certainly be a rather pedestrian process, it is a one-time effort that nets an ongoing return in every area that previously had to research and correct information discrepancies.

Ongoing Synchronization

Once external synchronization is complete, the final phase of data synchronization, ongoing synchronization, is put in motion. This phase involves the ongoing process of the seller (the source) (1) notifying the buyer (the recipient) that there has been a change to one or more of the information elements that the parties are trying to keep in sync, (2) conveying the updated information, and (3) ensuring that the recipient understands, agrees with, and has implemented the change.

The mechanisms by which this source/recipient interchange takes place vary by industry sector implementation. They range from direct information exchange between sources and recipients to the use of a global registry for ID and standards policing. They may or may not include one or more intermediary service providers and allow for several of the internal functions to be handled in a hosted (versus in-house) setting.

Regardless of how the source and the recipient connect with one another to keep their data stores in sync, each must complete the internal, external, and ongoing synchronization stages described. With mechanisms in place to ensure that all internal data stores remain in sync (1) within each organization and (2) between each organization, the interchange approach can be initiated.

It should be noted that any data synchronization approaches that do not utilize some sort of central repository or product data utility (PDU) rely solely on the willingness of all participants to voluntarily follow the standards established for that community. This "honor system" approach has typically met with varying degrees of failure compared to approaches that rely on a single central registry to enforce adherence to agreed-upon standards.

In addition, using more than one organization as certified "onramps" to access (1) the registry and (2) all participants using the registry has traditionally proven more effective than having only one onramp. This avoids concerns over potential monopolistic conditions, keeps competition alive, and generally ensures higher quality, lower prices, and freedom of choice for all concerned.

Regardless of the number of onramps to the registry, there can only be one central repository. As soon as there is more than one registry, you introduce the added challenge of trying to keep the multiple registries in sync with one another. Historically, this has proven to be an undesirable and less effective approach.

APPENDIX 4 - SAVINGS CALCULATION OVERVIEW

What could global data synchronization mean to your organization? Here is a high-level outline to help you identify what it is costing your organization to manually handle item exceptions in your orders and invoices. [NOTE: This is by no means the only area of savings that you can expect to accrue from successful data synchronization.]

Manual intervention is costly not only in terms of the literal cost of human resources involved, but also in terms of the opportunity cost of the missed work that that resource would have otherwise been able to do—had he or she not been interrupted to address the exception. By reducing item exceptions, we liberate expensive human resources to be applied to other, higher return tasks.

The following questions are designed to arrive at a rough estimate of the value of synchronizing core information elements between a buyer and a seller. These savings come from reducing item exceptions between the four interacting departments of the buyer and seller: purchasing, order processing, accounts receivable, and accounts payable. Additional administrative savings will be realized in areas such as contract management, rebate reconciliation, shipping/receiving, etc.

Sell-Side Company

Questions to be posed to the head of order processing for a sell-side company:

- If we could remove inaccuracies in the base item information—by synchronizing with our customers—would it make a noticeable difference in your exception handling?
- On average, what percent of our inbound orders kick out with exceptions caused by discrepancies in one or more of these base item elements? [Example: item number, partner IDs, or price discrepancies]
- Approximately what percentage of time—per staff member—is spent researching and resolving these exceptions? How many of your staff members are affected?

Questions to be posed to the head of accounts receivable for a sell-side company:

- If we could remove inaccuracies in the base item information—by synchronizing with our customers—would it make a noticeable difference in your exception handling?
- On average, for what percent of our outbound invoices do our customers call with exceptions caused by discrepancies in one or more of these base item elements? [Example: item number, partner IDs, or price discrepancies]
- Approximately what percentage of time—per staff member—is spent researching and resolving these exceptions? How many of your staff members are affected?

Buy-Side Company

Questions to be posed to the head of purchasing for a buy-side company:

- If we could remove inaccuracies in the base item information—by synchronizing with our vendors—would it make a noticeable difference in the exceptions found in our orders?

- On average, what percent of our outbound orders kick out—on the vendor's side—with exceptions caused by discrepancies in one or more of these base item elements? [Example: item number, partner IDs, or price discrepancies]
- Approximately what percentage of a buyer's time is spent researching and resolving these exceptions? How many buyers are affected?

Questions to be posed to the head of accounts payable for a buy-side company:

- If we could remove inaccuracies in the base item information—by synchronizing with our vendors—would it make a noticeable difference in your exception handling?
- On average, for what percent of our inbound invoices do we have to call our vendors with exceptions caused by discrepancies in one or more of these base item elements? [Example: item number, partner IDs, or price discrepancies]
- Approximately what percentage of time—per staff member—is spent researching and resolving these exceptions? How many of your staff members are affected?

  Knowing (1) the percentage of orders or invoices that are affected by these discrepancies, (2) the percentage of an average staff member's time spent resolving the discrepancies, and (3) the number of staff involved, we can calculate a rough estimate of the value of avoiding the discrepancies.

Estimating Per Partner Value

Separately calculate the following for purchase orders and invoices. Then combine the results to determine the total value of converting a particular partner to item synchronization.

 # Of Documents w/ Errors =
[Total # Docs] x [Average % of Docs w/ Errors]

Total Employee Hours per Year* =
[40 hours/week] x [50 weeks]

* Note: Adjustments may have to be made for (1) normal work hours/week or (2) average total workweeks available per year.

Total Staff Hours Spent on Errors =
[# Of Staff Involved] x
[Avg. % of Time Spent on Errors per Staff Member] x

[Total Employee Hours per Year]

Staff Member Cost per Hour =
[Annual Fully Loaded Cost per Employee**]/[Total Employee Hours per Year]

** **Note: The fully loaded cost per employee varies from company to company. Numbers typically used range from $80,000 to $120,000 per year per employee.**

Total Cost of Errors* =**
[Total Staff Hours Spent on Errors] x [Staff Member Cost per Hour]

*** **Note: This is only the cost of the time of the staff involved in the research and resolution. There are other costs not considered here.**

Average Error Cost per Document =
[Total Cost of Errors]/[# of Documents w/ Errors]

Purchase Orders And Invoices:

Annual Value of Converting a Particular Partner to Item Synchronization =
([Avg. Error Cost per PO] x [Avg. % of POs w/ Errors] x [Avg. # of POs per Year]) +
([Avg. Error Cost per Invoice] x [Avg. % of Invoices w/ Errors] x [Avg. # of Invoices per Year])

It should be noted that there are additional savings that can be realized from item synchronization that are not considered here. These additional savings can include the impact of order delays, incorrect shipments, late payments, etc.

ABOUT THE AUTHORS

WILLIAM L. ROSENFELD

William Rosenfeld is Vice President of Retail Practices for Sterling Commerce. He has over 30 years of systems experience. He has spent the last 6 six years fully engaged in implementing data synchronization. As a solution provider, he managed the development of the core UCCnet system and is listed by the US Patent Office as one of three inventors of the "Commercial Data Registry System". For the last several years he has provided technical direction for the teams that created Sterling's data synchronization products. He currently serves as a voting member of the Global Data Synchronization Network (GDSN) Task Force that directs the international standards efforts in this area.

Earlier, he managed and provided technical direction to AppNet's Business Intelligence practice. For 18 years he focused on management reporting, warehousing, planning, and decision support applications for a wide variety of large companies and functional areas. He has particular expertise in Consumer Package Goods industries and the Sales and Finance functions within corporations.

Prior to joining AppNet's predecessor company (Research & Planning), Mr. Rosenfeld worked for Shawmut Bank. There he managed the bank's initial Automated Teller Machine implementation and was responsible for coordinating the numerous impacted organizations. He also managed a team of programmers and analysts responsible for the bank's checking and savings systems, among others. Earlier, he worked for SofTech, where he became experienced in analyzing and designing massive systems. One such large project was the redesign of all financial systems for the Federal Government's Energy and Research Development Administration (predecessor to the Department of Energy).

JOHN L. STELZER

John Stelzer is Director of Industry Development for Sterling Commerce. Since 1984, he has been providing education and consulting on electronic data interchange, electronic commerce, and e-business—to date, educating more than 27,000 professionals from over 16,000 companies.

Since 1998, Stelzer has been extensively involved in global data synchronization, serving on a number of data synchronization standards committees. He's authored several executive primers on the topic. He writes a monthly data synchronization column for Frontline Solutions. His article on "An Executive's Eye View Of Global Data Synchronization" was published as the cover article for Business Integration Journal. He's a Certified UCCnet Implementation Consultant. He has created and conducts a full-day course on "How To Implement Global Data Synchronization". To date, he's conducted dozens of Webcasts and delivered more than 100 presentations on the topic.

Stelzer is also widely recognized as an expert on supply chain integration and collaboration in the retail sector—having worked in that area since 1984. He is widely interviewed on the topic, writes a monthly CIO column for ebizQ's Executive Corner, pens a bi-monthly column for the AHMA Eagle, and contributes ad hoc articles to a variety of other publications.

AIDC Serialisation Work Team Teleconferences

Frequency	Weekly
Day	Thursdays
Time	08:30 – 09:30 EST 14:30 – 15:30 CET Please check you local time!

Phone Numbers

US	877-864-7187
International	+1-720-348-8446
Pass Code	*1527657*

Objective Serialisation Work Team

Serialisation: (definition to be added later)

Serial Number:

1) A code, numeric or alphanumeric, assigned to an individual instance of an entity for its lifetime. Example: Product model AC-2 with serial number 1234568 and product model AC-2 with serial number 1234569. A unique individual item may be identified with the combined Global Trade Item Number (GTIN) and serial number.

(2) Specific instance of the Object Class being tagged.

Objective Serialisation Work Team

To determine the global healthcare industries size and structural requirements for specific data elements (e.g., lot numbers, serial numbers) to support patient safety and product authentication for regulated products.

Objective Serialisation Work Team

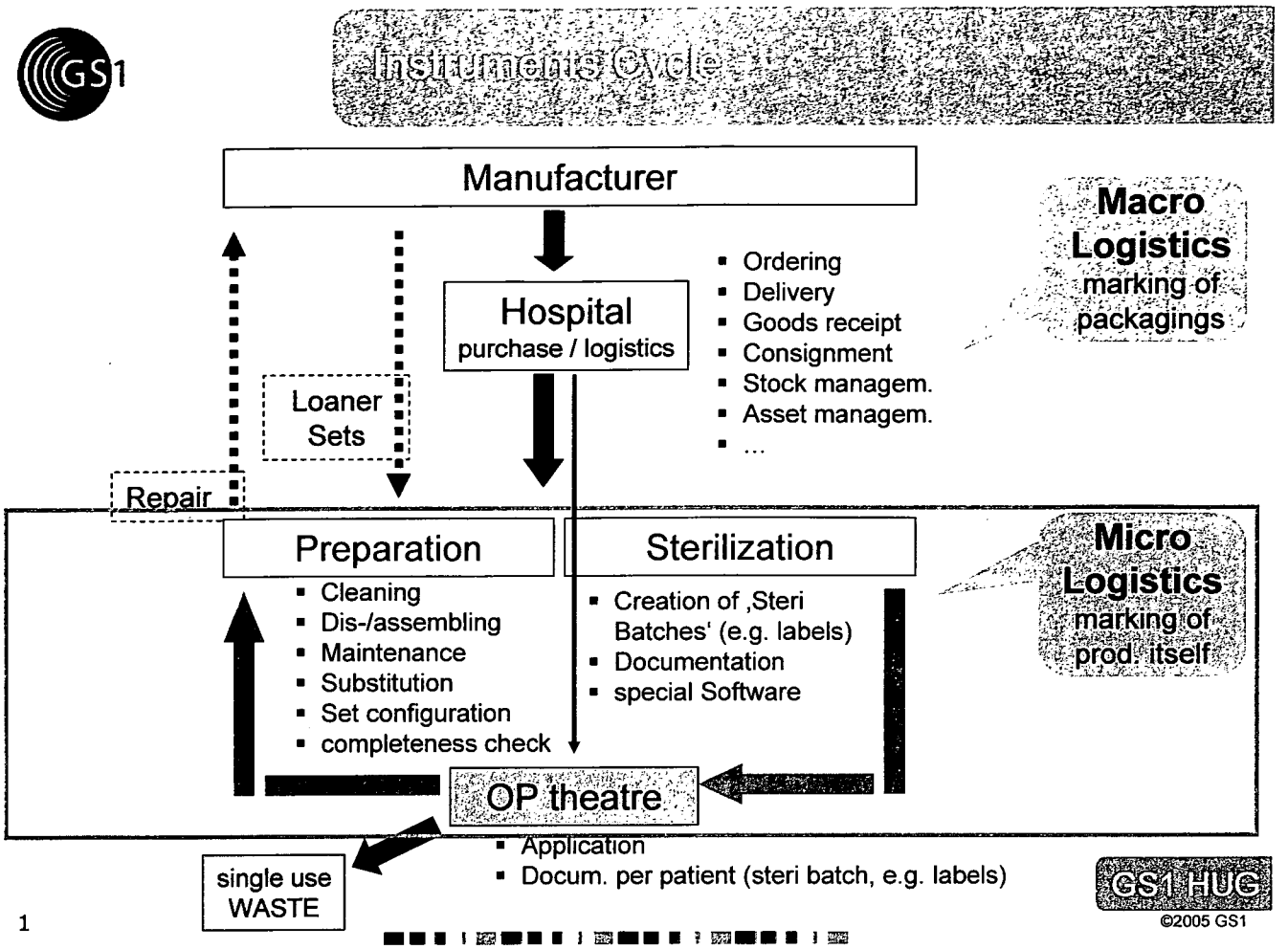
Vaccines
Biologics
Therapeutic nutritional products
Pharmaceuticals
Medical Devices
Instruments
Implants

(GS1 HUG™ categories of products)

Scope Serialisation Work Team's Scope

The Serialisation WT will review and document business and regulatory requirements for serialisation by:

- Size (capacity needed)
  - All Healthcare
  - By product
  - By product (GTIN)
  - By lot
  - By serial number
- Meaningful numbers versus randomization & affect on capacity
- Decentralization/centralization of allocation & affect on capacity
- Structure
  - Numeric length
  - Alpha-numeric length


Instruments Cycle
Manufacturer
Macro Logistics marking of packagings
Hospital purchase / logistics
Ordering
Delivery
Goods receipt
Consignment
Stock managem.
Asset managem.
...
Loaner Sets
Repair
Preparation
Cleaning
Dis-/assembling
Maintenance
Substitution
Set configuration
completeness check
Sterilization
Creation of ‚Steri Batches' (e.g. labels)
Documentation
special Software
Micro Logistics marking of prod. itself
OP theatre
Application
Docum. per patient (steri batch, e.g. labels)
single use WASTE
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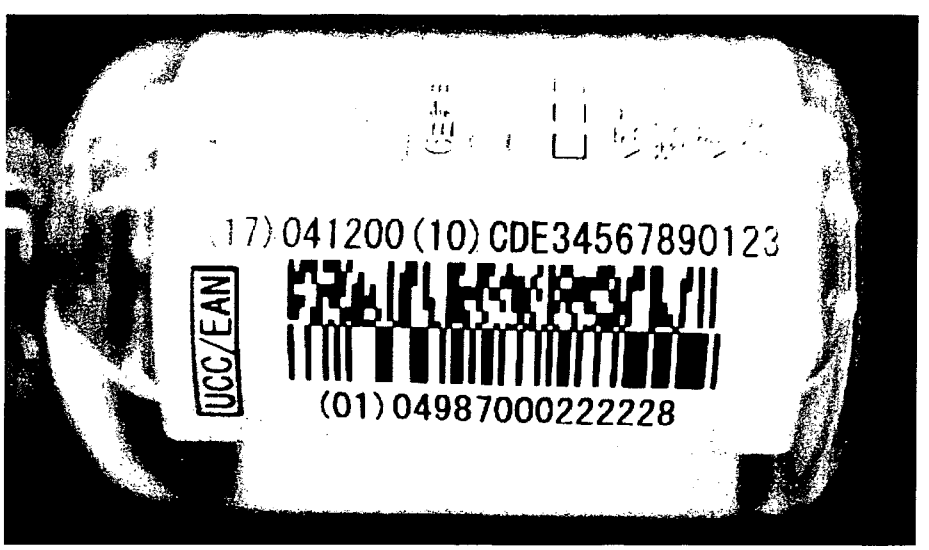
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UCC/EAN
(01) 04987000222228

GS1 Antitrust Caution

Many of the user companies of the GS1 System compete with each other. The competition is both horizontal and vertical. This means that every activity of GS1 must be measured against the prevailing anti-trust laws, which proscribe combinations and conspiracies in restraint of trade, monopolies and attempts to monopolize, and unfair or deceptive acts or practices. These are very broad. Violations of the anti-trust laws can result in injunctions, treble damage judgments, heavy fines, and even imprisonment.

Strict compliance with the anti-trust laws is and always has been the policy of the GS1. GS1 exercises extreme care to avoid not only violation, but anything that might raise even a suspicion of possible violation.

An action, seemingly innocent when taken by itself, may be viewed by anti-trust enforcers as part of a pattern of activity which constitutes an anti-trust violation. Therefore, participants on GS1 committees, task forces, work groups, task groups, or other similar bodies, must always remember the purpose of the committee, task force, or work group is to enhance the ability of all industry members to compete more efficiently and effectively to provide better value to the consumer or end user. However, because GS1 activity almost always involves the cooperation of competitors, great care must be taken to assure compliance with the anti-trust laws.

This means:

- Participation must be voluntary, and failure to participate shall not be used to penalize any company.
- There shall be no discussion of prices, allocation of customers or products, boycotts, refusals to deal, or market share.
- If any participant believes the group is drifting toward impermissible discussion, the topic shall be tabled until the opinion of counsel can be obtained.
- Meetings shall be governed by an agenda prepared in advance, and recorded by minutes prepared promptly after the meeting. Agendas, where appropriate, and minutes are to be reviewed by counsel before they are circulated.
- Tests or data collection shall be governed by protocols developed in consultation with and monitored by counsel.
- The recommendations coming out of a GS1 committee, task force, work group or task group are just that. Individual companies remain free to make independent, competitive decisions.
- Any standards developed must be voluntary standards.

GS1 and Healthcare

January 17 & 18, 2006
Vanderbilt Plaza - Nashville

The global language of business

www.gs1.org

AGENDA

- Integration Meeting HUG and HLS
- Global Healthcare Initiative
  - Governance
  - Roadmaps
  - Communication
- Next Steps

Meeting with HUG & HLS leadership teams December 6, 2006 - Pfizer NY

Participants

HLS
- Ron Bone - McKesson
- Mike Rose - J&J Corporate
- John Howells - HDMA
- Tom Pizzuto - Wyeth
- Ted Ng - McKesson
- Tim Marsh - Pfizer

Global Office Staff
- Chris Adcock
- Michel van der Heijden
- Gay Whitney
- Chuck Schramek
- Bob Celeste
- Ulrike Kreysa

HUG
- Rich Hollander - Pfizer
- Volker Zeinar - B.Braun
- Ed Dzwill - J&J Pharma
- Tom Werthwine - J&J Med Device
- Jackie Elkin - Medtronic
- Peter Tomicki - Baxter
- Steve Hess - Merck
- Mark Walchak - Pfizer

GS1 US Staff
- Mike Meranda
- Dennis Harrison

Consultant
- George Simeon

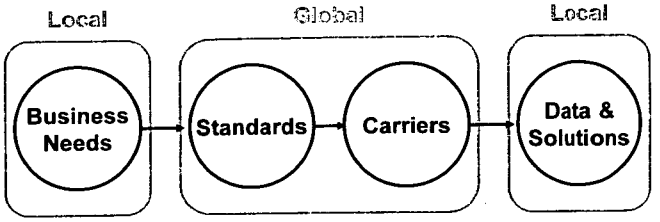
Reminder of the GS1 vision

GS1 is now a single global organization with offices in over 100 countries.

At GS1, we see one vision, speak with one voice, act as one organisation.

Our strength is our single face to the outside world.

What we need



Users, service providers & regulators are asking for...

- **One** global strategy for healthcare
- **One** point of contact
- **Coordination** across all GS1 activities
- **Unified** activities in standards development

Our thoughts today...

- HUG and HLS have overlapping memberships
- User resources are stretched
- ONE approach and strategy is needed when talking to regulatory bodies
- The more users are behind the standards, the better and quicker will implementation take place
- With one group, interactions between groups and alignment work is not necessary
- Solutions which reflect and consider all possible GS1 standards will be better and stronger
- This reflects the structure of GS1

Alone we are strong – together we are stronger!

One global healthcare standard

One roadmap

One organisation

Key thoughts on integration

Successful collaboration is required

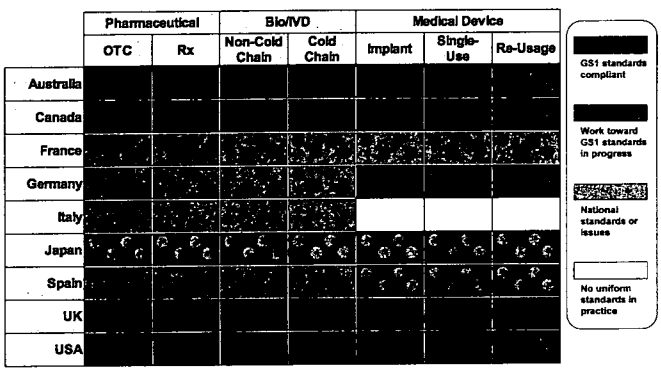
- Learn from the experiences of HUG & HLS
  - ✓ what did each do right?
  - ✓ what were the key skills?
  - ✓ where were there inefficiencies?
- What are potential enablers?
- What are potential barriers

Strategy

1. Develop and propose user-led global standards that proactively meet the demands of regulators.
2. Integrate the full range of healthcare stakeholders into our steering committee, advisory and working groups. Specifically develop communication tools to interest healthcare providers.
3. Consider the full healthcare sector when developing standards in order to maximize global interoperability.
4. Involve Solution Providers early on in the appropriate technical, implementation and technology search, working and advisory groups.
5. Ensure that healthcare standards are interoperable with other GS1 business group standards and requirements as far as possible.
6. Proactively propose solutions to meet evolving regulatory and legislative needs as well as actions which enhance patient safety and supply chain efficiency.

Global Healthcare Initiative

- Initial focus on Top 9 Countries:
  - ✓ USA, Japan, Germany, UK, France, Italy, Spain, Canada, Australia
  - ✓ They represent the major markets in terms of spending on healthcare world-wide
  - ✓ They are often leaders in the implementation of new healthcare initiatives
- Does not mean that we will not continue to include the needs and engage the industry in all GS1 Countries
- GS1 Member Organisations (MOs) will
  - ✓ utilize their contacts with all healthcare stakeholders
  - ✓ act as forums for building consensus
  - ✓ be drivers of consistent and interoperable standards implementation



Global Healthcare Initiative

Healthcare is a unique sector in terms of complexity of products, service providers, regulation, legislation, and variance across nations.

Products

- Pharmaceuticals: Rx, OTC
- Medical Device: Implant, Re-usable, Single-use
- Bio/IVD: Cold-Chain, Non Cold-Chain

Scope of Principal Stakeholders

- Manufacturers: Global
- Distribution/Wholesale: National/Regional
- Service Providers: National/Regional
- Regulators: Local (USA)/National/Regional(EU); some have global view

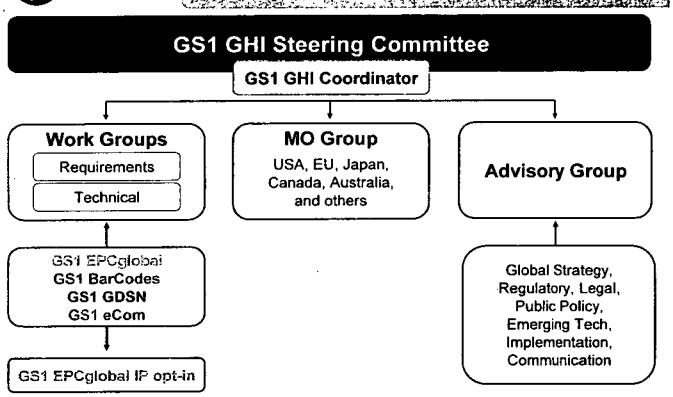
Global **Healthcare** Initiative

Implications
- Specific healthcare sectors may need individualized solutions (e.g. implants)
- Variable speed of adoption of carriers and solutions across medical sectors and countries
- Solutions may be locally adapted to local supply chain particularities and legislation (i.e. privacy)
- National drivers behind standards adoption are different:
  - ✓ USA: Counterfeit Pharmaceuticals -> e-Pedigree
  - ✓ Spain & Italy: Traceability
  - ✓ UK: Patient Safety
  - ✓ France & Australia: e-Commerce and Supply Chain Efficiency

Stakeholder Approach
- Understand the needs and requirements of different groups
- Focused communication and invitations to participate
- Distinguish between global language issues and local implementation issues

Global Healthcare **Initiative**

Only Global Standards can ensure that the healthcare supply chain evolves in an interoperable manner.
- Users will only be asked for requirements once
- The number of working groups will be reduced
- Development will be done in a harmonized manner
- There will be one pace and one direction



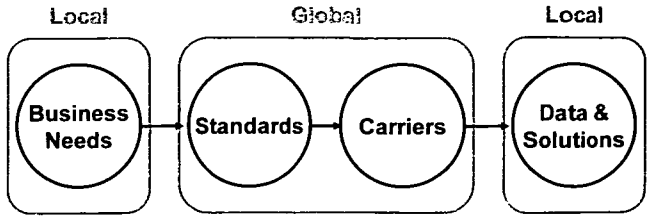
The GS1 Global Health Initiative Steering Committee

Will provide legitimacy, direction, speed and ability to commit for all actors in our major countries
- Strategic, not operational
- Makes decisions from a selection of options
- Validates and assigns resources to projects
- Sets priorities when resources are scarce

The GS1 Global Health Initiative Steering Committee

Should be composed of users whose corporate business strategy include standards designed to increase patient safety and increase the efficiency of the supply chain.

- Members (Voting and Non-Voting)
- Regulatory
- Hospital
- Sectors
- National insurance/healthcare (i.E. VA or national system)
- Distributors/wholesale
- Retail pharmacy
- GPO



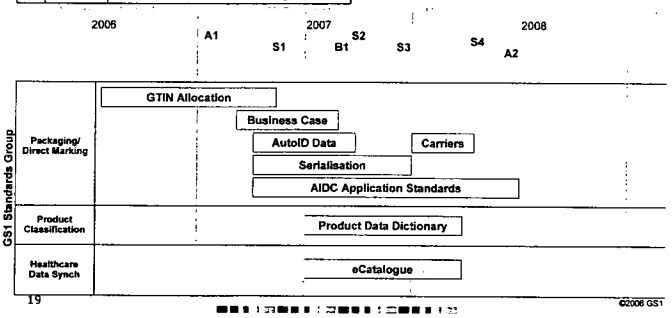
HUG Standards Development Strategy

Version 1.1
13 Nov 06

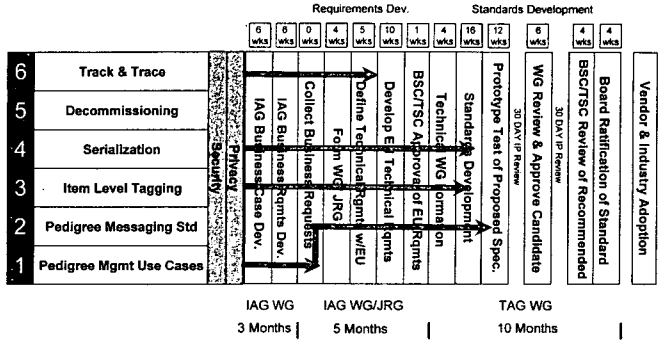
Milestones

A1	26 Jul 06	Adopt existing GS1 Application Standards in Healthcare
A2	31 Dec 07	GSMP: Prioritised AIDC Application Standards
S1	31 Oct 06	GSMP: GTIN Allocation Rules for Healthcare
S2	31 Mar 07	GSMP: Healthcare Business Data AutoID Standard
S3	30 Jun 07	GSMP: Healthcare Product Serialisation Standard
S4	30 Sep 07	GSMP: Healthcare Data Carrier/Scanning Standard

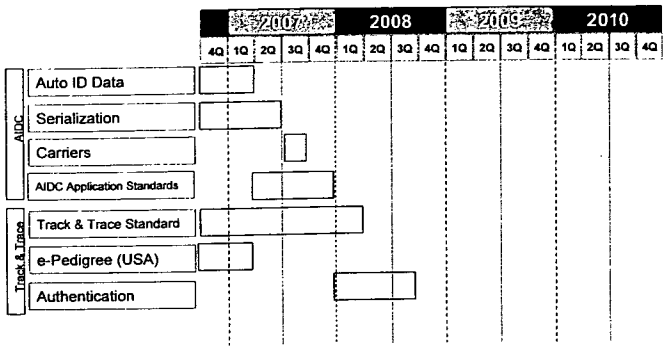
B1	28 Feb 07	HUG Business Case for Packaging/Marking AIDC



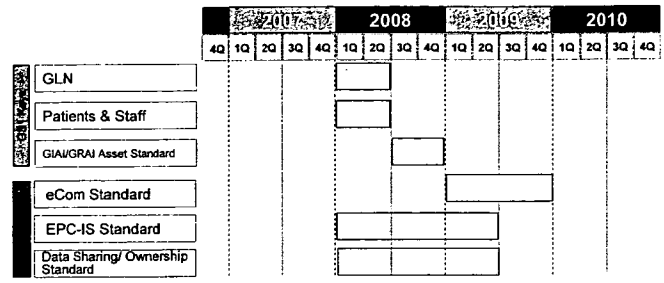
HLS Standards Roadmap As of October 2006



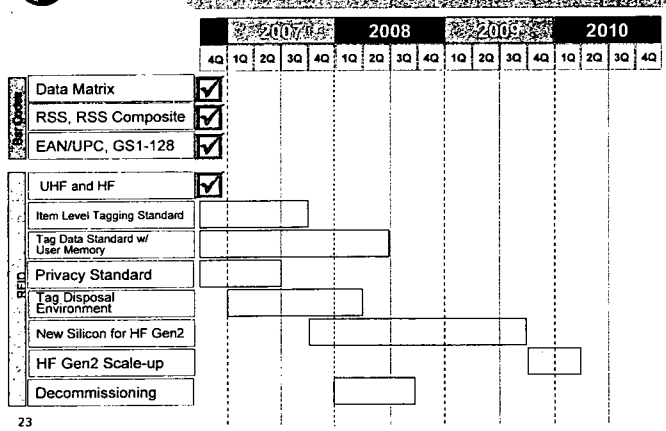
Roadmap Standards



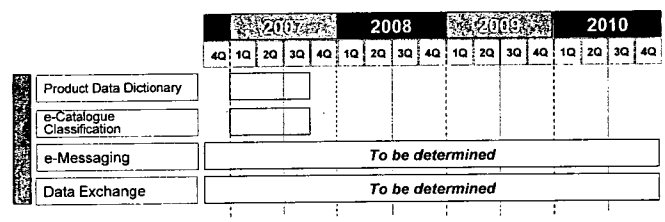
Roadmap Standards



Roadmap Carriers

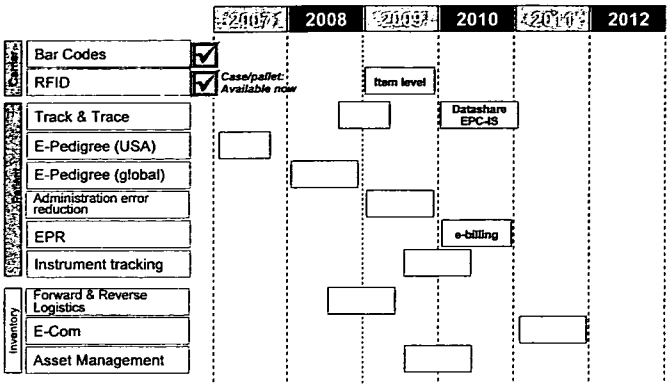


Roadmap Data



Medical catalogue and a GDSN extension in healthcare is an urgent issue for the healthcare industry. To prevent diversion GS1 has to start the work on this topic and to develop a strategy for it.

Roadmap Solutions



Serialisation as an example of collaboration and coordination

Serialisation

Initial discussion: How to address some current and potential U.S. regulations at the state and federal level about controlled substances and electronic pedigree.

Evolved to defining a way to **serialise pharmaceuticals** at **pallet, case and packaging and item level.**

Focus then moved to global work, covering all healthcare themes.

HUG HLS Integration

HLS + HUG

Our joint work on serialisation is just one example of how joining forces makes us stronger…

Communication objectives / goals

- Inform GS1 stakeholders of the amalgamation of the three existing healthcare task forces into the 'Global Healthcare Initiative'
- Position the GHI as a positive step to making GS1 the *de facto* global standard in healthcare
- Inform the internal audience (GS1 members and subscribers) why GHI has been created and what it means
- Inform the external audience (the wider healthcare industry) that GHI is relevant to them, and is a 'step forward'
- Capitalize on this news to further increase awareness of the GS1 brand and sub-brands and understanding of their potential contributions to the Healthcare sector
- Attract new participants from the Healthcare sector to the GS1 standards development process

Next Steps

Action Items and Conclusions

- **Actions**
  - Agreement to develop one common Roadmap for Healthcare
  - Agreement to review the Governance
  - Agreement that broad Communication is a Key Success Factor
- **Conclusions**
  - Goals and Objectives of HUG and HLS are different. We reached a better understanding where they converge, but also where convergence is not meaningful.
  - GS1 will need to get better grip on a joint face to the user. We made good progress, but there is ample room for improvement.
  - By working together, in joint teams, we will learn how to act as one organization

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: June 8, 2006

TO: Randall Lutter, Ph.D.
Associate Commissioner for Policy and Planning

Margaret Glavin
Associate Commissioner for Regulatory Affairs

FROM: Andrew vonEschenbach, MD
Acting Commissioner of Food and Drugs

Thank you for submitting to me the Counterfeit Drug Task Force Report – 2006 Update. I strongly concur that increasing the safety and security of the nation's drug supply and protecting it from the increasing sophisticated threat of counterfeit drugs is critically important. I commend you and the rest of the Counterfeit Drug Task Force on your efforts in developing this report and its recommendations to further this goal. I appreciate the fact-finding efforts that the Task Force undertook, such as holding the February 2006 public workshop and soliciting public comment, to understand the issues and provide me with informed recommendations.

I endorse the report and its recommendations. This includes the recommendation not to further extend the stay and to issue a compliance policy guide (CPG) that discusses FDA's enforcement focus regarding pedigree requirements. Please move forward with these recommendations, pursuant to FDA's good guidance practice (GGP) process (21 CFR § 10.115), as appropriate.

Andrew C. von Eschenbach, M.D.

FDA COUNTERFEIT DRUG TASK FORCE REPORT: 2006 UPDATE

I. INTRODUCTION

This report is based on the work of the Food and Drug Administration's (FDA or Agency) Counterfeit Drug Task Force.[1] It is the third report issued by the Agency since 2004 to address FDA's and the private sector's response to the emerging threat of counterfeit drugs entering the U.S. drug supply. This report contains recommendations to FDA's Acting Commissioner regarding actions that the public and private sector can take to further speed the adoption of electronic track and trace technology and for the use of pedigrees in general, to increase the safety and security of the U.S. drug supply.

After discussing the background and public comment on the issues addressed in this report, we discuss our recommendations or conclusions regarding:

- The expiration of the stay of 21 CFR §§ 203.3(u) and 203.50;
- The extent to which electronic track and trace technology is being used across the supply chain for electronic pedigrees and the use of radio-frequency identification (RFID) for drug products in the drug supply chain; and
- Technical issues related to the implementation of electronic track and trace technology, such as mass serialization, universal and uniform pedigrees, data management, and privacy issues.

II. BACKGROUND

A. The Counterfeit Problem

Counterfeit prescription drugs are illegal, generally unsafe, and pose a serious threat to the public health. Many are visually indistinguishable from authentic drugs. As we stated in our first Counterfeit Drug Task Force report in 2004 (2004 Report),[2] we believe that counterfeiting is quite rare within the U.S. drug distribution system because of the extensive scheme of federal and state regulatory oversight and the steps taken by drug manufacturers, distributors, and pharmacies, to prevent counterfeit drugs from entering the system. However, we are concerned that the U.S. drug supply is increasingly vulnerable to a variety of increasingly sophisticated threats. We have witnessed an increase in counterfeiting activities and a more sophisticated ability to introduce finished dosage form counterfeits into legitimate drug distribution channels over the years.

B. The 2004 Counterfeit Drug Task Force Report & 2005 Update

In 2004, the Task Force issued a report outlining a framework for public and private sector actions that could further protect Americans from counterfeit drugs, including implementation of new track and trace technologies to meet and surpass goals of the Prescription Drug Marketing Act (PDMA).[3] This framework called for a multi-layer approach to address the problem and included the following measures:

- Secure the ***product and packaging***
- Secure the ***movement of drugs*** through the supply chain
- Secure ***business transactions***
- Ensure appropriate ***regulatory oversight and enforcement***
- Increase ***penalties***
- Heighten ***vigilance and awareness***
- International ***cooperation***

In order to implement these measures, the Task Force Report stated, among other things, that:

- Widespread use of electronic track and trace technology would help secure the integrity of the drug supply chain by providing an accurate drug "pedigree," which is a record of the chain of custody of the product as it moves through the supply chain from manufacturer to pharmacy;
- RFID is a promising technology as a means to achieve electronic pedigree (e-pedigree);
- Widespread adoption and use of electronic track and trace technology would be feasible by 2007; and
- The effective date of certain regulations related to the implementation of the PDMA should be delayed until December 1, 2006 in order to give stakeholders in the drug supply chain time to focus on implementing widespread use of e-pedigree.

In 2005, the Task Force issued an annual update report (2005 Report)[4]. The 2005 Report assessed FDA's and industry's progress toward implementing the 2004 recommendations. In the 2005 Report, the Task Force found, among other things, that:

- Stakeholders had made significant progress in developing and implementing RFID during the previous year;
- FDA was encouraged by the progress stakeholders, standard-setting bodies, and software and hardware companies had made toward implementing an e-pedigree for drug products and that we were optimistic that progress would continue in an expeditious manner toward meeting FDA's 2007 goal of widespread use of e-pedigree across the drug supply chain;

was submitted to Congress in June 2001 (2001 PDMA Report to Congress), concluded that we could address some of the concerns raised by the secondary wholesale industry through regulatory changes, but that some of the changes requested by the secondary wholesale industry would require statutory change.[8] Since submitting the report to Congress, FDA has continued to delay the effective date of these provisions.

In February 2004,[9] FDA again delayed the effective date of the particular provisions until December 1, 2006, because we were informed by stakeholders in the U.S. drug supply chain that industry would adopt electronic track and trace technology by 2007. When widely adopted, this technology could create a de facto e-pedigree that would document the movement of the drug from the place of manufacture through the U.S. drug supply chain to the final dispenser. If properly implemented, e-pedigree could meet the statutory requirements in section 503(e) of the Act.

In our 2006 fact-finding effort, we sought comment on whether to continue the delayed effective date, let the regulations go into effect, amend the 1999 final rule, or take other steps.

What We Heard

Most of the comments[10] to our February 2006 notice advised FDA to implement the regulations and let the stay expire. Some said the regulations should be implemented as currently written, without amendment. Others suggested amending the final rule to either 1) exempt the passing of pedigree along primary supply chain routes or the "normal chain of distribution," or 2) phase-in implementation, starting with requiring pedigrees for those drugs that are susceptible to counterfeiting and diversion, or 3) require a pedigree for "one forward-one back" in the distribution chain (as opposed to a pedigree that documents all prior sales transactions back to the manufacturer). A couple of comments suggested that we extend the stay in order to give industry more time to continue moving toward adoption of electronic track and trace technology and e-pedigree. A few wanted the stay to be extended in order to give time to amend the regulations. The amount of time requested for extending the stay varied from 5 years to indefinitely. We also received one citizen petition from a secondary wholesalers' trade association requesting that the stay be extended.

Some comments suggested that FDA work with Congress to eliminate the provision exempting the authorized distributor of record from having to pass a pedigree. They claimed that it was too confusing to recognize when a pedigree should or should not be passed.

Several comments asserted that implementation of the PDMA regulations would speed the development of new, less expensive ways to provide pedigree.

Discussion

We carefully considered several options and recommend that FDA no longer delay the effective date of §§203.3(u) and 203.50 past December 1, 2006. Regulations defining "ongoing relationship" and "authorized distributor of record" are scheduled to go into effect thereafter. In our 2006 fact-finding efforts, we gave stakeholders and the public ample opportunity to provide their input, but we did not hear the same arguments that we heard on previous occasions regarding why we should further extend the stay. Rather, this time, an overwhelming majority of the comments favored allowing the stay to expire.

The PDMA was signed into law in 1988. We believe that FDA can no longer justify delaying implementation of these regulations. In its 2001 PDMA Report to Congress, FDA shared the concerns that were raised regarding implementation of the regulations. By recommending implementation of the stayed provisions, we are supporting the law that Congress passed and has since retained. Furthermore, our extensive experience with counterfeit and diversion drug cases reveals that the secondary wholesale market is where much of the illegal activity occurs. Allowing the stay to expire will provide clarity in the drug supply chain regarding who is and is not an ADR, requiring those secondary wholesalers who may be involved in illegal activity to provide pedigrees. Continuing the stay would perpetuate the current confusion and further allow opportunities for counterfeit and diversionary practices to flourish.

We do not intend to put secondary wholesalers out of business. We continue to be sensitive to the concerns that they raised several years ago, even though we did not hear these concerns during our current fact-finding effort. Therefore, as explained below, we recommend that FDA take an enforcement approach that focuses on products most susceptible to counterfeiting and diversion, which should relieve some of the burden that secondary wholesalers might confront when these regulations go into effect.

Most of the comments we received in this fact-finding effort recommended that the regulations be implemented as is, while others advocated a phased-in approach, whereby the regulations would apply to a limited number of drugs at first. We agree that the regulations should be implemented as is. Many of the recommended changes to the pedigree requirements would require a change in the law. We believe that the regulations as currently written appropriately interpret and implement the PDMA, as Congress intended.

Although the regulations do not provide for a phased-in approach, we propose that FDA publish a Compliance Policy Guidance (CPG) before the stay expires that will contain a list of factors for FDA field personnel to consider in focusing their efforts when carrying out their duties in enforcing the law. We propose that these factors reflect a risk-based approach in which FDA uses its limited resources to focus on drug products that are most vulnerable to counterfeiting