abordés : la réduction des erreurs médicales, l'authentification des produits, la traçabilité des produits et l'amélioration de la gestion de la chaîne d'approvisionnement.

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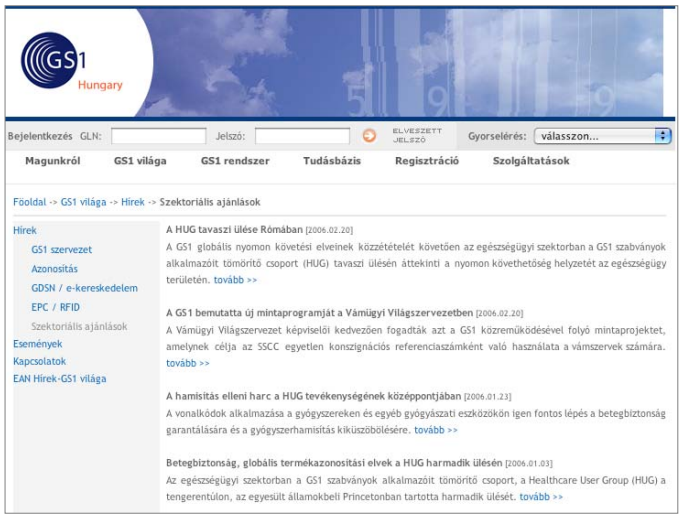

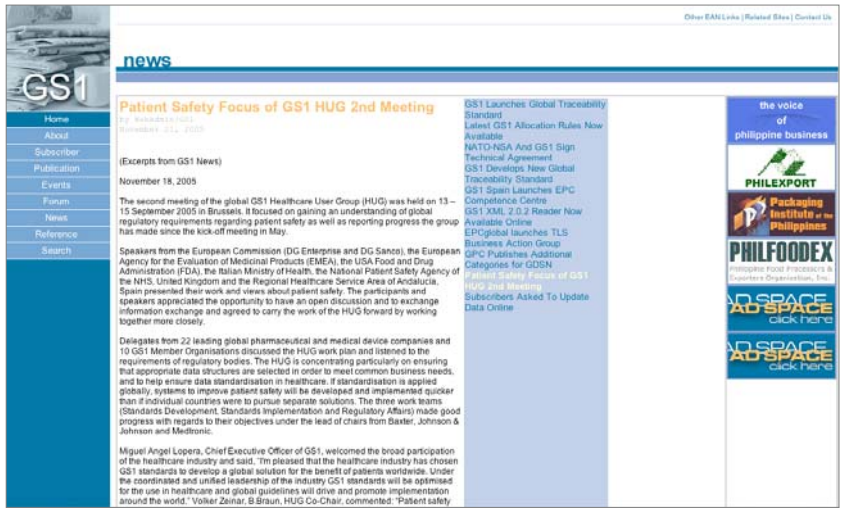

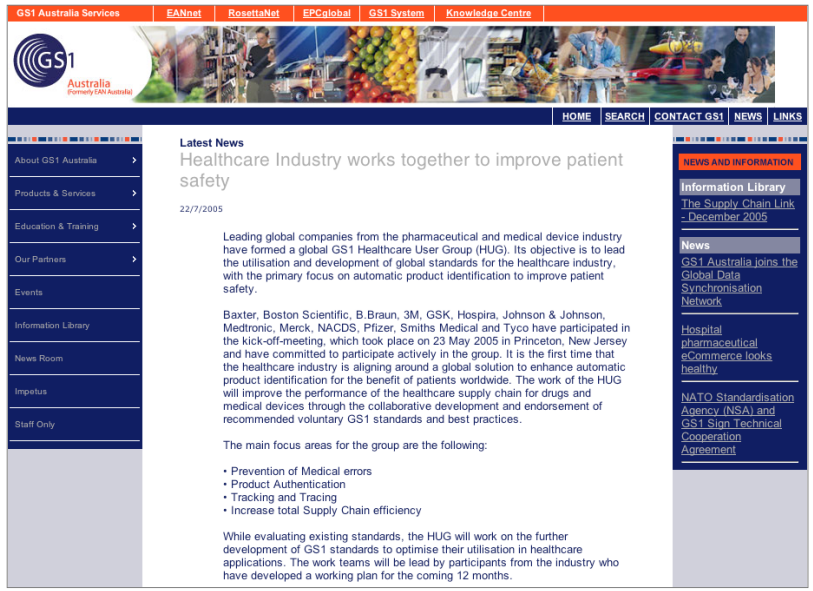

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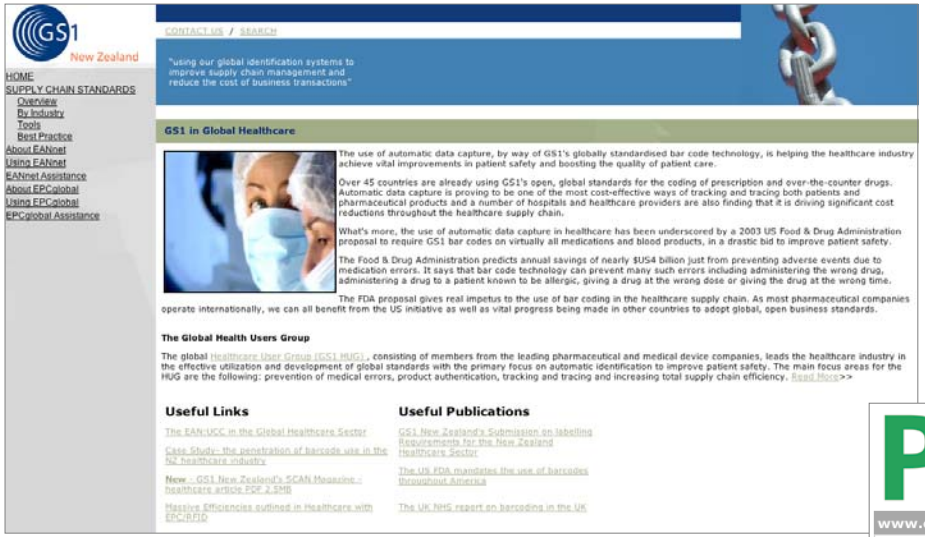

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- MEAT & DELI RETAILER
- THE NATIONAL PROVISIONER
- PL BUYER
- REFRIGERATED & FROZEN FOODS
- REFRIGERATED & FROZEN FOODS RETAILER
- SNACK FOOD & WHOLESALE BAKERY
- STAGNITO'S NEW PRODUCTS MAGAZINE

FOOD BEVERAGE

WHAT WE NEED IS ...

A Global Auto ID Standard Can Help Solve Counterfeit Issues

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

There are pressing issues in health care 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 unique serial number as it, and the supporting infrastructure, is being developed with open standards.

Global commonalities

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 EAN International) recently established a global Healthcare User Group.

The idea here is that HUG will help align the health care industry to the effective use of global standards for automatic identification. These 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. F&DP

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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 lead the utilisation and development of global standards for the healthcare industry, with the primary focus on automatic product identification to improve patient safety.

Baxter, Boston Scientific, B.Braun, 3M, GSK, Hospira, Johnson & Johnson, Medtronic, Merck, NACDS, Pfizer, Smiths Medical and Tyco have participated in the kick-off-meeting, 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 Medical 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 health care 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 Andalucía, Spain presented their work and views about patient safety. The participants and speakers appreciated the opportunity to have an open discussion and to exchange information exchange and agreed to carry the work of the HUG forward by working together more closely.

Delegates from 22 leading global pharmaceutical and medical device companies and 10 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
GS1 HUG - Newsletter No. 1

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

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

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

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

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

HUG - Focus areas and Working Teams

The main focus areas for the group are the following:

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

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

The HUG Leadership Team

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

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

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

The global Healthcare User Group
GS1 HUG™ - Newsletter No. 2

Welcome to the second edition of the GS1 HUG™ Newsletter! We have initiated this newsletter to inform you regularly about our activities and progress in the global Healthcare User Group, GS1 HUG™.
We look forward to receiving your comments, feedback and questions, possibly for inclusion in future newsletters.

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

Our new brochure gives more information about the GS1 HUG™ in a comprehensive format. Mission and Vision are explained as well as the objectives and focus areas. The HUG work teams; Communication and Coordination, Instruments and Implants, Membership, Standards Development, GTIN Allocation Rules, Standards Implementation / Regulatory Affairs, Business Case and Vaccines & Biologicals, are described with their objectives, scope and deliverables. The brochure can be requested from the GS1 Global Office or downloaded from the HUG website at www.gs1.org/hug/

Second meeting of global Healthcare User Group (GS1 HUG™) 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 60 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 automatic product identification the whole GS1 product and service portfolio was discussed and business managers from GS1 BarCodes, GDSN and EPCglobal attended the meeting.

Paul Pandiscio, VP Global Supply Chain welcomed the participants in the name of **Johnson & Johnson.** He outlined the importance of the supply chain in healthcare – it is essential to know where the product is and where it is not. He sees significant prospect and potential in the global Healthcare User Group and supports its goals.

The HUG work team leaders from B.Braun, Medtronic, Johnson & Johnson Medical Devices and Pharmaceuticals, Baxter and Pfizer gave detailed information about the objectives and first results of their groups.

Canadian Pilot Project for Vaccines

Lisa Belchak from the **Public Health Agency of Canada (PHAC)** informed the HUG participants about their Automated Identification of Vaccines Pilot (AIVP) Project, which was established to test the feasibility of using bar coding technology to quickly, accurately and automatically transfer

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Articles:

WHAT WE NEED IS...

A global auto ID standard can help solve counterfeit issues

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

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

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 unique serial number as it, and the supporting infrastructure, is being developed with open standards.

Global commonalities

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 EAN International) recently established a global Healthcare User Group.

The idea here is that HUG will help align the health care industry to the effective use of global standards for automatic identification. These 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. FADP

With Pfizer since 1990, Rich Hollander has responsibility for all areas of global package design and development for Pfizer's Animal Health, Consumer Healthcare and Human Health businesses. Hollander is an active leader on various committees, work groups and task groups aimed at addressing issues within pharmaceutical packaging. He currently serves as co-chair and communications chair for the GS1 Healthcare User Group (www.gs1.org/hug).

HUG

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Benefits of barcoding in the pharmaceutical industry

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

One of the main concerns in healthcare today is patient safety. In 2000, the Institute of Medicine (IOM) published its report *To Err is Human*[1] and an increasing number of publications are reporting on medical errors, which happen across the world.[2-4] Automatic identification technology (barcoding) is one of the tools that is acknowledged in reducing such errors.[5] It is contributing to improving efficiency and increasing accuracy of data entry into automated systems. The possibility of capturing data via barcode scanners, in conjunction with computerised databases, enables healthcare professionals to verify whether the right drug was used at the right time for the right patient in the right dose on the right route ("five patient rights"). Barcoding has the potential to be not only cost-effective but to save lives while producing a strong return on investment.

Medical errors and usage of barcodes

A barcode is a graphic representation of data that is machine-readable. Barcodes are a fast, easy and accurate way of capturing and entering data. They do not contain descriptive data, but are just a reference number to a computer file with the relevant data.

In a hospital, barcodes can be used to improve processes in the following areas:

- Patient registration and admission for:
  - Patient forms.
  - Patient labels and wristbands.
  - Patient records.
  - Patient accounting and billing.
- Patient safety, clinical care delivery and patient tracking by using barcodes for:
  - Pharmaceuticals down to unit dose level.
  - Medical devices down to unit of use level.
  - Identification of hospital staff and patients.
  - Order requisitions, test/results and patient charts/medical records.
- Product, supply and material management for:
  - Inventory control/tracking.
  - Materials tracking and logistics.
  - Tracking of reusable/refurbished equipment and supplies.
  - Reverse supply chain (eg, product recalls and warnings).

Taking into account the significant benefits of automatic product identification, the Department of Health and Human Services in the USA has issued a final rule requiring electronically readable barcodes on the packaging of hospital administered pharmaceutical products, biologicals and blood products. This will be introduced in April 2006.[6]

Already, in 40 countries worldwide, mandates for automatic product identification exist today – others are in the phase of developing regulations for barcoding of healthcare products, acknowledging the advantages for patient safety.[7,8] While studies conducted in Veteran Affairs hospitals (USA) in the 1990s showed that the use of barcodes reduced medication administration error rates by up to 86%, only a small number of hospitals have recently started to use this technology to improve patient safety. Current estimates indicate that only 2–6% of hospitals in the USA are using barcodes to reduce medication administration errors.[8] It is expected that the number of hospitals will increase significantly in the near future, with more products carrying a barcode and more publications reporting the benefits of barcodes.[10-12]

Global standards for pharmaceuticals and medical devices

The healthcare industry has recently recognised the need for global standards in healthcare and in May 2005, leading global companies from the pharmaceutical and medical device industries formed the global GS1 Healthcare User Group (GS1 HUG™).[13] Its mission is to lead the healthcare industry to the effective utilisation and development of global standards, with the primary focus on automatic identification to improve patient safety. The group currently has 34 members from manufacturers, hospitals, regulatory bodies and associations who are committed to working towards a global solution to enhance automatic product identification for the benefit of patients worldwide. The main focus areas are as follows:

- Prevention of medical errors.
- Product authentication.
- Tracking and tracing.
- Increasing total supply chain efficiency.

The work of the GS1 HUG™ will improve the performance of the healthcare supply chain for pharmaceuticals and medical devices, through the collaborative development and endorsement of recommended voluntary GS1 standards and best practices. The group includes representatives from all types of stakeholders in the healthcare supply chain – more participants from hospitals are very welcome to join and contribute. Working groups are developing global voluntary guidelines for the marking of pharmaceuticals and medical devices; special teams are also working on marking of vaccines and biologicals, instruments and implants. The GS1 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 separate solutions. The next GS1 HUG™ meeting will take place in Rome from 21 to 23 March 2006. For participation and other details please contact the author.

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Traceability and counterfeiting

Other aspects that have to be considered are the effects of barcoding on streamlining the supply chain and inventory control. In combination with electronic messaging, full supply chain control and effective traceability of the products is possible. This will help to prevent counterfeiting – a topic which, today, worries the healthcare industry and regulatory bodies and is increasing in importance across the world.

Counterfeiting is a bigger issue in developing countries,[14] but even in the USA the number of cases investigated by the FDA has increased significantly in the last year.[15] Increasingly, in Europe too, concerns are raised that through the more open markets and the rise of "drugs through the internet", fake products can enter the supply chain.[16] However, traceability and integrity of the supply chain can be ensured through additional data for product identification such as expiration date, lot/batch number and serial number. Only when this data is available throughout all processes and partners in the supply chain will it be possible to combat counterfeiting effectively. With new barcode symbologies (eg, Data Matrix and RSS), it is possible to carry all this information even on very small items and packages.

Most importantly, the use of barcodes on drugs and medical devices will be an important step to improve patient safety. Furthermore, it allows the tracking of medicinal products before, during and after a medical procedure. Data can also be captured in the electronic patient record with little manual input, enabling traceability in the case of recalls but also better calculation of costs for the treatment. ■

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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[1]. A high percentage of healthcare costs are generated by medical devices, and through the rapid progress in technical innovation, the global market figure for 2006 is expected to exceed US$260 billion[2].

Global medical device market is expected to exceed US$260 billion in 2006

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

Counterfeiting

There are 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[3]. Medical device manufacturers are also reporting counterfeiting of their products, which causes effects on the safety of device users and patients, as well as effects on the manufacturers themselves (e.g. by loss of sale and loss of reputation when counterfeit 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.

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

Medical errors

In 2000, the Institute of Medicine (IOM) published its report *To Err is Human*[4] 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[5]. To date, no such rule has been released for medical devices, despite pressure from the largest American hospital chains such as Premier and the American Hospital Association[6]. However, the FDA has organised an official meeting to discuss unique device identification, where stakeholders were given the opportunity to express their opinion[7].

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

Gary Hartley
Manager for strategic initiatives
GS1 NZ

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; most of us don't think about them very often but they are one of the most ubiquitous "products" around and it is hard to imagine a world without them. Bar codes were "invented" over 30 years ago in response to an industry-led need to be able to uniquely identify products moving through various supply chains in an automated manner.

GS1 is a global organisation dedicated to the design and implementation of global standards, technologies and solutions to improve the efficiency and visibility in supply and demand chains. GS1 is a neutral, not-for-profit standards (and related services) organisation.

More than 30 years on, GS1's suite of standards has broadened to include electronic commerce tools such as XML, EDI messaging; next-generation technologies and solutions such as data synchronisation (the Australian catalogue is built on a GS1 system); electronic product code (EPC) global using radio frequency identification (RFID) technologies; and product traceability.

GS1 operates in more than 20 industry sectors and sectors ranging from fast moving consumer goods (FMCG) to healthcare, transport and logistics and defence.

Along with its member organisations, GS1 plays a leading role in supply and demand chain management improvement worldwide for large, small and medium-sized organisations. Formed in 2004 from the joining together of European Article Numbering (EAN) International and the Uniform Code Council (UCC), GS1 has a presence in 101 countries driven by more than a million companies who execute more than five billion transactions a day.

GS1 in healthcare

GS1 is widely recognised as the leading standards organisation in the global healthcare industry. In 56 countries worldwide, GS1 standards have been chosen as the key to identify pharmaceutical products uniquely. A number of major regulatory bodies have mandated them, including those in the US, Japan, Brazil and the UK among others.

In July 2005, the GS1 global Healthcare User Group (HUG) was established as a voluntary global group of GS1 members and invited supply chain participants from around the world. 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.

The group is comprised of senior executives from global pharmaceutical companies, hospitals, logistics organisations and regulators. ▶

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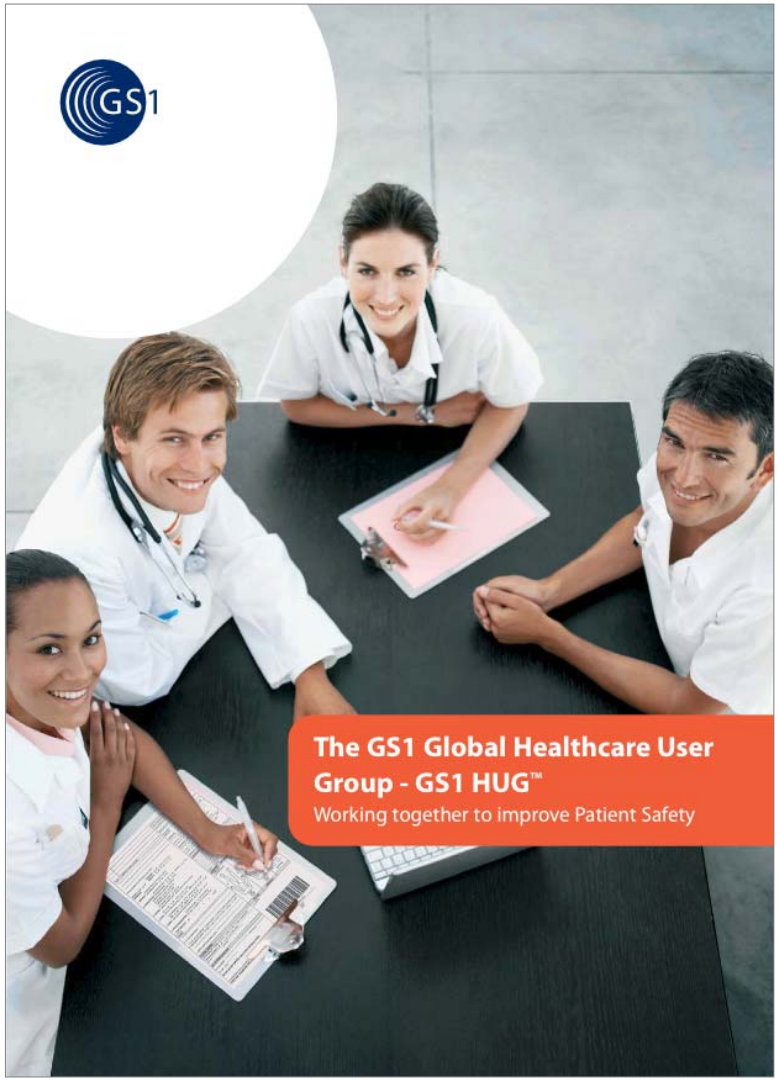
HUG Brochure:



(www.gs1.org/docs/patient_safety/hug_brochure.pdf)

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GS1

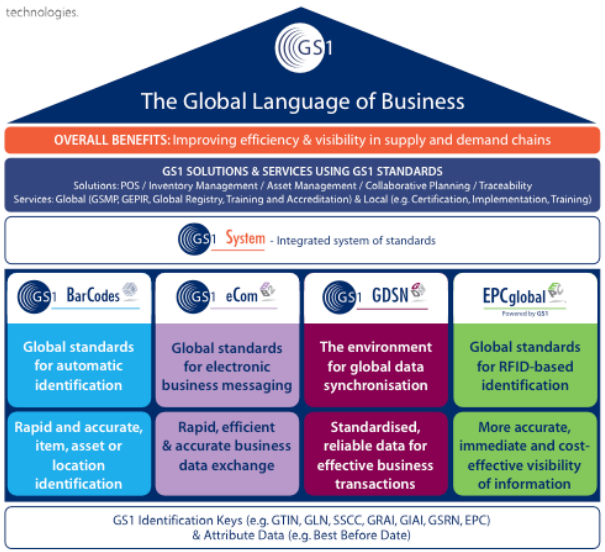
GS1 is a global organisation dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility in supply and demand chains.

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

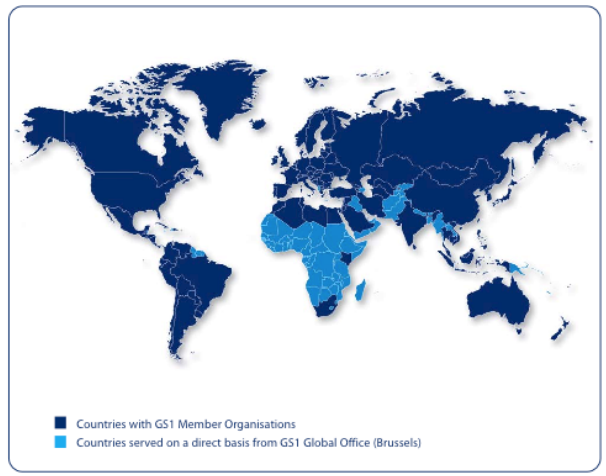
GS1 is a neutral, not-for-profit standards (and related services) organisation.

We offer a diversified portfolio of products, solutions and services, including the GS1 System of standards, the most widely used supply chain standards system in the world.

Our portfolio ranges from GS1 BarCodes to GS1 eCom (electronic commerce tools) to next generation technologies, such as GS1 EPCglobal (using RFID), and solutions such as GS1 GDSN (Data Synchronisation) and GS1 Traceability.



GS1 Around the World



We operate in more than 20 industry sectors ranging from Retail, Food and Fast Moving Consumer Goods to Healthcare, Logistics and Defence.

GS1 and its Member Organisations play a leading role in supply and demand chain management improvement worldwide for large, small and medium-sized organisations.

Formed from the joining together of EAN International and the Uniform Code Council (UCC), GS1 is truly global, with a presence in **over 103 countries** driven by more than **a million companies** that execute over **five billion transactions each day** using GS1 standards, solutions and services.

(www.gs1.org/docs/patient_safety/hug_brochure.pdf)

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HUG

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 endorsement of recommended voluntary GS1 standards and best practices.

Mission and Vision

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

The **vision** of the GS1 HUG™ is to become the single source for regulatory agencies and trade organizations (manufacturer, wholesaler, distributor, hospital and pharmacy) 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 world-wide 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 Lopera, President & CEO of GS1.

Objectives

The **objectives** of the HUG are to:

- Work with key partners in the healthcare supply chain to develop and optimise the use of global standards to ensure accurate and fast movements of goods from manufacturer to distributor, healthcare provider, hospitals or public pharmacies.
- Facilitate awareness in the healthcare sector of new technologies and methods of doing e-business.
- Provide advice and recommendations to GS1 on issues and opportunities in the healthcare sector.
- Promote best practice implementation in the health-care area including the whole product and service portfolio of GS1.
- Promote the implementation of GS1 voluntary, 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 Zeinar, B.Braun

(www.gs1.org/docs/patient_safety/hug_brochure.pdf)

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Focus Areas

The main **focus areas** for the group are the following:

1. **Prevention of Medical Errors**
   Encoding of 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. Encoding of the unit of use package to enable automated verification to ensure the right device for the right patient.

2. **Product Authentication**
   Ensure that the packaging and associated labelling are genuine by utilizing a GS1 data structure, enable authentication of individual packages, cases or pallets.

3. **Tracking and Tracing**
   Utilizing a GS1 data structure, work 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"
Rich Hollander - PFIZER

GS1 HUG™ - Today and Tomorrow

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 help to improve patient safety will be developed and implemented quicker than if individual countries were to pursue separate solutions.

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

"If standardisation 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, 2005

(www.gs1.org/docs/patient_safety/hug_brochure.pdf)

HUG

Communication and Coordination

HUG Work Teams:

Communication and Coordination

Leaders:
Rich Hollander
PFIZER
Jim Willmott
SMITHS MEDICAL

Scope
- Identify key areas for which we establish recommendations and end-users to address.
- Build communication and coordination infrastructure.

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.

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

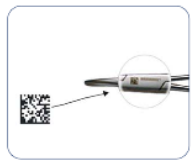
Instruments and Implants Marking

Objectives
Analysis of the necessity of marking instruments and implants, taking into account the practical application in hospitals and technical feasibility.

Leader:
Volker Zeinar
B.BRAUN

Scope
Level of track and trace (e.g. set level or instrument level), packaging and/or direct marking, data content, data carriers, regulatory compliance.

Deliverables
Process descriptions, industry baselines, technical framework / obstacles (manufacturer and end users side), recommendations.



Membership

Leaders:
Volker Zeinar
B.BRAUN
Jim Willmott
SMITHS MEDICAL

Scope
Identify and prioritise the stakeholders.

Objectives
Organize HUG enlargement to progressively include all stakeholders.

Deliverables
List of preferred contact persons.

Standards Development

Objectives
- Detail a realistic supply chain standards development process for adoption by GS1 that is optimised 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.

Leader:
Peter Tomicki
BAXTER

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.
- Recommendation and participation in GS1-GSMP optimisation for healthcare.

*GSMP = Global Standards Management Process

(www.gs1.org/docs/patient_safety/hug_brochure.pdf)

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HUG

GTIN® Allocation Rules

Leaders:
Mark Walchak
PFIZER
Mark Hoyle
TYCO HEALTHCARE

5 425000 030065
For illustration only

Scope
International in scope, to include all pharmaceutical products (Over The Counter [OTC] and Prescription [Rx]) and medical devices (FDA classification I, II, III plus their subset and the 4 subject levels - non-invasive, invasive, active, special rules and EU classification I, IIa, IIb, III).

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

Deliverables
Guideline Document - where applicable (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 divergences in GTIN allocation as these can add significant cost to products and global supply chains.

GS1 Standards Implementation/Regulatory Affairs

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

Leaders:
Jackie Rae Elkin
MEDTRONIC
Tom Werthwine
JOHNSON & JOHNSON MEDICAL DEVICES

Scope
International in scope, to include all GS1 service offerings: bar coding, RFID* (EPC* tags), identification system (e.g., GTIN*, SGTIN*, GLN*, GSRN*), business messaging, data synchronisation.

*GTIN = Global Trade Item Number
*GLN = Global Location Number
*GSRN = Global Service Relation Number
*SGTIN = Serialized Global Trade Item Number - this is a key (GTIN) with an attribute (serial number)
*EPC = Electronic Product Code
*RFID = Radio Frequency Identification

Deliverables
- Maintain database of regulatory agencies and auto identification policies.
- Maintain database of GS1 HUG™ members' adoption status.
- Develop publication "Global Guidelines for Automatic Product Identification of Pharmaceuticals and Medical Devices".

Business Case

Leader:
Ed Dzwill
JOHNSON & JOHNSON PHARMA

Scope
Regulatory bodies and supply chain participants.

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

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

Vaccines and Biologicals

Objectives
Develop a global standard and increase adoption across the supply chain for vaccines and biological data aimed at improving patient safety and reducing medication errors.

Leaders:
Stephen Hess
MERCK
Bruce Cohen
GLAXOSMITHKLINE

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

Deliverables
Global standard for vaccines and biologicals with agreed data elements and data carriers.

(www.gs1.org/docs/patient_safety/hug_brochure.pdf)

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Join the GS1 Global Healthcare User Group - GS1 HUG™

For more information or to joint the HUG, contact Ulrike Kreysa at ulrike.kreysa@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, 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

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/

GS1 - The global language of business

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GS1 HUG

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