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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
ENFORCEMENT COMMITTEE AND
WORK GROUP ON E-PEDIGREE MEETING
MINUTES**

DATE: March 11, 2009

LOCATION: Holiday Inn – San Diego Bayside
4875 North Harbor Drive
San Diego, CA 92106

**BOARD MEMBERS
PRESENT:** Robert Swart, PharmD, Committee Chair
Stanley C. Weisser, RPh
James Burgard, Public Member

STAFF PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Joshua Room, Deputy Attorney General
Kristy Schieldge, DCA Senior Staff Counsel
Tessa Fraga, Analyst

Call to Order

Chairperson Rob Swart called the meeting to order at 9:31 a.m.

The meeting began with a brief video created by Pfizer, Inc. which reveals the dangers of buying counterfeit medication online.

Dr. Swart provided background on e-pedigree. The 2008 legislative session ended September 30, which is the date when the Governor signed SB 1307(Ridley-Thomas). This law now staggers implementation of e-pedigree requirements in California away from 2011 to:

- 50 percent of a manufacturer's products by 2015
- The remaining 50 percent of the manufacturer's products by 2016
- Wholesalers and repackagers must accept and pass e-pedigrees by July 1, 2016
- Pharmacies and pharmacy distribution centers must accept e-pedigrees by July 1, 2017

Dr. Swart noted that there is preemption language that would repeal California's provisions if federal law regarding e-pedigrees is enacted, or if federal standards are enacted, they would take effect in California. He also noted that there are provisions that define drop shipments, 3PLs, repackagers and manufacturers. Grandfathering provisions for drugs already in the supply chain are included.

Dr. Swart stated that the board will ultimately have to develop regulations for various components, including inference. No action on these regulations is planned for several years.

A. Workgroup on E-Pedigree

1. Discussion of Proposed Comments for the Food and Drug Administration's (FDA) "Proposed Guidance for Industry on Standards for Securing the Drug Supply Chain -- Standardized Numerical Identification of Prescription Drug Packages"

Dr. Swart stated that the Enforcement Committee will now have an opportunity to discuss the FDA's request for comments on "Draft Guidance for Industry on Standards for Securing the Drug Supply Chain -- Standardized Numerical Identification for Prescription Drug Packages".

Dr. Swart explained that the FDA's document is fairly broad, but that the content is very similar to comments provided by California in regard to the e-pedigree standards. He stated that the FDA is now requesting additional comments specifically focused on the standardization of numerical identification of prescription drug packages. He noted that the comments are due to the FDA by April 16, 2009 and encouraged all in attendance to submit written comments.

Dr. Swart explained that, under 2007 federal law Federal Food and Drug Administration Amendments Act of 2007 (FDAAA), the FDA was charged with developing a standardized numerical identifier to be applied to a prescription drug at the point of manufacturing "sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug." He noted that this would be the serialized identifier referenced in California's e-pedigree law.

Dr. Swart provided his opinion that labeling should be required on all packaging down to the smallest unit and that this is more crucial than the visual appeal of the label.

Dr. Swart reiterated that, at today's meeting, the workgroup on e-pedigree will have the opportunity to discuss this request for comments and determine whether the board should submit comments in support of the FDA's identification of this identifier. Also, since the FDA will be attending this meeting, the Workgroup on e-pedigree will be able to ask questions of the FDA regarding this process

Public Comments:

The committee generally discussed serialization issues. There was some concern regarding the eight-digit serialization number that would be the random portion of the unique identifier, and whether that is a sufficient number size to allow for lack of duplication and reuse over a period of time. The committee agreed that an alpha-numeric identifier for the 8-digit random number would be a better standard.

The committee expressed support for the FDA moving ahead with this standard, nearly one year early.

2. Discussion of Comments for FDA's Proposed Guidance for Industry on Unique Device Identification (UDI) Systems

Dr. Swart stated that, on February 12, 2009, the FDA convened a hearing on "Unique Device Identification System." The hearing was convened to enable the FDA to eventually "promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary [of Health and Human Services] requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number."

Dr. Swart noted that, while California's e-pedigree requirements exclude dangerous devices, the board still regulates the distribution of dangerous devices within, throughout and into California. He also noted that the issue is being provided for the committee as information and for discussion.

Ms. Herold stated that the FDA will initiate a comment period within the next six months. She also noted that this will affect the Board of Pharmacy and its licensees as they regulate those that sell, ship and store dangerous devices within the state of California.

Public Comments:

Ron Bone (McKesson Corp.) shared that the meeting held in Maryland, hosted by the FDA, was well attended by those within the supply chain. He noted that there were four panels discussing the issues and that submissions were provided following the meeting. The meeting promoted significant focus for UDI systems.

Mr. Room asked Mr. Bone whether he views the UDI requirements as a similar undertaking to e-pedigree.

Mr. Bone responded that, with UDI, the process is much more complicated and has many issues to address. The identification criteria will vary based on product. He also

noted that there had been discussion on the issue of risk-based products with relation to priority of recalls, etc.

3. Discussion and Updates to Implement Electronic Pedigree Requirements – Presentations

a. Ilisa Bernstein – Food and Drug Administration (FDA)

Dr. Bernstein provided an overview of the Guidance for Industry. She explained that 505D of the FDA Standards Development Act gives the FDA authority to develop standards for identification, validation, authentication, and tracking and tracing. She noted that the FDA is working to have standards finalized for serialization identification prior to the March 2010 deadline. Thus, the January 2009 draft was issued with opportunity for comments from the industry.

Dr. Bernstein reviewed the proposed Standardized Numerical Identifier (SNI), which would essentially result in a Serialized National Drug Code (NDC) as it is a combination of each product's NDC and a unique eight-digit serial number. She identified specific characteristics of the serialized NDC which were modified based on comments provided by industry.

Dr. Bernstein stated that the draft Guidance was announced in the Federal Register. She provided specific questions submitted by the FDA along with the draft which they are requesting comment on by industry.

Dr. Bernstein provided information for web site links to the draft Guidance Federal Register Notice and instructions for filing comments, which are due by April 16, 2009.

Questions from the Board:

Dr. Swart questioned the decision of excluding the lot number from the SNI. He stated concern about how that will effect patient safety in relation to e-pedigree and recall notification.

Dr. Bernstein responded that the SNI will link to a data base which will provide the expiration date, lot number, etc. She added that the information Dr. Swart is referring to would be a standard of track and trace.

Stan Weisser questioned whether it is feasible at this point in the decision process to reconsider the eight- digit number.

Dr. Bernstein responded that comments will be considered and changes will be made as necessary to the final draft. She added that nothing is final at this point.

Mr. Weisser questioned the FDA's decision not to address the case and pallet identifiers issue.

Dr. Bernstein responded that the law requires an SNI for pallets. She added that the FDA feels there should be an SNI for cases as well. However, more information is needed before they would be able to provide a recommendation in the future. Therefore, they are seeking comments from industry and are hoping to receive the necessary information.

Mr. Weisser mentioned that it was included in the comments submitted by the Board of Pharmacy.

Dr. Bernstein responded that they did receive some comments and information, but that it was not substantial enough to be able to provide an educated recommendation.

Ms. Herold explained that the board requested in their comments in 2008 that the NDC be part of a serialized number on the individual unit. She noted that the FDA appears to be including that in their Guidance. She stated that the ability to link the serialized number to a particular case or pallet is necessary for the wholesalers.

Mr. Room explained that the board requested that the serialization be included at the unit level, as that is the most crucial. There has been an assumption that, in order for the serialization system to be effective and workable, serialization would need to occur at the case and pallet level as well. He added that the board can choose to reaffirm by submitting additional comments in regards to case and pallet level serialization.

Mr. Weisser referenced the board's 2008 comments to the FDA. He quoted a section of the letter which states that the board believes that a full track and trace system would require SNI's on both levels – the individual unit and the case/pallet.

Mr. Room stated that the letter is a reflection of California law. He noted that California law does not state requirements relating specifically to case and pallets.

Ms. Herold added that if inference is allowed in the future, then it may be necessary to address SNI's at all levels within regulations.

Jim Burgard expressed concern regarding the individual serialization involving eight digits. He stated that, as large quantities of items are serialized, the process will become more complex for manufacturers. Mr. Burgard stated that this complexity should be considered.

Dr. Swart stated that it will be necessary for the manufacturers to provide input on what is the optimal amount of digits within the serialization.

Mr. Weisser reiterated that using only eight numerical digits is a limiting factor.

Public Comment:

Mike Durschlag (Allermed Laboratories) commented that the standards are geared towards identifying drugs in the distribution system. He asked Dr. Bernstein if the same standards will apply when a manufacturer distributes directly to a physician.

Dr. Bernstein responded that that issue is outside the scope of the proposed Guidance and standards and would need to be addressed later.

Mr. Bone (McKesson) asked about the opportunity to have the UDI and SNI on the same package. This would be important for kits, where both a drug and a device are present.

Dr. Bernstein stated this has not been resolved. She did note, however, there has been discussion within both SNI and UDI workgroups on the subject and that they recognize the need for compatibility within the supply chain.

Steve Gray (Kaiser Permanente) asked if there is any significance in the pairing of the numbers within the eight digit structure of the SNI. He referenced the Generic Product Indicator (GPI) used on retail products, explaining that the numbers are paired to provide information on the type of product it is. He also asked if the SNI digits could be developed in a way to provide information on where the product originated.

Dr. Bernstein stated that the Guidance indicates the eight digit number is to be created by the manufacturer or repackager of the product. She added that, except for the requirement that the SNI must be unique for each package, the Guidance does not specify how the number is to be generated. She encouraged such suggested comments to be submitted.

Mr. Room identified that there is tension between those in the supply chain who want the number to have specific representation and those who want the number to be random because of the flexibility it provides. He stated that both GS1 and the FDA have indicated that it is by reference to the database to retrieve such identifying information, rather than by reference to the number itself.

Dr. Gray responded that the user is the consumer, and that they would not have access to the database. He added that consumers want to know where the product comes from, especially in relation to whether the drug originated from a manufacturer in another country. He reiterated his suggestion to consider this within the comments provided.

b. Allison Hite - Congressman Buyer's Office

Ms. Hite provided an update on e-pedigree implementation on a federal level. She stated that there is a bit of a standstill with the new chairman of Energy and Commerce. She encouraged any support and influence that any individuals or organizations in California may be able to provide in bringing the issue forward to Chairman Waxman, as the state has a strong representation with regard to e-pedigree of drugs. Ms. Hite stated that legislation at this time is indeterminable as how Chairman Waxman plans to handle food and drug regulation is not known. She indicated that there was a hearing regarding food safety, and foresees two separate bills as a result of that hearing, with food safety being addressed first and drug safety following.

Ms. Hite noted that they have made significant strides and have attempted to mirror California's efforts thus far in terms of the timeline of serializing drugs, as well as a track and trace system. Ms. Hite stated that Chairman Waxman is in support of having any related legislation which occurs at the federal level be influenced by legislation which is put in place in California. She explained that they are seeking assistance from the FDA on their legislation before moving forward.

Ms. Herold noted that, with regard to regulation development, the Congressman's office has been very clear thus far in not wanting to disrupt any efforts by states with respect to addressing serialization and pedigree. She stated that the early version of the bill seemed to directly follow the California model versus what other states have done. She asked if Congressman Buyer is going to continue with that plan of following the California model, or if they are waiting for input from Chairman Waxman.

Ms. Hite responded that the goal is to have one standardized pedigree standard. She stated that they are moving forward with flexibility in the language in order to meet the final goal. She noted that they felt the California timeline is more than adequate for the process.

c. Bob Celeste - GS1

Mr. Celeste provided an update on the standards development and adoption. He reviewed the reason for GS1's involvement in the serialization and global standardization process.

Mr. Celeste stated that, in order to achieve patient safety and healthcare supply chain efficiency, there are "foundational" steps to be addressed. Those steps include Standardized Product Identification (GTIN), Standardized Location Identification (GLN) and Standardized Product Definition (GDSN). Additionally, Mr. Celeste explained that the "pillars," which includes track and trace and e-pedigree, are the benefits which build on those foundational steps.

Mr. Celeste provided definitions for GS1's standards. He stated that the NDC is embedded within the GTIN number and a serial number is included. He explained that

the GTIN is then placed within a Global Data Synchronization network, where the information about that product can be obtained. Mr. Celeste also explained the creation of the Global Location Number and registry.

Mr. Celeste provided an example of how a product is ultimately tracked through the supply chain by use of identifiers. He added that GS1 is looking at the various issues raised by the pharmaceutical industry relating to traceability adoption and the use of identifiers versus carriers.

Mr. Celeste summarized the comments provided by GS1 to the FDA :

- Pallet and case level – GS1 is suggesting that the supply chain be able to use the serialized shipping container number as well as the Global Returnable Asset Identifier (GRAI)
- Blood and blood products serialization – conflicts with serial number standards
- Requested FDA to consider adopting GTIN's so that they can be accepted within their system
- Requested FDA to consider a sunset of duplicate data that is automated

Mr. Celeste noted that application identifiers can be added to bar codes.

Mr. Celeste stated that a number of hospitals and group purchasing organizations have established a deadline of 2010 for the GLN “sunrise.” He added that 2012 is the “sunrise” date for GTIN, which has more impact for medical devices.

Mr. Celeste discussed the issue of bar code quality with relation to the use of a verifier, which reads and depicts the quality of a barcode. He explained that a test card is used to ensure that a readable bar code is produced. He explained that a good quality bar code ensures readability and prevents sending bad bar codes into the supply chain.

Mr. Celeste stated that the current pedigree standards allow for reliable movement and disposition, but also contains redundant product and location data. He indicated that, with the use of current and emerging standards, supply chain partners will have:

- Reliable product descriptions
- Reliable location hierarchy
- Reliable lookup and authentication

Mr. Room questioned whether the intent is for the data to be “pushed down” at each level, creating a static database at some point.

Mr. Celeste responded that China, for example, does not want their data in a US database. Therefore, the standards accommodate multiple Discovery Services.

Mr. Room asked if there would be a loophole for reliability of individual recipient data in that situation.

Mr. Celeste responded that the equivalence between the system and e-pedigree needs to be discussed further.

Mr. Weisser asked how manufacturers can protect their data from regions with more loose systems that allow for the potential of counterfeiting.

Mr. Celeste responded that the negotiations between Discovery Services and authentication procedures, as well as agreements that need to take place are involved and time consuming. He added that there is no guarantee that counterfeiting in another country would not occur, but noted that manufacturers have control over where they store their data. Mr. Celeste added that, currently, only the US is interested in having multiple Discovery Services, so it would only involve domestic pharmaceuticals and medical devices.

Mr. Celeste explained that an inference paper is being written and is currently in draft mode. He explained that the paper will discuss the general uses of inferences, how inference is currently being used, and risk mitigation. Mr. Celeste noted that the paper will take one more month for completion and provided a brief summary of what the inference paper encompasses. He noted that the paper will be finalized within a month to be published.

Mr. Celeste stated that GS1 is currently working on the subject of Radio Frequency Identification (RFID) with relation to providing supply chain security and privacy. They are also reviewing the business benefits of serialization and granular events. Mr. Celeste explained that this refers to the specific benefits to the supply chain, as well as patient safety, once serialization is in place.

Mr. Room asked if Mr. Celeste could provide insight to support why the FDA should adopt the GTIN as the standard for serialization.

Mr. Celeste responded that many countries have already adopted GTIN as the standard. He explained that the adoption to strictly GTIN (rather than native GTIN) would involve a lengthy conversion process. He added that the first step is to register a GTIN. Mr. Celeste referenced the peanut butter recall and how the standards were misused. He added concern over the difficulties in obtaining medication bedside within hospitals.

Mr. Room asked for a projected impact in using the SNI relating to global compatibility and distribution.

Mr. Celeste responded that there are currently explicit difficulties, as the NDC is only accepted within the US.

Public Comments:

Steve Gray (Kaiser Permanente) referenced his earlier comment regarding the consideration by FDA to have the SNI be assigned digits that reflect its origin, for example, rather than being randomly assigned. He pointed out that, unlike other products such as clothes or toys, there is no way for a consumer to identify whether their prescription drugs were manufactured in another country.

Mr. Celeste responded that the GLN would identify where the item was manufactured. He also stated that one of their application identifiers is the country of origin. Therefore, a bar code can provide the information as Dr. Gray is suggesting. He added that it is up to the supply chain to decide what is included within the bar code.

Dr. Gray asked if GS1 sees the multiple Discovery Services referenced as an entity that would need to be licensed by the FDA or government regulated.

Mr. Celeste responded that he is unsure. He stated that discussions are needed to determine what process is necessary in order for Discovery Services to be trusted in terms of legitimacy and security of data.

Dr. Gray asked if proprietary privacy is also being incorporated into the discussions on security and privacy.

Mr. Celeste responded that discussions relating to proprietary privacy within the network are taking place.

d. John Danese - Oracle

Mr. Danese provided a presentation on Oracle's drug supply chain integrity strategy. He noted that a presentation was made by Oracle to the board one year ago immediately prior to the deadline extension. Mr. Danese stated that, at that time, Oracle was not ready for a 2009 deadline, and that the extension to 2011 allowed Oracle and its customers the time needed to be fully prepared with implementation. Mr. Danese also provided a brief background on the company.

Mr. Danese reviewed the main "drivers" of the direction Oracle is taking in their strategy. They are:

- The US States – CA e-pedigree law now 1/1/15 and federal preemption language
- US Federal – FDA Amendments and Globalization Act
- Europe, Middle East and Africa (EMEA) – Countries are developing serialization databases and initiatives independently
- GS1 Healthcare – global traceability standards

Mr. Danese added that their customers are focused on product serialization as it is being addressed in Europe. He stated that Oracle has placed focus on their initial product release in terms of the serialization aspects, and indicated that they have taken a “wait and see” approach to see how the pedigree requirements evolve.

Mr. Danese explained that Oracle has been meeting regularly with a customer focus group in order to collaborate on the design of their product. He stated that, as a result of those meetings, they have been able to identify three main types of responses on what manufacturers are currently doing to prepare for implementation. Those are:

- Forge ahead with serialization efforts and lighten up effort around pedigree
- Refocus on European Union products and serialization
- Wait and see approach – putting projects on hold and doing nothing actively

Mr. Danese also provided specific responses from their customers, both large and smaller pharmaceutical companies, in relation to the current status of e-pedigree and serialization as well as how to address the European markets and their requirements.

Mr. Danese pointed out that the urgency around serialization remains high, based on a survey of their customers. He added that many are continuing with their serialization efforts, which is what drives Oracle’s product development.

Mr. Danese reviewed the business benefits in addition to regulatory compliance, which includes product and channel integrity, regulatory compliance and better management of returns. He noted that returns are a huge cost. He emphasized that serialization allows a link between the return receipt and the original shipment/invoice, thus reducing the opportunity for illegitimate products being returned.

Mr. Danese provided information on a new product, the Oracle Pedigree and Serialization Manager (OPSM), which will be developed to ensure supply chain integrity. He explained that the software application will enable companies to implement mass-serialization of drug products and share serialized product data. Mr. Danese stated that the product will protect public health, achieve compliance with global electronic pedigree and related regulations, protect brand integrity and provide cost savings.

Mr. Danese stated that a partner/consumer serial validation portal will be provided so that manufacturers will get additional views into where their product is consumed while customers will be able to serial authenticity, check for recalls, etc.

Mr. Danese addressed the prior questions from the board and public regarding cases and pallets being serialized and unique identifiers for those levels. He explained that the OPSM will be able to generate the unique identifiers for product packaging at the smaller saleable unit levels (blister packs, boxes and cases). The system will not provide serialization on the pallet and container unit level. Those numbers can, however, be accepted from a warehouse management system and be captured as part of their packaging hierarchy. Mr. Danese noted that the OPSM will allow for cross-

referencing of codes (GTIN, GTIN, UPC) at each unit level, so that multiple identification numbers can be used.

Mr. Room asked if Oracle plans to submit FDA comments on the issue of the serialization number.

Mr. Danese responded that they have provided comments on the standards. He does anticipate that they will provide comments on the unique identifier aspect as well.

e. Other Interested Manufacturers, Wholesalers, Pharmacies and their Associations

No other comments from manufacturers, wholesalers, pharmacies and associations were provided.

Ms. Herold requested that the board provide additional comments to the FDA on this subject. She noted that the comments are due prior to the next board meeting. She suggested that the Enforcement Committee Chair collaborate with the Board President to determine additional comments to the FDA, addressing the issue of the quantity of digits and whether an eight digit format will be sufficient for the needs of the supply chain. She added that she feels comments should also be provided by the board in support of a unique identifier at the case and pallet level, as the board will be required to develop regulations on inference, but that the board should not be specific as to what the unique identifier should look like because they do not have the knowledge to determine that.

Mr. Room added that the board is pleased to see the FDA taking the same approach as required by California law to focus on serialization at the unit level first.

Motion: Dr. Swart and President Schell to collaborate and submit additional comments to the FDA on the board's support of the unique identifier at the case and pallet level as well as a potential format in terms of quantity of digits and alphanumeric layout.

MOTION: SW/JB

SUPPORT: 3

OPPOSE: 0

B. Enforcement Committee

1. Discussion of Policies Involving Home Generated Pharmaceutical Waste Take-Back by Pharmacies

Dr. Swart provided background on drug take-back programs. He explained that last year, SB 966 (Simitian, Chapter 542, Statutes of 2007) directed the California Integrated

Waste Management Board (CIWMB) to develop the parameters for “model” drug take-back programs in pharmacies. These model programs are intended to provide consumers with the ability to dispose of unwanted prescription and over-the-counter drugs (but NOT controlled substances) without flushing them down the toilet or tossing them into the garbage. Under SB 966, these guidelines were to be in place by December 2008.

Dr. Swart explained that state and federal law regulates prescription medicine until it is dispensed to patients. It is not regulated again unless it is collected at consolidated points, at which point it becomes medical waste, and must be handled and destroyed in specific, mandated ways.

Dr. Swart stated that patients are often confounded about what to do with unwanted medicine. Californians increasingly want “green” options for disposing of unwanted medicine, which current law does not allow. He added that there is no viable process, other than to make the discarded drug products unpalatable (mixing with kitty litter or other substance, wrapping in duct tape, etc.) and then placing them in the trash. Dr. Swart noted, however, that some drugs may be flushed down the toilet, and are specifically labeled by the manufacturer to dispose of in this manner.

Dr. Swart indicated that pharmacies have in some cases agreed to take back unwanted drugs from patients. However, this acquisition by pharmacies is not authorized in law. He advised that some communities periodically offer community take-back events, or special days at landfills where the public can take back drugs.

Dr. Swart explained that some drug manufacturers (and the state of Maine, where there is a pilot program underway) provide mailers that patients can use to send unwanted medicine to a predetermined location for destruction. This is the process preferred by the DEA for controlled drugs.

Dr. Swart emphasized the greatest problem for the board with drug take-back programs, which is the potential for these drugs to be diverted to the streets. He stressed that there is a serious prescription drug abuse problem in the US, and the uncontrolled aggregation of prescription medicine is an attractive enticement. In some cases, drugs collected in bins could re-enter the prescription drug supply if pharmacies or wholesalers (or others) sell these items back into the supply chain.

Dr. Swart pointed out that pharmacies are areas where health care is provided. He shared that concern has been expressed that it is difficult for this purpose to be combined with a recycling center, where high sanitation is not necessarily a priority.

Dr. Swart stated that pharmacies have also expressed concern that they may be required to absorb the costs of paying for disposal of these returned drugs, for sorting out controlled drugs (which potentially would require a pharmacist’s time) and for assuring the safety and periodic emptying of collection bins.

- Model Guidelines for Home Generated Pharmaceutical Waste Approved by the California Integrated Waste Management Board (CIWMB)

At the January 2009 and October 2008 Board Meetings, the board discussed concern with the proposed model program guidelines as drafted by the California Integrated Waste Management Board. However, the board did express its support for such programs on a voluntary basis with appropriate, specified safeguards.

Ms. Herold provided the board's concerns with provisions in the draft model program guidelines at a committee meeting of the Integrated Waste Management Board (CIWMB) on November 10. Specifically, Ms. Herold stressed the opinion of the board that the program should be established as voluntary.

Dr. Swart stated that, on November 13, the CIMWB adopted the Model Guidelines without incorporating the additional changes listed in the board's November letter. However, a number of other entities also provided comments to guidelines. For this reason, the CIWMB agreed to consider modifications to the Model Guidelines at its February 2009 meeting.

Ms. Herold again provided written comments and testified to the CIWMB on February 18.

- Senate Bill 26 (Simitian)

Dr. Swart indicated that Senator Simitian has introduced SB 26, which would direct the board to coordinate with other state agencies, local governments, drug manufacturers and pharmacies to develop sustainable efficient policies to manage pharmaceutical waste and the disposal of devices.

- Comments Sought by the Federal Drug Enforcement Administration on Disposal of Controlled Substances by Persons not Registered with the DEA – Docket No. DEA-316A

Underlying what is a national problem about how to deal with unwanted and unused drugs, the Drug Enforcement Administration is currently seeking comments on "Disposal of Controlled Substances by Persons Not Registered with the Drug Enforcement Administration." Dr. Swart advised that comments for this item are due March 23, 2009.

Ms. Herold explained that there is a new Integrated Waste Management Board. She stated that they view take-back drugs as a good thing, and are open to discussions on funding. Ms. Herold indicated that there are two versions of model guidelines available. There is question as to whether the guidelines will be feasible for the board to enforce. SB 26 provides amendments to address those issues.

Dr. Swart noted that the law to date has prohibited the take-back of drugs.

Ms. Herold responded that SB 26 addresses this issue and that provisions have been made.

Dr. Swart encouraged industry comments.

Ms. Herold shared that pharmacists are not to accept controlled drugs that are returned. Instead, only law enforcement can accept these items. The involvement of the DEA in establishing policy in this area is another indicator of the movement underway to provide green methods of disposing of unwanted pharmaceuticals.

Ms. Herold encouraged the board to provide comments to the DEA on this topic.

Dr. Swart suggested that the board provide input to Ms. Herold and board staff, which will in turn provide the comments to the DEA.

Discussion continued regarding drug take-back with respect to accountability and return receptacles.

Public Comments:

Dr. Gray (Kaiser Permanente) stated concern over this issue gaining publicity and leading to confusion and misinformation. He indicated that, aside from general confusion, there are actually two problems with relation to diversion of the unwanted and returned drugs. Not only might the drugs be resold by pharmacies or wholesalers, but they are sometimes also being gifted to non-profit programs, which is prohibited by law. Dr. Gray suggested that efforts be made to coordinate information provided by the DCA Boards. He also suggested that FDA coordinate their responses with those of the California Board of Pharmacy.

Ms. Herold stated that the DEA is moving in the right direction to stop this, but she is concerned about pushing the DEA too much on this topic. Unwanted drugs within long-term hospice care are the biggest concern, which is the DEA's focus.

In response to coordination of the other boards within DCA, Ms. Herold stated that she has been asked to meet with the other boards to discuss take-back and provide updates. She added that the donation of drugs is apparently not an issue.

There was discussion in relation to drug samples, and Ms. Herold stressed that pharmacies are not to take back drug samples.

Motion: Draft comments to the DEA regarding the disposal of controlled drugs by persons not registered with the DEA.

M/S: JB/SW

SUPPORT: 3

OPPOSE: 0

2. Update on Activities to Implement E-Prescribing in California

Dr. Swart explained that a number of patient and health care advocates have strongly pressed the need for increased use of e-prescribing. He stated that a principal reason is that statistics indicate that medication errors cost the health care system \$77 billion and cause 7,000 deaths annually. Dr. Swart stressed that a number of these errors could be prevented by full implementation of e-prescribing. Other savings have been projected from redirected time currently spent by prescribers and pharmacies in verifying and switching prescription orders.

Dr. Swart stated that by the mid-1990s, the board had sponsored legislation and promulgated regulations to ensure that e-prescribing was authorized in California law. Since then, various provisions have been added or amended to keep law supportive of allowing electronic prescriptions. He noted that a current deterrent is that controlled substances cannot be e-prescribed. This has caused additional problems and limited the usefulness of e-prescribing within doctor's offices. Dr. Swart indicated that the DEA provided guidelines in the past on the subject, which only made the process more cumbersome.

Dr. Swart advised that, on November 20, 2008, the Board of Pharmacy hosted an e-prescribing forum in conjunction with the Department of Consumer Affairs' Professionals Achieving Consumer Trust Summit. He noted that the other healing arts boards whose licensees prescribe drugs attended this forum, as did our stakeholders and public interest groups. The Dental Board and Medical Board joined the forum as partners.

Dr. Swart noted that the California HealthCare Foundation (CHCF) is strongly advocating adoption of e-prescribing. They also hosted a November 20 forum in San Francisco on e-prescribing.

Dr. Swart explained that, since then and among other projects, the CHCF has been working with the executive staff of the Medical Board and the Board of Pharmacy to host a series of statewide events where physicians and pharmacists could earn continuing education (CE) credits and simultaneously work through issues limiting adoption of e-prescribing. The CHCF is currently in the discussion phase and hope to have a "road show" they can take throughout California in the next few months.

Ms. Herold added that there is a forum scheduled for Visalia at the end of March. There will be two sessions on that day, with members of the Medical Board and physicians scheduled to attend. Additional forums to allow physicians and pharmacists the

opportunity to discuss and collaborate on the issues limiting the adoption of e-prescribing which will occur throughout the remainder of the year. The board has been asked if it is interested in participating and if so, the board will grant CE to pharmacists who attend these events. The Medical Board has already agreed to do this for their licensees. Ms. Herold will work on arranging for Board of Pharmacy licensees to be able to receive CE for attending the event.

Dr. Swart reiterated his support for providing CE to those who attend.

Additionally Assembly Bill 718 has been introduced to require all prescribers and pharmacies to have the ability to transmit and receive prescriptions by electronic data transmission. Dr. Swart noted that the sponsor of this bill is a technology firm, Reed Elsevier, Inc.

Dr. Swart stated that he was concerned about smaller pharmacies, as well as those located in rural areas, being able to comply with the ability to e-prescribe.

Ms. Herold provided information that the Governor's Healthcare Initiative has the same deadline of January 1, 2012, which will affect every prescriber and every pharmacy and thus will have wide impact.

There was discussion on the language of the legislation and the potential for enforcement discretion by the board and staff, as there is no specific consequence for the inability to e-prescribe.

Dr. Gray (Kaiser Permanente) noted that this is only a preliminary version of the bill and pointed out that it may evolve. He stated that federal law is already in place which establishes the standards and parameters for e-prescribing and transmission through the National Council for Prescription Drug Programs (NCPDP). He added that those may become the standards required in order for an entity to claim that they have the ability to e-prescribe. He also mentioned the incentives and penalties for e-prescribers if they are involved (or not) in federal billing. Dr. Gray added that this law will pertain to all prescribers. He raised the question of who would be the actual enforcement entity. Dr. Gray stated that there may be a requirement for the board to adopt regulations to further define what will be in effect by 2012. Dr. Gray recommended that future action in regards to this bill be discussed at the next Legislation and Regulation Committee meeting.

MOTION: To grant continuing education credit to licensees who participate in the events being held by the California Health Care Foundation throughout California.

M/S: RS/JB

APPROVE: 3 OPPOSE: 0

3. California's Controlled Substance Utilization Review and Evaluation System (CURES), a presentation and question and answer session led by the Department of Justice, Bureau of Narcotics Enforcement

Dr. Swart explained that, in mid-December, the board and California pharmacies were advised that effective January 1, 2009, the California Department of Justice would have a new data collection vendor for CURES, and that all California pharmacies were to submit data to this new vendor beginning January 1, 2009. He pointed out that this was a short transition, and the board has learned that some pharmacies are having transmission issues.

Kathy Ellis (Department of Justice – Bureau of Narcotic Enforcement “CURES” division) provided an overview and explanation of the CURES program, including the use of a vendor who collects the data submitted by pharmacies to create a database used by practitioners. Ms. Ellis discussed the recent change to a new data collection vendor after having the same vendor for the past 10 years. She explained that the State of California required them to go out for bids for a new vendor and that the turnaround time for switching vendors was very short. Ms. Ellis concurred with industry feedback that the transition has not been seamless as expected.

Ms. Ellis provided history on the development of the CURES and the program's database. She noted that, as a lesson learned in the recent transition, a turnaround in contracts is necessary in the future.

a. Implementation Issues Surrounding the New Data Collection Vendor for CURES

Ms. Ellis explained that, after implementation, many errors were noticed in the vendor's program. Specifically, the main issue was that the Department of Justice (DOJ) was receiving data in invalid formats. Additionally, there were errors involving patients' date of birth and gender. Ms. Ellis pointed out that the validation criteria have since been corrected to ensure erroneous input of those statistics will not be accepted.

Ms. Ellis indicated that the vendor has been tracking the complaint calls coming in because of the errors, and provided a log to the DOJ. Additionally, she noted that the vendor is receiving a large amount of faxes for data submissions; some which are numerous pages in length. She referenced pharmacy law regulations which state that if a pharmacist is providing more than twenty-five prescriptions within a six month period, they are to be sent electronically.

Ms. Ellis emphasized that they are working with the vendor to correct the issues. She stated that the DOJ is now receiving more data than they are rejecting, which is significant improvement. She also indicated that a letter will be sent to pharmacists in the near future to detail the implementation issues she has reviewed. Ms. Ellis indicated that the letter will stipulate a grace period to allow software vendors to make modification for the new vendor's format.

b. Moving to Provide Online, Near Real Time Reports to Practitioners on Controlled Substances Dispensed to Patients by July 1, 2009

Ms. Ellis stated that their automation project, which will automate the Patient Activity Report (PAR), will be rolling out in July, 2009. She explained that this will result in allowing authorized practitioners, prescribers and pharmacists to have access to patient activity information via web browser 24 hours a day in “real time.” She noted that the project, which began in 2003, is currently in the test phase.

Ms. Ellis indicated that a notification system will also be rolled out. The alert system will be state wide and will allow for notifications to prescribers, physicians and pharmacists, on a voluntary basis, when there are potential doctor shoppers, theft, forgeries, inappropriate call-ins, etc. in their area

Ms. Ellis reviewed other projects in progress, but explained that the timeline for completion and rollout is unknown as they are dependent on funding and grant money. One such project is the “Direct Dispense”, which will impact practitioners and veterinarians and allow them to enter their data online via web browser rather than sending it manually. Ms. Ellis added that another project in progress involves automation for an on line system for “0 fill” reporting when a pharmacist has no data to report. Ms. Ellis also indicated that integration is being developed to allow providers within hospitals to review patients’ records during an office visit and have instant information on any controlled substances that have been prescribed and dispensed to that patient. She also noted a nationwide prescription drug program that is being developed which will result in a hub for prescribers to be able to share information between states.

Ms. Ellis concluded that by sharing that the automation of the PAR is in final testing stages at this time. Following testing, the DOJ will attempt to pilot the program by finding pharmacists and practitioners who would be willing to run test data prior to the actual rollout. She provided contact information for those who may be willing to assist with the pilot testing of the program.

Questions from the Board:

Dr. Swart asked if the formatting issues currently being seen with the CURES database are primarily preventable when the pharmacists are on the correct format.

Ms. Ellis confirmed, but that the vendor is also responsible for some of the formatting issues as well. She gave examples of relevant formatting issues that have since been addressed with the vendor.

Dr. Swart commented that he is hearing fewer complaints about the system. He clarified that most of the current errors are relating to the format being input by the users.

Ms. Ellis confirmed and noted that some pharmacists are providing data in the format as required by the 2005 ASAP format of the prior program. She added that the validation process has been “relaxed” as she has discussed the requirements in length with the vendor.

Mr. Weisser asked if there has been disruption in patients getting their medications

Ms. Ellis responded that there has not.

Ms. Herold referenced the reports provided by Ms. Ellis which list the formatting issues and database errors that were identified. She asked specifically about the errors relating to an invalid pharmacy identifier and asked whether those incidents would lead to lost data.

Ms. Ellis responded that they were losing the data initially, but that it was corrected within a couple of weeks.

Ms. Herold asked if the formatting issue has been corrected. She voiced concern over whether that data is making it into the database if that entry error can still be allowed to occur.

Ms. Ellis explained how an error message would be sent to the user as a result of the invalid entry. Those error messages resulted in a very high volume of calls to the DOJ. Ms. Ellis stated that the new letter being drafted to pharmacists will explain that adjustments have been made in the program which will remove the errors messages and that the data has, in fact, been collected and accepted into the database.

Ms. Herold asked if there is anything the board needs to share with pharmacies that would help reduce the amount of errors. She stated that the letter being drafted by the DOJ can be sent out via a subscriber alert. Ms. Herold asked if pharmacists can assume that the data being submitted is collected and accurate at this point.

Ms. Ellis confirmed that they can. She added that the earlier data that was rejected was saved and the vendor has been instructed to “rerun” that data in order to add it to the database.

Ms. Herold asked how the board can assist with informing pharmacists of the appropriate format that the data must be submitted, how they should clarify if there is a valid error occurring and who to contact for assistance with those errors.

Ms. Ellis responded that the DOJ will share the validation criteria with the pharmacists. She added that warnings will be given for user input error until July 1, 2009. Beyond

that, user errors on required data fields will be rejected, with a correction required and resubmitted within 14 days.

Ms. Herold stated that the report can be placed on the board website.

There was discussion as to whether pharmacists would have the required software as there is an issue with regard to proprietary software.

Ms. Herold asked Ms. Ellis if the letter is going through review at this point.

Ms. Ellis confirmed.

Ms. Herold stated that she wants to support the CURES program and assist in ensuring that pharmacists are clear on the data format requirements, as the program is such a valuable tool. She indicated that they will not take any action at this point while the DOJ moves forward with distribution of their letter. She reiterated that DOJ should contact the board if there is anything they can do to help.

Mr. Weisser asked about the likelihood of switching to a new vendor in the future.

Ms. Ellis responded that it is always a possibility. She explained that the new vendor was chosen because they were below the cost of the current vendor in the bid process. She stated that prescription monitoring programs are growing nationwide and want to be a part of the bidding. Ms. Ellis emphasized that CURES is taking the necessary efforts to avoid the aggravation that occurred with the recent transition of the new vendor.

Anne Sodergren asked how current the data will be when a user accesses the data once the "real time" automation project is in place.

Ms. Ellis responded that the new vendor uploads the submitted data several times a week.

Ms. Sodergren asked where the information comes from that will be provided in the notification alert system.

Ms. Ellis responded that it comes directly from the source. An example of one such source is from physicians calling and providing the information.

Ms. Herold asked if there is any lag in inputting the information being reported by prescribers as required by them.

Ms. Ellis confirmed that there is lag.

Ms. Herold asked if there is a "clear picture" of those people who are "doctor shopping."

Ms. Ellis responded that there is not. She stated, however, that staff workload should be reduced as a result of additional automation, which will allow for the opportunity to catch up on the input of information provided by pharmacists.

Ms. Herold asked if the Medical Board is involved in identifying prescribers who don't submit to CURES.

Ms. Ellis responding that she is unsure.

Public Comments:

Janice Dang, Supervising Inspector, asked if the notification system can include physicians whose registration license has been revoked.

Ms. Ellis responded that she would need to discuss the addition with the IT department. She noted that they do obtain information from the DEA weekly which provides data on registrants whose licenses have been revoked, expired, etc. She agreed that the information would be valuable, but indicated that the DEA data is nationwide and, thus, may not be useable due to its large volume.

Ms. Dang referenced the CURES reports and explained that, with regard to compounding of controlled drugs, the active ingredient is not included or displays as "unknown" She asked if there is a way to reject those entries with an error message to the user.

Ms. Ellis responded that this is a requirement within the data entry to identify what the main ingredient of the controlled substance is. She reiterated that this is a requirement, but they are not getting the data accurately. CURES is trying to correct this issue.

Dr. Gray commented that Kaiser has experience with the DEA list which provides the information on expired, suspended and revoked licenses. He pointed out that there are several subcategories related to the reasons for a revoked license. Dr. Gray also stated that an expired DEA registration does not mean that the registrant is no longer authorized, as it may be due to delays in renewal processing. He noted other variances in expired registration. He stated that caution should be applied if CURES overreacts on such matters as it may affect patients.

Ms. Ellis responded that this was another validation issue. She also stated that, in the case of a DEA expired license, the vendor was originally rejecting the entry. CURES instructed them to stop rejecting those types of entries and to collect the data.

Dr. Gray noted the lag time within the DEA database which need to be taken into consideration as well.

5. Update Regarding Arrests and Criminal Convictions of Board Applicants and Licensees

Dr. Swart explained that the public and board licensees expect the board to act to remove from practice or deny licensure to those with substantially related convictions.

Dr. Swart stated that, as part of the board's regulatory process, the board requires fingerprint background checks on all applicants. In addition, the board recently implemented a change to the renewal forms for all individual licensees requiring self-certification of criminal convictions or discipline imposed by other regulatory agencies as part of the renewal process.

Dr. Swart pointed out that, in recent years the board has become inundated with fingerprint results. Whereas in 2000/01 the board received 608 arrest and conviction notifications, in 2007/08 the board received over 3,000. Additionally, Dr. Swart pointed out that about 30% of individual renewal applicants fail to complete the self-certification on the renewal form.

Dr. Swart indicated that, when it became clear that the board could not address this increased workload with existing resources, the board submitted a request to increase board staff through the Budget Change Proposal process. Board staff was recently advised that their request to establish a Criminal Conviction Unit was approved and included in the Governor's budget. Dr. Swart stated that the unit will consist of 6.5 positions and will be responsible for completing investigations on applicants and licensees who are either arrested and/or convicted of a crime and to determine if the arrest or conviction is substantially related to the duties and functions of the license obtained and therefore warrants action by the board.

Dr. Swart advised that board staff has begun recruitment to fill some of the Criminal Conviction Unit positions; however will not be able to fully staff this unit until July 2009, when the board's budget will be augmented to fully fund the unit.

Dr. Swart added that, more recently, SB 389 (Negrete McLeod) was introduced. He explained that this legislative proposal requires all specified agencies, including the board, to require state and federal level criminal background checks for all applicants as well require all licensees who have not previously undergone state and federal criminal background checks, to complete that as a condition of renewal.

Dr. Swart shared that this is going on throughout the Department of Consumer Affairs. He explained that there are approximately 150 pharmacist licensees who were licensed prior to the fingerprinting requirement established in September, 1949. He stressed that the Board of Pharmacy has moved further along than other boards in completing criminal background checks on licensees who were not previously conducted.

6. Department of Consumer Affairs' Policies Regarding Pursuit of Interim Suspension Orders Discussion

Dr. Swart explained that on December 15, 2008, the Deputy Director of Legal Affairs for the department, Doreathe Johnson, issued a memo reiterating the department's policy to encourage the practice of licensing agencies to use Interim Suspension Orders (ISO) and PC 23s when the conduct of a licensee is such that the board cannot afford to wait for the completion of the administrative process, before taking action to ensure the safety of the public. He added that the memo directs all DCA licensing agencies to institute procedures for ordering interim suspension orders as warranted as well as to make recommendations regarding specific conditions when the agency shall pursue a suspension via a PC 23. The memo further provides suggested parameters.

Dr. Swart stated that the board uses all legal actions authorized, including both ISOs and PC 23s when a case is egregious and immediate public harm is eminent. With the implementation of the Criminal Conviction Unit we anticipate an increase in the number of such actions as the board will have sufficient resources to more promptly address violations that warrant immediate suspension.

Dr. Swart advised that the board had received five PC 23 suspensions over the last fiscal year as appropriate, and that they are using them as encouraged.

Mr. Room stated that the low number of ISO's should not reflect poorly on the board. He added that, in his opinion, ISO's are typically used only in very specific and constraining circumstances. He noted that it is often more cost effective to go straight to the accusation and have a speedy hearing.

7. Public Comment for Items Not on the Agenda

The meeting was adjourned at 2:34 p.m.



**Guidance for Industry:
Standards for Securing the Drug Supply
Chain– Standardized Numerical Identification
for Prescription Drug Packages
(DRAFT GUIDANCE)**

Ilisa B.G. Bernstein, Pharm.D., J.D.
U.S. Food and Drug Administration
Office of the Commissioner/Office of Policy
ilisa.bernstein@fda.hhs.gov

FDA Standards Development (New 505D of the Act)

- Secretary shall prioritize and develop standards for
 - Identification
 - Validation
 - Authentication
 - Tracking and Tracing
- Rx drugs**
- Serialization (Identification) deadline: March 2010



Proposed Standardized Numerical Identifier (SNI) Serialized NDC

Example of a serialized National Drug Code (sNDC)

NDC

SERIAL NUMBER

5 5 5 5 5 6 6 6 7 7

+

1 1 1 1 1 1 1 1

labeler code + product code + package code

unique 8 digits

- Expiration date and/or lot or batch number – not included
- No recommendation for data carrier
- Machine and human readable
- Compatible with GS1 serialized GTIN

Additional issues for comment

- What about SNI for case and pallet?
- Alpha-numeric?
- Blood and blood components – ISBT 128 or Codabar?



Important Info

- **Draft Guidance:**
www.fda.gov/oc/guidance/drugsupplychain.html
- **Federal Register Notice:**
 - 74 FR 3054 January 16, 2009
 - <http://frwebgate3.access.gpo.gov/cgi-bin/PDFgate.cgi?WAISdocID=7095088148+0+2+0&WAISaction=retrieve>
- **Comments due: April 16, 2009**
 - www.regulations.gov
 - Docket: FDA-2009-D-0001



Standards Development and Adoption Update

California Board of Pharmacy

March 11, 2009





Who is GS1?

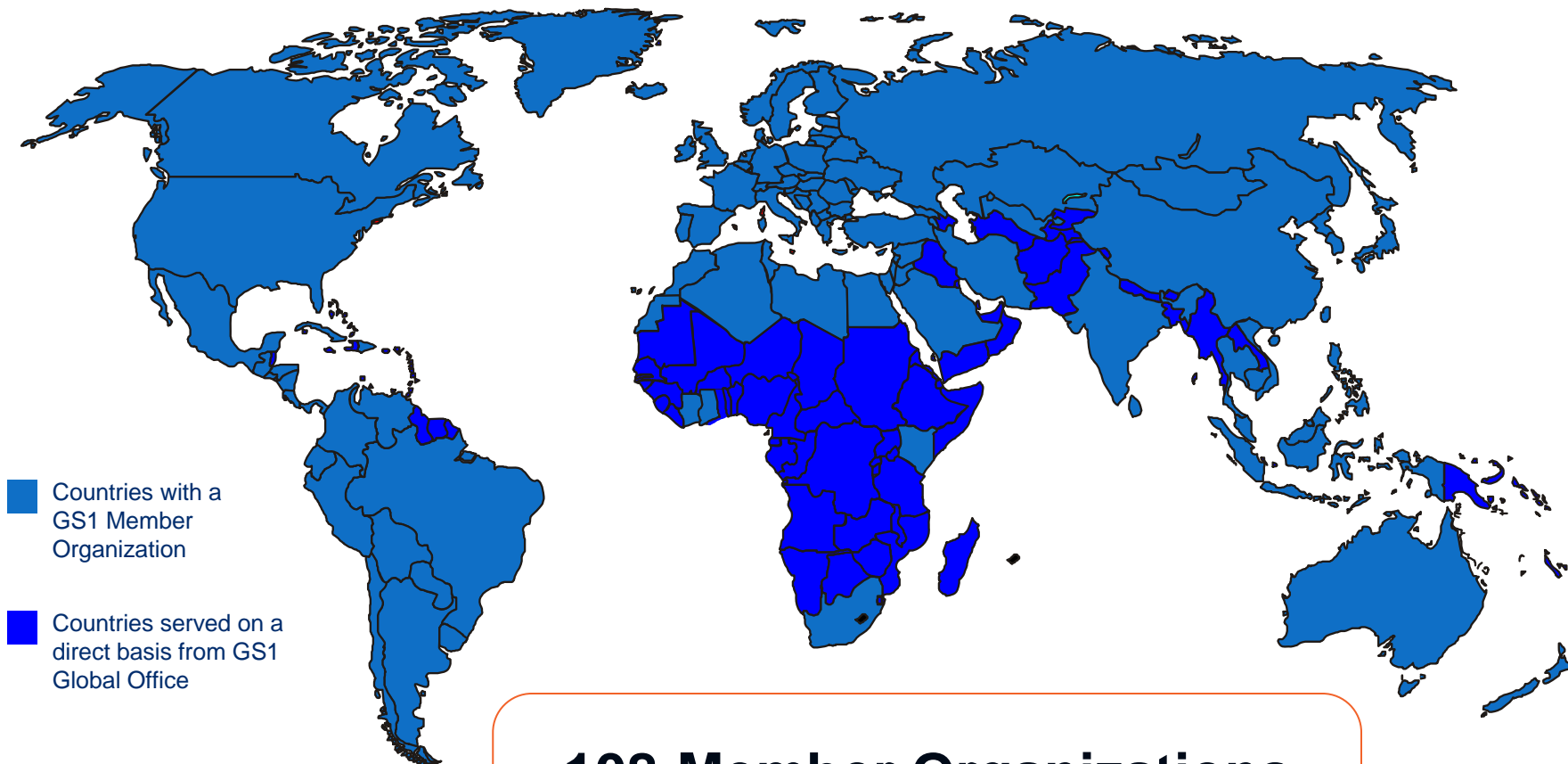
GS1 is a not-for-profit organization dedicated to the design and implementation of **global standards** to improve the efficiency and visibility of **supply chains** globally and across sectors

- **108** member organizations
- **35** years of experience
- **Neutral** platform for all supply chain stakeholders
- Over a **million** companies doing business across **150** countries
- Over **6 billion** transactions a day

GS1 is the most widely used supply chain standards system in the world



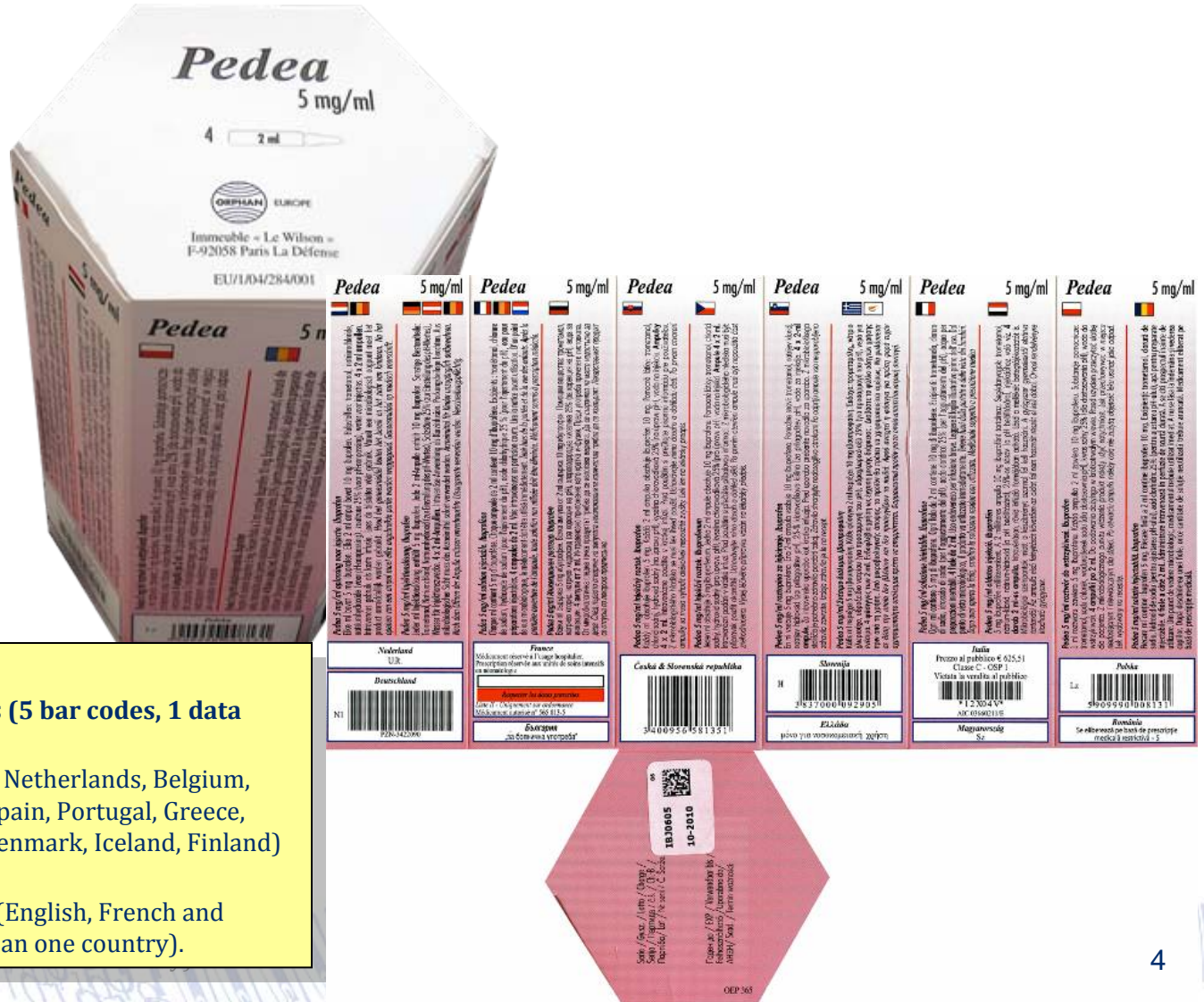
GS1 Around the World



108 Member Organizations
150 Countries Served



Why Global Standards?



The package has:

- 6 machine readable codes (5 bar codes, 1 data matrix).
- 17 flags (UK, Ireland, Malta, Netherlands, Belgium, Germany, Austria, France, Spain, Portugal, Greece, Cyprus, Norway, Sweden, Denmark, Iceland, Finland) (not Italy)
- 12 different language texts (English, French and German are used in more than one country).



Why Global Standards?



The package has:

- 6 machine readable codes (5 bar codes, 1 data matrix).
- 17 flags (UK, Ireland, Malta, Netherlands, Belgium, Germany, Austria, France, Cyprus, Norway, Sweden, Denmark, Portugal, Italy) (not Italy)
- 12 different language texts (English, French and German are used in more than one country).

Imagine what this could do to supply chain processes

5 mg/ml	5 mg/ml	5 mg/ml	5 mg/ml	5 mg/ml
Pedeia 5 mg/ml	Pedeia 5 mg/ml	Pedeia 5 mg/ml	Pedeia 5 mg/ml	Pedeia 5 mg/ml





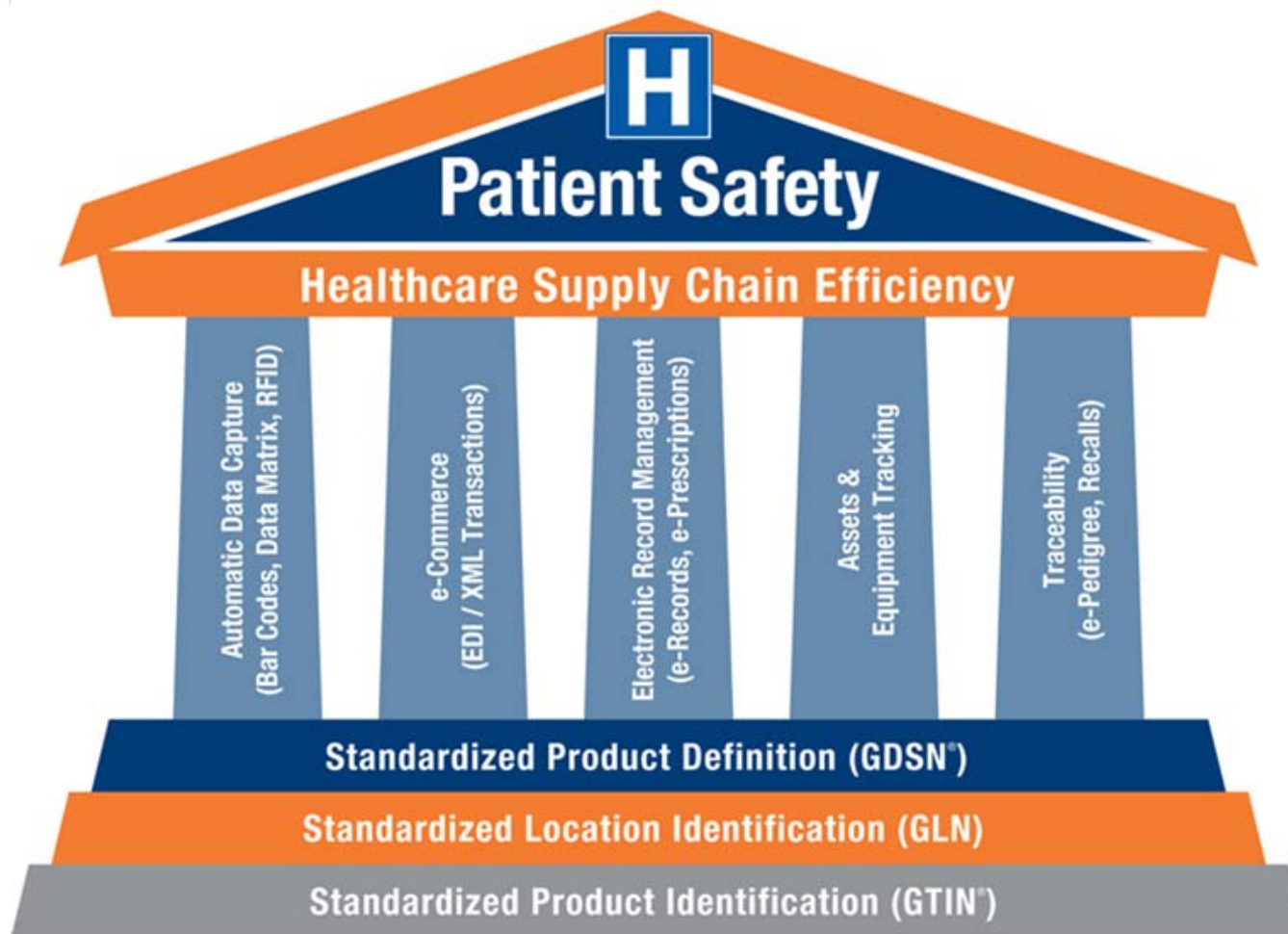
Contents

- The Fundamentals
- Significant Events
- Quality
- Pedigree future (DPMS, EPCIS, Discovery)
- Business Benefits and New Processes



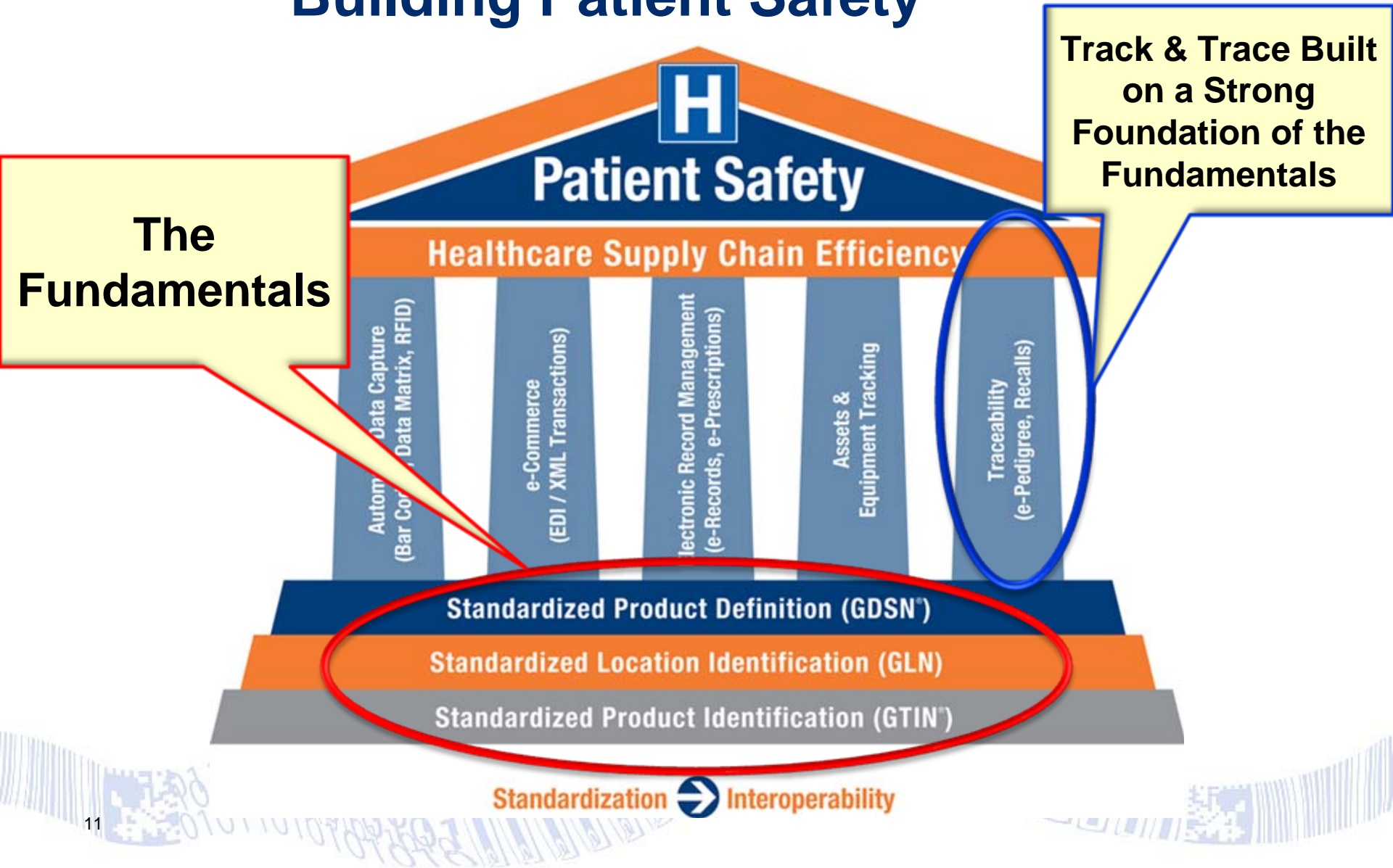


Building Patient Safety



Standardization  Interoperability

Building Patient Safety





TANDARDS IN ACTION

GTIN

EPCIS

GLN

???



GDSN

GLN REGISTRY
FOR
HEALTHCARE

DISCOVERY
SERVICES





STANDARDS IN ACTION

Definitions

- GTIN[®] (Global Trade Item Number)[®]
- GDSN[®] (Global Data Synchronization Network)[®]
- GLN (Global Location Number)
- EPCIS (EPC Information Services)





STANDARDS IN ACTION





STANDARDS IN ACTION



NDC → GTIN:

(01) 00314141999995





STANDARDS IN ACTION



NDC → GTIN:

(01) 00314141999995

SERIAL NUMBER: 165APX3E





STANDARDS IN ACTION



SN:

STATIC DATA

MANUFACTURER
TIN: (01) 00314141999995
RAND
STRENGTH: 25mg
1000 PILLS
TC

GDSN:
Global
Data
Synchronization
Network

NDC → GTIN:

(01) 00314141999995

SERIAL NUMBER: 165APX3E





TANDARDS IN ACTION



GDSN: STATIC DATA

- MANUFACTURER
- GTIN: (01) 00314141999995
- BRAND
- STRENGTH: 25mg
- 1000 PILLS
- ETC

GLN:
Global
Location Number

NDC → GTIN:
 (01) 00314141999995
 SERIAL NUMBER: 165APX3E

DYNAMIC DATA

SHIP DATE	2/1/09	2/15/09	3/1/09
SHIP FROM	MANUFACTURER GLN - A	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C
SHIP TO	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C	RETAIL STORE GLN - D
RECEIVED DATE	2/8/09	2/20/09	3/10/09





STANDARDS IN ACTION



GDSN:

STATIC DATA

- MANUFACTURER
- GTIN: (01) 00314141999995
- BRAND
- STRENGTH: 25mg
- 1000 PILLS
- ETC

DYNAMIC DATA

SHIP DATE	2/1/09	2/15/09	3/1/09
SHIP FROM	MANUFACTURER GLN - A	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C
SHIP TO	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C	RETAIL STORE GLN - D
RECEIVED DATE	2/8/09	2/20/09	3/10/09

GTIN:

(01) 00314141999995

SERIAL NUMBER: 165ADY3E

GLN Registry for Healthcare®

- GLN - B (1100004570208)
- WHOLESALER NAME
- ADDRESS
- PHONE NUMBER
- ETC

STATIC DATA



STANDARDS IN ACTION

DYNAMIC DATA



SN: STATIC DATA

MANUFACTURER
 GTIN: (01) 00314141999995
 RAND
 STRENGTH: 25mg
 1000 PILLS
 NDC

- Manufacturer's Database
- GTIN - (01) 00314141999995
 - SERIAL NUMBER: 165APX3E
 - PRODUCTION DATE
 - EXPIRY DATE
 - LOT NUMBER
 - RAW MATERIAL DATA

DYNAMIC DATA

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 (01) 00314141999995
 SERIAL NUMBER: 165APX3E

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GLN Registry for Healthcare®

- GLN - B (1100004570208)
- WHOLESALER NAME
- ADDRESS
- PHONE NUMBER
- ETC

STATIC DATA



TANDARDS IN ACTION



SN:

STATIC DATA

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STATIC DATA

TRACEABILITY

DYNAMIC DATA

- EPCIS
- DISCOVERY SERVICES



STANDARDS IN ACTION



DYNAMIC DATA

GDSN: STATIC DATA

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- GTIN: (01) 00314141999995
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STANDARDS IN ACTION

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GLN Registry for Healthcare®

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TRACEABILITY

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- DISCOVERY SERVICES



STANDARDS IN ACTION

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- EPCIS
- DISCOVERY SERVICES



Contents

- The Fundamentals – cont.
- Significant Events
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- Pedigree future (DPMS, EPCIS, Discovery)
- Business Benefits and New Processes





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SSCC-18

SSCC-96

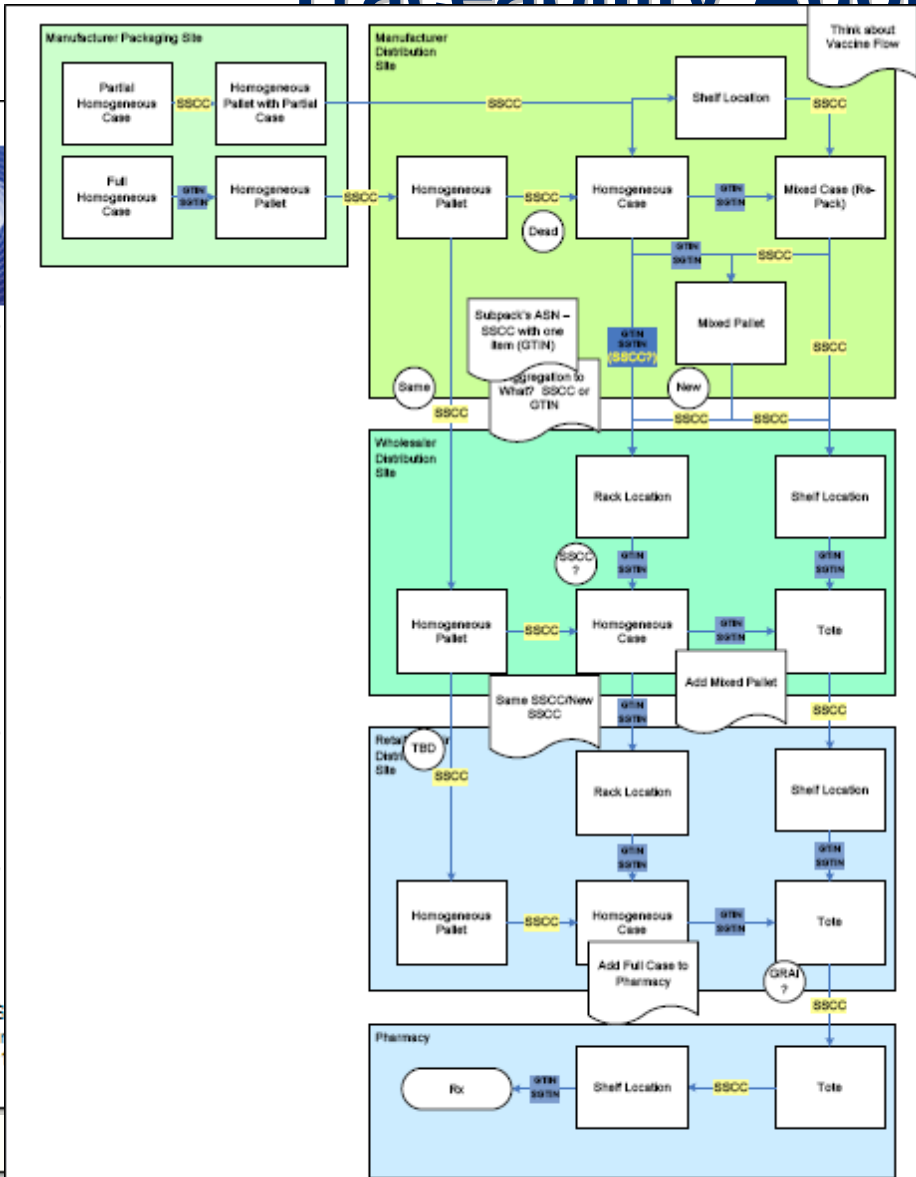
SSCC-18

SSCC-96

Global HLS

option Road

nal Version v



ation

Barcode 6

Note Different Frequency

6

One Data Carrier

2-D Data-Matrix

-ECC200 format

-AI(01) + AI(21)

data encoded

+

Text Backup

-Human-Readable

AI(01) + AI(21)



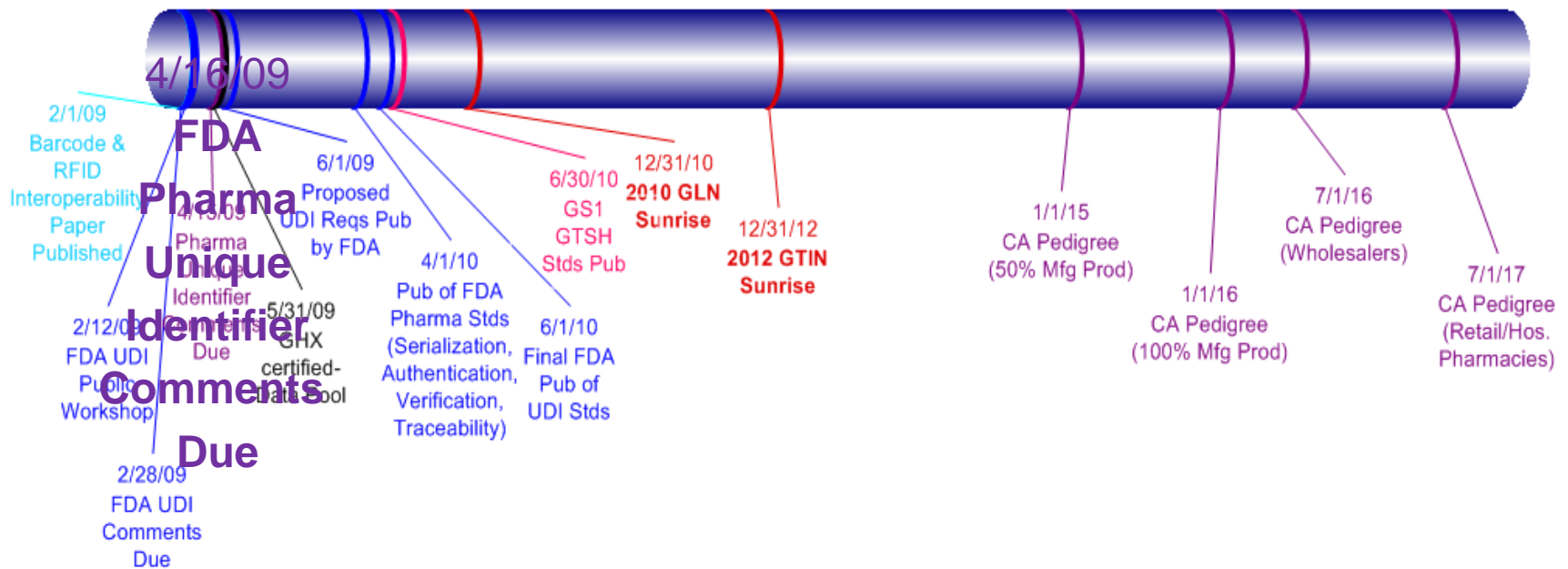
Contents

- The Fundamentals
- Significant Events
- Quality
- Pedigree future (DPMS, EPCIS, Discovery)
- Business Benefits and New Processes



U.S. Healthcare Community Initiatives

2/16/2009





Traceability Adoption

Guidance for Industry Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes.

Comments and suggestions regarding this draft document should be submitted in the *Federal Register* of the notice announcing the availability of this guidance. Submit comments to the Division of Dockets Management (HFA-209), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number listed in the notice of availability in the *Federal Register*.

For questions regarding this draft document contact (OC) Office of Policy, 301-796-4830; (CDER) Office of Compliance, Jennifer Devine at 301-796-6210 or Stephen Ripley at 301-827-6210.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner (OC)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Affairs (ORA)
January 2009
Procedural

FDA-2009-D-0001

GS1 COMMENT

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
[Docket No. FDA-2009-D-0001]

EXECUTIVE SUMMARY _____ 1
BACKGROUND _____ 2
WHO IS GS1? _____ 3
GS1 & HEALTHCARE _____ 4
COMMENTS REGARDING FDA DRAFT GUIDANCE FOR STANDARDIZED NUMERICAL IDENTIFICATION FOR PRESCRIPTION DRUG PACKAGES _____ 5
Use of NON-INDIC BASED IDENTIFIERS _____ 6
SUGGESTING THE CURRENT LINEAR BAR CODE ON PRESCRIPTION DRUGS _____ 6
COMMENTS REGARDING QUESTIONS POSED IN THE DRAFT GUIDANCE (DOCKET FDA-2009-D-0001) _____ 7
FDA'S REQUEST FOR INFORMATION _____ 7
FDA Question 1: Identifiers for pallet and intermediate levels of packaging _____ 7
FDA Question 2: SNI format: Numerical alpha-numeric _____ 7
FDA Question 3: Blood and Blood Components _____ 8

© 2009 GS1

DDM
Entry Date 1-15-09
Creation Date 1/16/09
Author A. Corbin

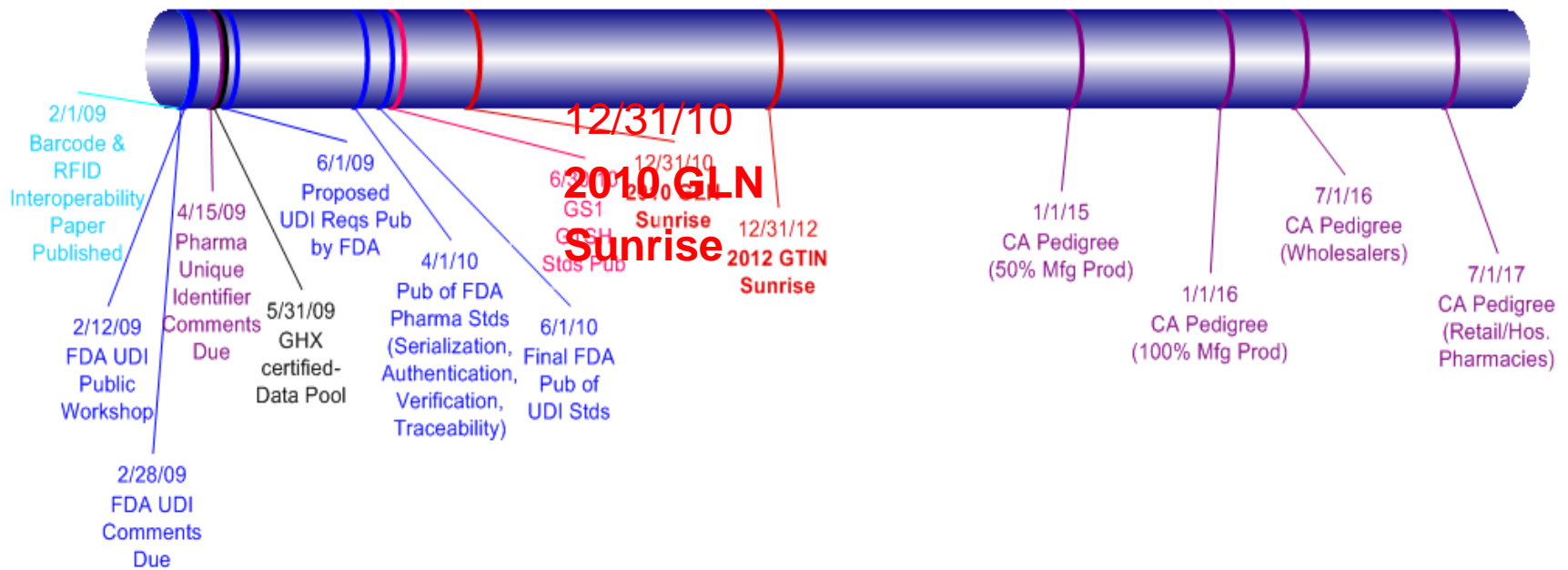
Drug Supply
Chain Drug

announcing the
standards for Securing
identification for
being issued under the
which requires FDA to develop
drugs. We are also
to questions posed in this
be.
at any time (see 21 CFR
your comment on this draft
on of the guidance, submit
pliance by [insert date 90 days
r].
copies of the draft guidance to
Drug Evaluation and Research,
Hampshire Ave., Bldg. 51, rm.

001 NAD

U.S. Healthcare Community Initiatives

2/16/2009





What is the Provider Pain?

Too many identifiers for the same healthcare location -- confusion, finger pointing, inefficiency

US

SAINT JOHN'S QUEENS HOSPITAL
1100004570208

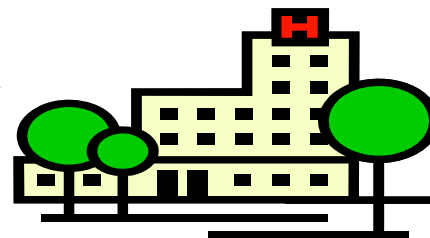
ST JOHN'S QUEENS HOSPITAL
100084547

SAINT **JOHNS** QUEENS HOSPITAL
JAOE

SAINT JOHN'S **QUEEN** HOSPITAL
50003000431

SAINT JOHN'S **QUEEN'S** HOSPITAL
CA2053

ST. JOHN'S QUEENS HOSPITAL
OM 12345



Many different names
different location numbers
for 1 hospital



2010 GLN Sunrise

“Adoption of GLN in healthcare by 2010*”

GLNs (Unique Location Identifier):

- Assigned by location owners.
- Used in appropriate business transactions and processes between trading partners.
- Hierarchy defined and maintained by location owners.
- GLN Registry for Healthcare® used to facilitate correct location identification.

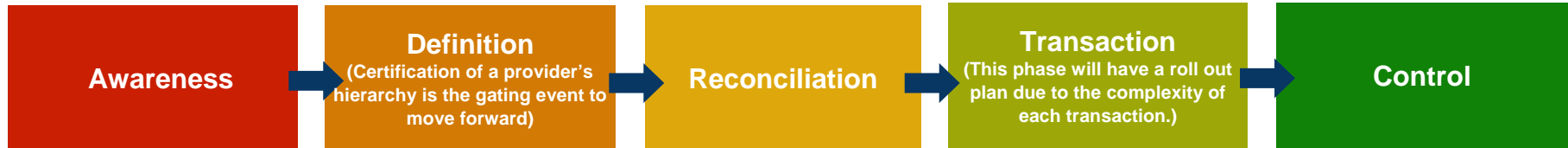
* December 2010





2010 GLN Sunrise

“Adoption of GLN in healthcare by 2010” Voluntary US Healthcare Implementation Path



SC leaders and staff know about GLNs, benefits, and standards in general, and commit to implement.

Organization accesses the GLN Registry, establishes users/approvers and reviews their hierarchy.

Organizations commit to utilize the GLN Registry for rosters/membership maintenance.

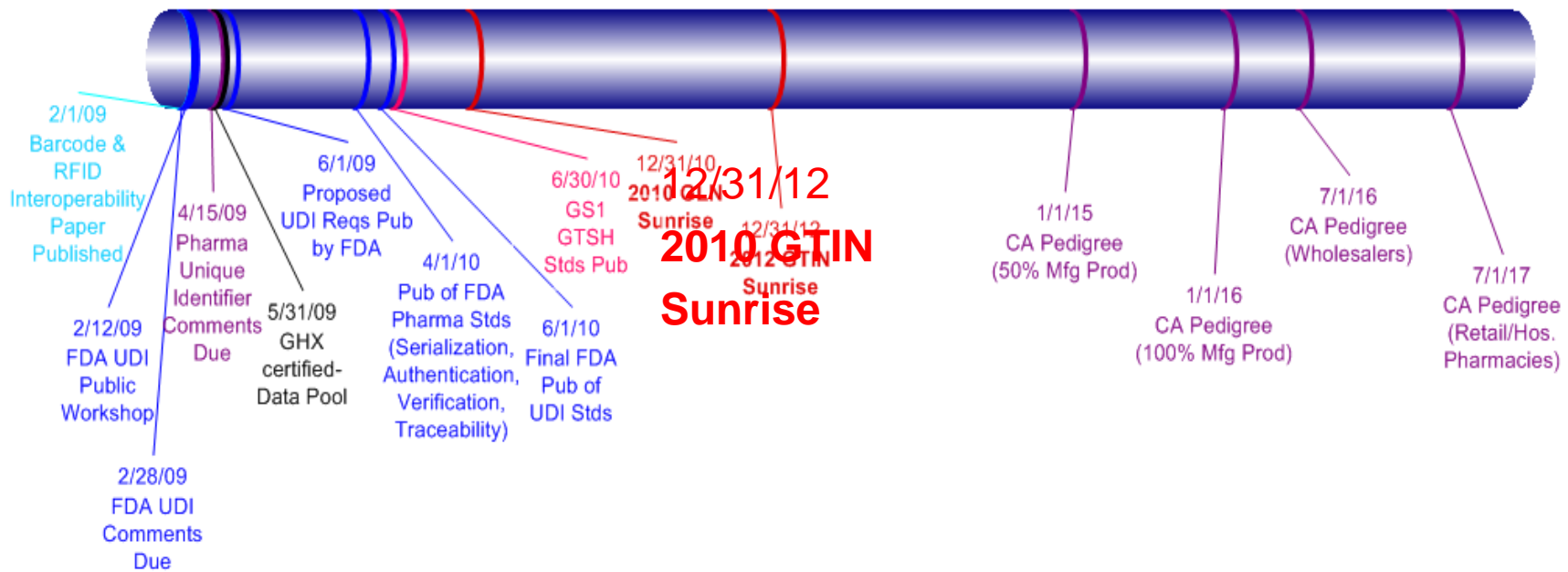
Organizations use GLNs in transactions to identify themselves and their trading partners, eliminating use of proprietary account numbers.

Data is maintained in the GLN Registry in “real” time to facilitate ongoing data quality and transactional efficiency.

Provider	<p>Enumerates locations to ship-to level with GLN.</p> <p>“Certifies” accuracy of data and maintains in “real-time”.</p>	<p>Provider maintains data in registry “real” time.</p> <p>Begin to utilize GLN to identify business partners in internal systems.</p>	<p>Place orders using GLNs.</p>	<p>Maintain GLN hierarchy in registry “real” time, resulting in database or record for business partners’ communication.</p> <p>Becomes final arbiter of GLN and all disputes are adjudicated via provider.</p>
GPO	<p>Assists member organizations with enumeration strategy and transitions ownership of GLNs to provider.</p> <p>Enumerates locations to ship-to level with GLN.</p>	<p>GPO stops using internal ID on rosters as providers certify their hierarchy and publish “GLN Only” roster membership lists to business partners.</p>	<p>Roster and fees using GLNs.</p>	<p>Maintain roster membership lists using only GLN, reporting/fees done by GLN.</p> <p>Adjudication assistance to members, but final sign-off by members.</p>
Distributor	<p>Assists member organizations with enumeration strategy when required.</p> <p>Enumerates locations to ship-to level with GLN.</p>	<p>Begin to utilize GLN to identify business partners in internal systems.</p>	<p>Take orders from providers.</p> <p>Send rebates/sales tracings to manufacturers using GLN.</p> <p>Communicate with GPOs using GLN.</p>	<p>Maintain info in systems utilizing GLN, ship/order/sales tracing/contracts.</p> <p>Access registry to maintain location information and accept final judgment of provider on accuracy of GLN.</p>
Manufacturer	<p>Assists member organizations with enumeration strategy when required.</p> <p>Enumerates locations to ship-to level with GLN.</p>	<p>Begin to utilize GLN to identify business partners in internal systems.</p>	<p>Accept orders, rebates/sales tracings via GLN.</p> <p>Report to GPO and Admin - fees via GLN.</p> <p>Communicate with distributors using GLN, including contracts.</p>	<p>Maintain info in systems utilizing GLN, ship/order/sales tracing/contracts.</p> <p>Access registry to maintain location information and accept final judgment of provider on accuracy of GLN.</p>

U.S. Healthcare Community Initiatives

2/16/2009





Same Product – Different Numbers*

■ Industry Distributor Numbers for 3M Product # 8630:

Nearly every hospital has a different Product ID for 3M 8630! Makes ordering, recalls, and proper identification to the patient difficult.

Allegiance	- M8630
Owens & Minor	- 4509008630
BBMC-Colonial	- 045098630
BBMC-Durr	- 081048
Kreisers	- MINN8630
Midwest	- TM-8630
Pacific	- 3/M8630
UnitedUMS	- 001880

* Source: Department of Defense Data Synchronization Study



Same Number Different Products *

Makes Sourcing of needed products difficult and increases errors in ordering and distribution to the patient.

■ *Part Number: 10313*

refers to:

Medtronic's - "NEEDLE CARDIOPLEGIA ADULT 16GA 5/8IN TIP 10IN"

Hantover's - "CARTRIDGE REPLACEMENT STUNNER YELLOW F/CALVES/HEAVY HOGS"

Chattanooga Group's - "ACCESSORY TRACTION **REPLACEMENT STRAP** XL FOR HALTER THORACIC RESTRAINT"

HF Scientific's - "TEST KIT WATER FREE CHLORINE DPD 25ML SAMPLE PHOTOMETRIC 1000/PK"

■ *Part Number: 1050 refers to:*

3M Company's - "DRAPE INCISE 35 3/8X 17 5/8IN"

Tyco's - "PAD TELFA 3 X 4IN STER"

* Source: Premier Inc. Product Item Master

2012 GTIN Sunrise

“Adoption of GTIN in healthcare by 2012*”

GTINs (Unique Product Identifier):

- Assigned to healthcare products.
- Used in business transactions.
- Marked on appropriate packaging levels.
- Scanned at points-of-delivery to enhance clinical process.
- Used in product returns and recalls.
- Registered in a GS1 GDSN-certified Data Pool.

*** December 2012**

2012 GTIN Sunrise



Adoption of GTIN by U.S. Healthcare by 2012” Voluntary US Healthcare Implementation Path

PHASES



Provider / GPO	<p>Know GS1 System Standards. Review internally what must be changed to accept.</p>	<p>Notify trading partners of need for GTIN, and possibly additional Application Identifiers (e.g. lot number, expiry date, serial number) Request ability to provide this information.</p>	<p>Terms and condition of contracts specify applicable GS1 Standards, specifically GTINs. The Information Technology staff begins to align internal systems to GS1 specifications. Initial testing begins.</p>	<p>Testing continues to use GTINs and other GS1 Standards in a majority of, if not all, transactions.</p>	<p>All products ordered and received are marked in accordance with GS1 Standards.</p>
Distributor	<p>Know GS1 System Standards. Review incoming material and the ability of internal systems to accept.</p>	<p>Notify trading partners of ability to accept GS1 Standards; specifically GTIN and possibly additional Application Identifiers (e.g. lot number, expiry date, serial number). Notify trading partners of requirement for GS1 Standards from customers.</p>	<p>Terms and conditions of contracts specify applicable GS1 Standards on products, specifically GTIN and possibly lot number, expiry date and serial number. The Information Technology staff begins to align internal systems to GS1 specifications. Initial testing begins.</p>	<p>Testing continues to use GTINs and other GS1 Standards in a majority of, if not all, transactions.</p>	<p>All products ordered, received and shipped are marked in accordance with GS1 Standards.</p>



2012 GTIN Sunrise

Adoption of GTIN by U.S. Healthcare by 2012” Voluntary US Healthcare Implementation Path

PHASES



Suppliers	Know of impending requirement. Determine the ability to meet or exceed requirement.	Notify trading partners of ability to accept GS1 Standards; specifically GTIN and possibly additional Application Identifiers (e.g. lot number, expiry date, serial number). Notify trading partners of requirement for GS1 Standards from customers.	Terms and conditions of contracts call for GS1 Standards on all products: GTIN and possibly lot number, expiry date and serial number. The Information Technology staff begins to align internal systems with this requirement. Initial testing begins.	Testing continues to use GTINs and other GS1 Standards in a majority of, if not all, transactions.	All products ordered and received are marked in accordance with GS1 Standards.
Software Providers	Know of impending requirement. Determine the ability to meet or exceed requirement.	Notify trading partners of ability to accept GS1 Standards; specifically GTIN and possibly additional Application Identifiers (e.g. lot number, expiry date, serial number). Notify trading partners of requirement for GS1 Standards from customers.	GS1 Standards are imbedded in all products, specifically GTIN and possibly lot number, expiry date and serial number. The Information Technology staff begins to align internal systems with this requirement. Initial testing begins.	Testing continues to use GTINs and other GS1 Standards in a majority of software.	All products have specific segments identified for GS1 Standards, following allocation rules in the specifications.



Contents

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Bar Code Quality

Where do all those measurements come from? . . . **Verification!**






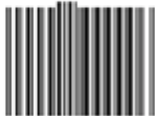




Bar Code Quality

Test Card for ISO/ANSI Based Verifiers

- Calibrated Conformance Standard is used to “verify the verifier”
- Traceable to National Institute of Standards and Technology (NIST)
- Important training tool for personnel in the correct use of verifiers
- Stops all arguments

CALIBRATED CONFORMANCE STANDARD
TEST CARD
FOR EAN/UPC SYMBOL VERIFIERS
USING 6 MIL APERTURES

EAN-13 MASTER GRADE	UPC-A MASTER GRADE
 5 012345 678900	 0 12345 67890 5
DECODABILITY: _____ <input type="checkbox"/>	DECODABILITY: _____ <input type="checkbox"/>
CONTRAST: _____ <input type="checkbox"/>	CONTRAST: _____ <input type="checkbox"/>
MODULATION: _____ <input type="checkbox"/>	MODULATION: _____ <input type="checkbox"/>
 DEFECTS (VOID)	 DECODABILITY (BAR)
_____ <input type="checkbox"/>	_____ <input type="checkbox"/>
CALIBRATION #: _____	CONTRAST _____ <input type="checkbox"/>
WAVE LENGTH: 670 nm	
EFF. APERT: 0.006 in.	
 BarCodes and eCom™ US	
• PER ANSI K3182 • PER ISO/IEC 15426 STANDARDS	
DATE ISSUED: _____	
<small>THE STANDARD IS CERTIFIED FOR 2 YEARS FROM IN SERVICE DATE WHEN HANDLED IN ACCORDANCE WITH USE OF CALIBRATED CONFORMANCE STANDARDS DOCUMENTATION.</small>	
<small>© 2008 GS1 US. ALL RIGHTS RESERVED.</small>	

PART NO. CCSV-1 REV Q-2



Bar Code Quality

Verifying the Verifier:

Calibrated Conformance Standard Test Cards

CALIBRATED CONFORMANCE STANDARD TEST CARD
FOR EAN/UPC SYMBOL VERIFIERS
USING 6 ML APERTURES

EAN-13 MASTER GRADE **UPC-A MASTER GRADE**



DECODEABILITY _____ X
CONTRAST _____ X
MODULATION _____ X

DECODEABILITY _____ X
CONTRAST _____ X
MODULATION _____ X

DEFECTS (VOID) DECODEABILITY (BARI)

CALIBRATION # _____
WAVE LENGTH # 670 nm
EFF. APER. 0.006 in.

BarCodes and eCom™

DATE ISSUED: _____
PART NO. CCBV-1 REV 0-2

CALIBRATED CONFORMANCE STANDARD TEST CARD
For Use with 10 ml Apertures and GS1-128 Symbols Only

GS1-128 Master Grade



(00) 00614141234567890

DECODEABILITY _____ X
CONTRAST _____ X Near _____ X
MODULATION _____ X Near _____ X

DEFECTS (SPOTS) _____ X

LOW DECODEABILITY _____ X

CONTRAST _____ X


CALIBRATION # _____
WAVE LENGTH # 670 nm
EFFECTIVE APERTURE 0.010 in. (0.250 mm)

BarCodes and eCom™

DATE ISSUED: _____
PART NO. CCBV-98 REV 0

CALIBRATED CONFORMANCE STANDARD TEST CARD
ITF-14 (Interleaved 2-of-5)
For Use with 20 ml Apertures Only

Interleaved 2-of-5 Master Grade



006141412343

DEFECTS (SPOTS) _____ X

LOW DECODEABILITY _____ X

CONTRAST _____ X

CALIBRATION # _____
WAVE LENGTH # 670 nm
EFFECTIVE APERTURE 0.020 in. (0.500 mm)

BarCodes and eCom™

DATE ISSUED: _____
PART NO. CCBV-59 REV 0

CALIBRATED CONFORMANCE STANDARD TEST CARD
For Use with 6 ml Apertures and GS1 Databar™ Symbology

GS1 Databar Expanded Master Grade
Also applicable for GS1 Databar Expanded Stacked



(01) 006141412343

DECODEABILITY _____ X
CONTRAST _____ X Near _____ X
MODULATION _____ X Near _____ X

GS1 Databar Limited Master Grade



(01) 006141412343

DECODEABILITY _____ X

GS1 Databar Omnidirectional Master Grade
(Also applicable for GS1 Databar Stacked, Stacked Omnidirectional, and Truncated Symbols)



(01) 006141412343

DECODEABILITY _____ X

DEFECTS (VOID) _____ X

LOW DECODEABILITY _____ X

CONTRAST _____ X

CALIBRATION # _____
WAVE LENGTH # 670 nm
EFFECTIVE APERTURE 0.005 in. (0.125 mm)

BarCodes and eCom™

DATE ISSUED: _____
PART NO. CCBV-08 REV 0

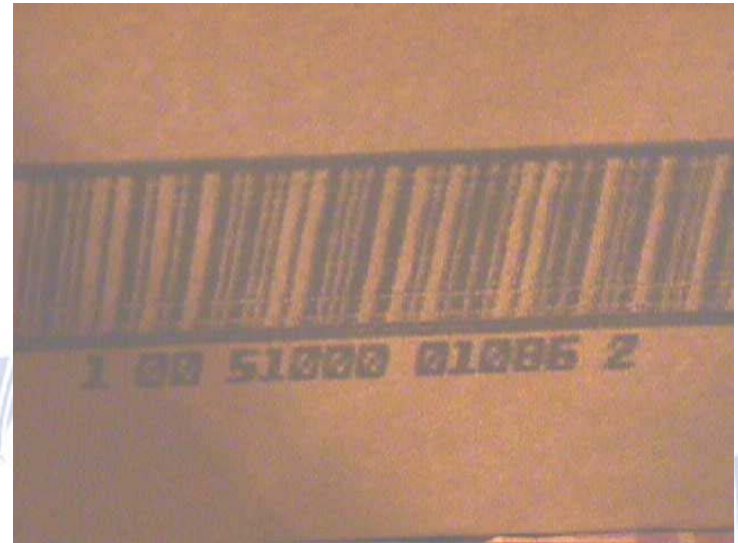
These cards stop all arguments and put you and your customer on the same page!



Bar Code Quality

What this does for you is:

- Prevents you from sending “bad” bar codes into the supply chain!
- Ensures readability of your bar codes throughout the supply chain.
- Lets you know what’s happening before it’s too late!





Contents

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STANDARDS IN ACTION



GDSN:

STATIC DATA

MANUFACTURER
 GTIN: (01) 00314141999995
 BRAND
 STRENGTH: 25mg
 1000 PILLS
 ETC

DYNAMIC DATA

Manufacturer's Database

- GTIN - (01) 00314141999995
- SERIAL NUMBER: 165APX3E
- PRODUCTION DATE
- EXPIRY DATE
- LOT NUMBER
- RAW MATERIAL DATA

DYNAMIC DATA

NDC → GTIN:
 (01) 00314141999995
 SERIAL NUMBER: 165APX3E

SHIP DATE	2/1/09	2/15/09	3/1/09
SHIP FROM	MANUFACTURER GLN - A	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C
SHIP TO	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C	RETAIL STORE GLN - D
RECEIVED DATE	2/8/09	2/20/09	3/10/09

GLN Registry for Healthcare®

- GLN - B (1100004570208)
- WHOLESALER NAME
- ADDRESS
- PHONE NUMBER
- ETC

STATIC DATA

TRACEABILITY

DYNAMIC DATA

- EPCIS
- DISCOVERY SERVICES



STANDARDS IN ACTION

DYNAMIC DATA



GDSN:

- MANUFACTURER
- GTIN: (01) 00314141999995
- BRAND
- STRENGTH: 25mg
- 1000 PILLS
- ETC

Manufacturer's Database

- GTIN - (01) 00314141999995
- SERIAL NUMBER: 165APX3E
- PRODUCTION DATE
- EXPIRY DATE
- LOT NUMBER
- RAW MATERIAL DATA

DYNAMIC DATA

NDC → GTIN:
 (01) 00314141999995
 SERIAL NUMBER: 165APX3E

SHIP DATE	2/1/09	2/15/09	3/1/09
SHIP FROM	MANUFACTURER GLN - A	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C
SHIP TO	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C	RETAIL STORE GLN - D
RECEIVED DATE	2/8/09	2/20/09	3/10/09

GLN Registry for Healthcare®

- GLN - B (1100004570208)
- WHOLESALER NAME
- ADDRESS
- PHONE NUMBER
- ETC

STATIC DATA

TRACEABILITY

- EPCIS
- DISCOVERY SERVICES



STANDARDS IN ACTION

DYNAMIC DATA



GDSN:

- MANUFACTURER
- GTIN: (01) 00314141999995
- BRAND
- STRENGTH: 25mg
- 1000 PILLS
- ETC

Manufacturer's Database

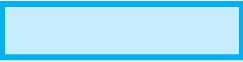
- GTIN - (01) 00314141999995
- SERIAL NUMBER: 165APX3E
- PRODUCTION DATE
- EXPIRY DATE
- LOT NUMBER
- RAW MATERIAL DATA

NDC → GTIN:
 (01) 00314141999995
 SERIAL NUMBER: 165APX3E

GLN Registry for Healthcare®

- GLN - B (1100004570208)
- WHOLESALER NAME
- ADDRESS
- PHONE NUMBER
- ETC

STATIC DATA



SHIP DATE	2/1/09	2/15/09	3/1/09
SHIP FROM	MANUFACTURER GLN - A	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C
SHIP TO	WHOLESALER GLN - B	RETAIL CHAIN WAREHOUSE GLN - C	RETAIL STORE GLN - D
RECEIVED DATE	2/8/09	2/20/09	3/10/09

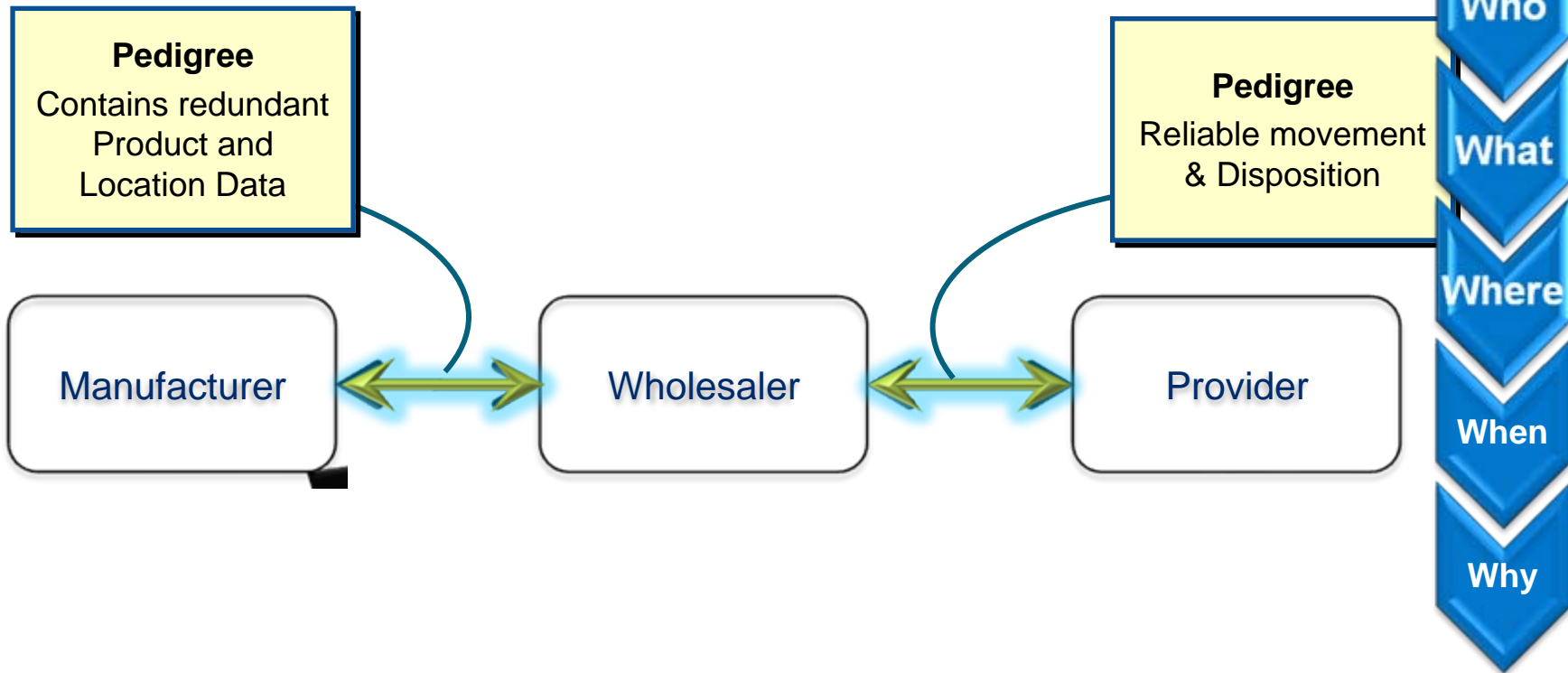
TRACEABILITY DYNAMIC DATA

- EPCIS
- DISCOVERY SERVICES



Today - Pedigree

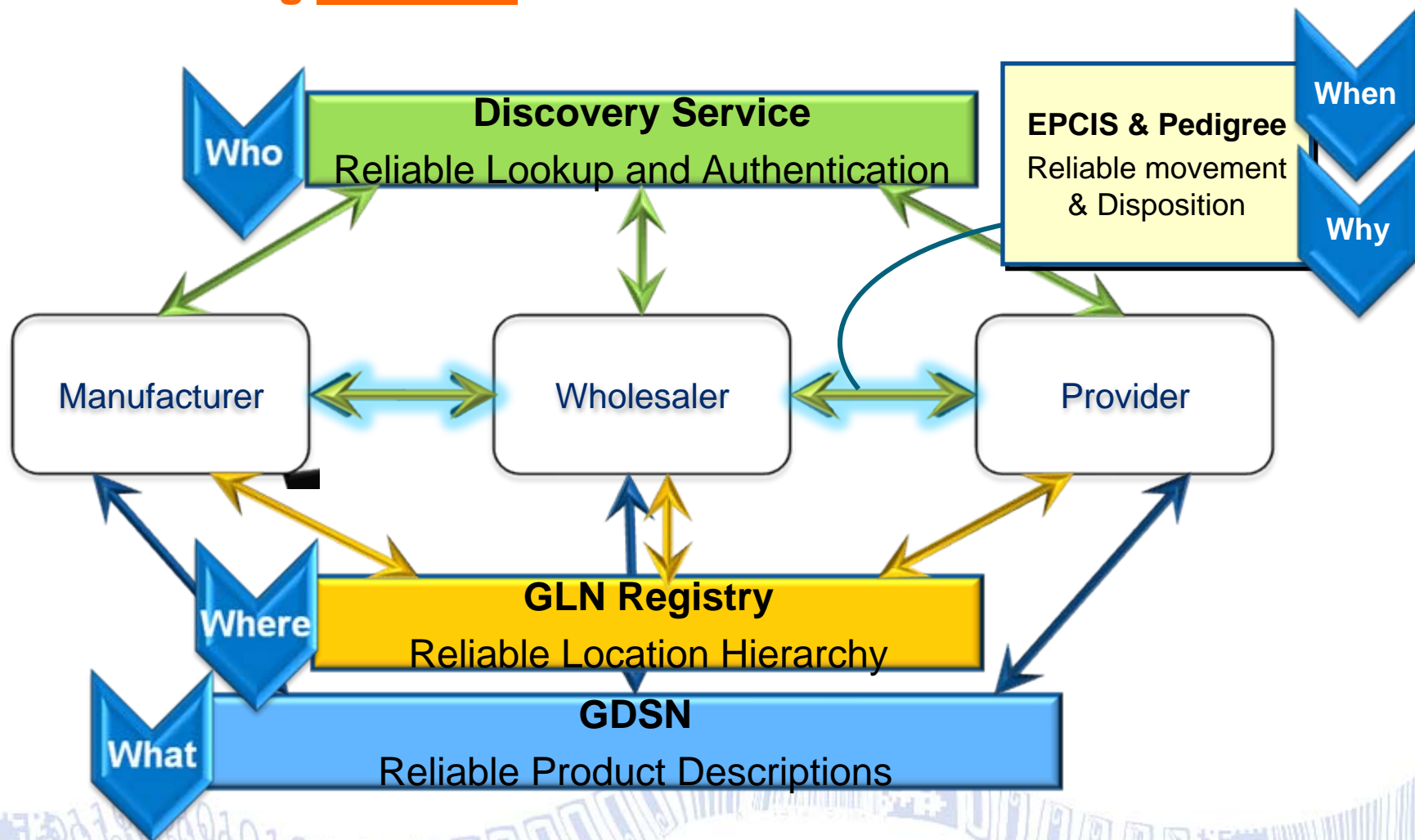
Using Current Standards





Tomorrow – Track and Trace

Using Emerging Standards





Tomorrow – Track and Trace Using Emerging Standards

The screenshot shows a Google Maps interface in an Internet Explorer browser window. The address bar shows 'http://www.google.com/maps'. The search bar is empty. The map displays the United States with a yellow path starting from the West Coast, moving through the central states, and ending in the Southeast. A red arrow points from a red box labeled 'Duplicate Product' to the path. The browser's taskbar at the bottom shows the Start button and various application icons, including 'Google Maps - Windo...'. The system clock shows 5:57 PM.

Product ID: 03567896538962

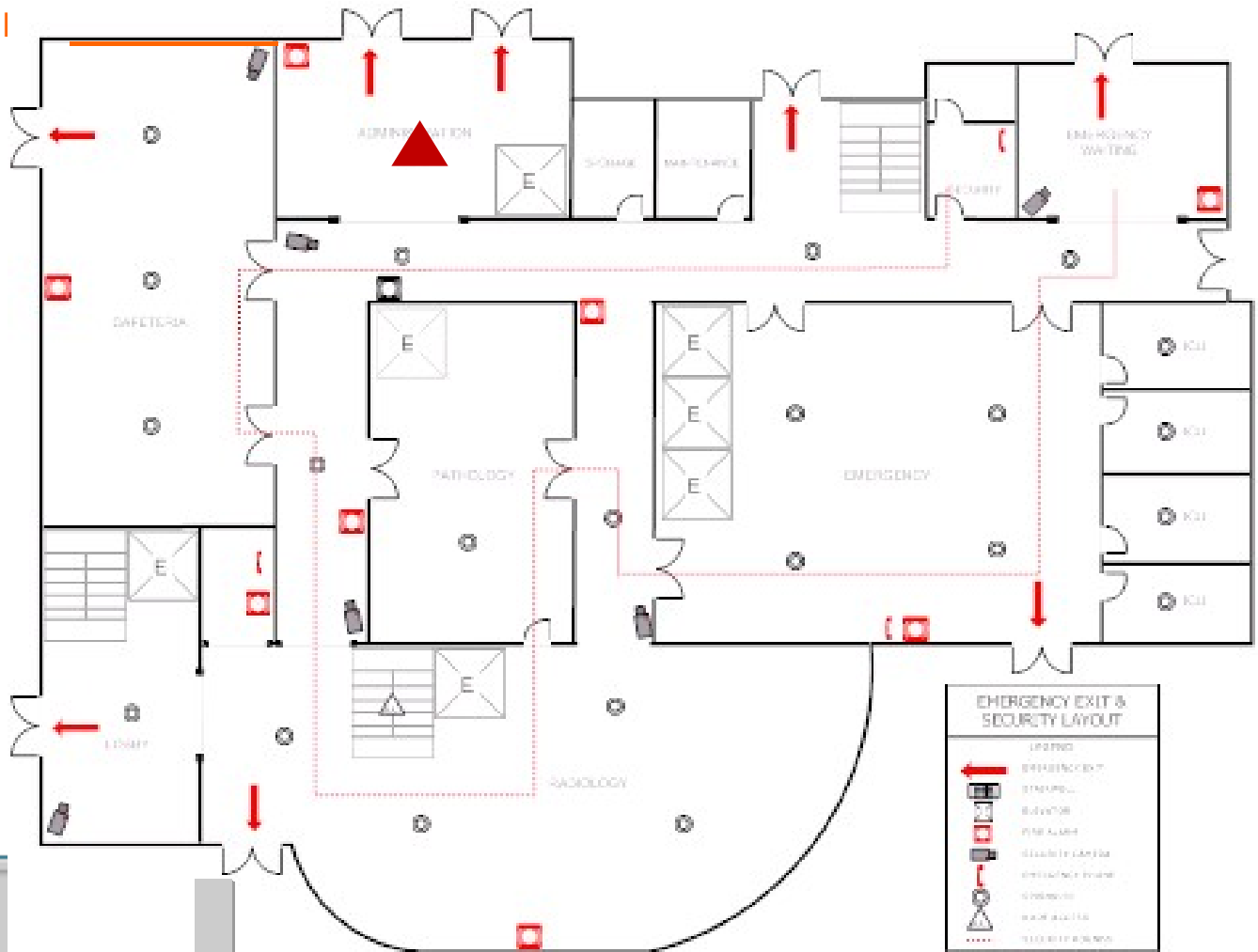
Lot #: 694184

Duplicate Product



Tomorrow – Track and Trace

Usi



- IV Pump
- Ready for Use
- Needs Maintenance
- Wheelchair



Contents

- The Fundamentals
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Inference Paper

The Practice of Inference

security policies and procedures as well as the plant.



Figure 1 - Layers of Trust, Inference Considerations

Verification of inferred items

- Trusted events – based on someone else did.
- Known events – based on someone did.
- Unknown event – exception or

Inference examples

Local Inference

- Manufacturers:
 - Scenario 1: All identifiers scanned as they are in the case.
 - Scenario 2: A case identifier scanned and the identifiers are associated another within the manufacturing system.
 - Scenario 4: The case is out

The Practice of Inference

U.S. Pharmaceutical Supply Chain Pedigree Regulatory Environment

This paper provides a general discussion on the tools of inference as it applies to the U.S. Pharmaceutical Industry.

Historical Use of Inference

- Used extensively today Shipping full cases They are not opened at point of receipt (use visual inspection, existing TP relationships and supporting documentation)
- Existing TP relationships (documented shipping accuracy or inaccuracy)
- Required to open cases – could increase risk and/or cases could appear to be tampered with eg. down-stream TP's (refer back to Risk Mitigation section)
- There are existing customers that require manufacturer's unopened cases (outside hospital)
- Current process for resolution of concealed shortages and other exceptions.
- Action Items: possibly add text concerning other parts of supply chain and current inference practices.

Assumptions

- Reader familiar with IATF documents (add web link)
- Reader familiar with US Pharmaceutical supply chain practices
- Use to individual companies to comply with current U. S. State and Federal Pedigree regulations
- The paper assumes Pedigree to mean the documentation of an origin and unbroken chain of custody or ownership. (In some jurisdictions).

Inference as a general concept

Within the context of the U.S. Pharmaceutical supply chain, Inference is defined as the process a supply chain partner uses to ensure there is enough evidence to accept the identity of packaged items without physically reading each identifier.

For example, a bar coded unit that is opened in a sealed case, the identity of the unit is inferred based on supporting evidence (add text: case does not have to be opened and items scanned).

Other General discussion items:

- Used in other product categories
 - Retail
 - Other Industries

The case for Inference

Supply Chain security, leading to Patient Safety: Besides the obvious impact on efficient movement of pharmaceuticals through the supply chain the industry quickly realized that this practice would induce more risk of foul play by breaching secure packaging parameters.

Efficient movement of Pharmaceuticals: The practice of inferring the contents of packaging based on secure corroborative information, best practices, trusted Trading Partner relationships and dividual security is thought as an appropriate means to provide the appropriate level of security and efficiency within the supply chain.

Inference became a topic of discussion within the industry as a result of discussions on serialization. (eg. many uses of discussion) As a result of industry serialization discussions and proposed Pedigree regulations (more us) specified that pharmaceuticals could not be received without validating that the items identified in the Pedigree were the same items that were received.

Example: a bar code example and an RRD example (for example: When bar codes for RRD now line speed requirements etc.) and RRD tags as the technology matures etc.) and RRD tags as the technology matures etc.) are used to mark individual items contained in further layers of packaging (inner



Traceability Adoption

Support Use of RFID within the supply chain

Security and Privacy Task Force

Work in Process

Traceability Adoption

Benefits beyond Regulatory Compliance

Business benefits of serialization and granular events data

Work in Process



Questions?

Bob Celeste

Director, Healthcare

GS1 Healthcare US

rceleste@gs1us.org





ORACLE®

Drug Supply Chain Integrity Strategy

John Danese
Strategy Director, Life Sciences Applications

Prepared for California State
Board of Pharmacy
March 11, 2009

ORACLE®



Safe Harbor Statement

The following is intended to outline our general product direction. It is intended for information purposes only, and may not be incorporated into any contract. It is not a commitment to deliver any material, code, or functionality, and should not be relied upon in making purchasing decision. The development, release, and timing of any features or functionality described for Oracle's products remains at the sole discretion of Oracle.



Update on Drivers

- **US States**
 - CA ePedigree law now 1/1/15 and federal preemption language
 - FL and other states are enforcing pedigree-only regulations today
- **US Federal**
 - FDA Amendments Act
 - Develop standards for UID and authentication tools by April 2010
 - FDA Globalization Act
 - Pilot for foreign finished drugs and ingredients announced
- **EMEA**
 - Italy, Belgium, others requiring serialization today
 - Turkey begins tracking serials mid-2009
 - EFPIA (European Federation of Pharmaceutical Industry Associations) has been working on a program to authenticate products at point of sale. 2009 pilot
- **GS1 Healthcare**
 - Global Traceability Standard for Healthcare

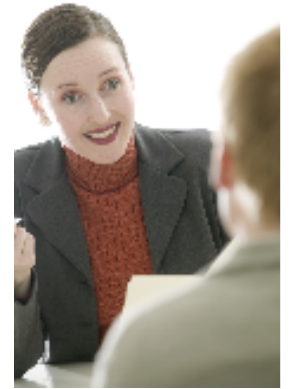


What are Manufacturers Doing?

- **We've seen a range of responses customers**
 - Forge ahead with serialization efforts and lighten up effort around pedigree
 - Refocus on EU products and serialization
 - Wait and see – put projects on hold and do nothing
- **Those continuing on current pace because serialization is inevitable**
 - They want control, rather than going down a path of trying to guess the next regulatory move
 - Many assume / hope there will be US federal action so they don't have to address different requirements state-to-state

...but there is considerable uncertainty about what the Fed will do

What Our Customers are Saying



“Current view is that this was an entirely compliance and risk-based activity, but **we are now looking at the cost of returns as well**”

“[The solution set we are piloting] **lacks robustness, maturity and functionality**”

“We’re **putting out bets on the EFPIA** approach in Europe”

“We’re **addressing the near-term European requirements on a case-by-case basis**, until the regulatory environment settles down and it makes more sense to take a more strategic global approach.”

-Large Pharma VP of Business Services

“**Returns/recall mgmt** is one of the motivators for the project”

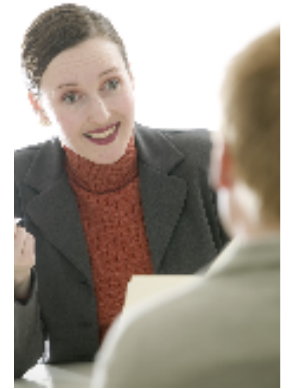
“We are planning to make a **vendor choice by end of 2009** and begin serialization implementation in early 2010”

“Frankly, we have been **cribbing many of our requirements from what we know about the Oracle pedigree and serialization strategy** in our discussions with business leaders”

“I polled fellow pharma and biotech CIOs in the area. They are **focusing on serialization and waiting for ePedigree requirements to clear up.**”

- Mid-Sized Pharma, CIO

What Our Customers are Saying



“We’re focusing on FL and TX, but are **concerned about PDMA enforcement**, so we’re **making sure we have ADR** with all of our manufacturers”

“We’re **concerned about the different ways we could receive data from our partners**...bar code standards, on-product markings, pedigree data.”

-Large Distributor, Regulatory Affairs Project Mgr.

“We are **focusing on enabling serialization** for our products on our packaging lines and in our distribution locations to **make sure we can sell into Europe** and to be prepared for what happens in the US”

-Large Pharma/OTC, Sr. eCommerce Analyst

“Our CMO partner is starting over with their pedigree and serialization pilot due to **viability problems with their solution provider**. We are now considering **taking this on in-house**. We’d would seriously consider Oracle if a solution were available by 2009 or early 2010”

- Small Pharma (outsources mfg) Director of SCM

Urgency Around Serialization Remains High

The screenshot shows a news article from the Centre Daily Times website. The article is titled "Survey Finds U.S. Biopharm Industry Is Moving Steadily Secure Distribution" and is dated Tuesday, Sep. 30, 2008. The sub-headline reads "67% of Respondents Reported Project at Least in Planning Stage or Already Underway Despite Mandated Regulations". The article text discusses the industry's progress in implementing item-level serialization, mentioning that 67% of manufacturer respondents are currently moving forward with their efforts. It also notes that 81% of respondents view serialization as an important compliance objective or beyond compliance, and 10% see it as a business priority. The article is partially obscured by a large grey arrow pointing from the left towards the right.

On the key question, "My organization's status for implementing item-level serialization," 67% of manufacturer respondents--represented by the first three categories below-- reported that they are currently moving forward with their serialization efforts:

- Serializing at least one product in commercial distribution
- Running a small-scale pilot
- Planning to start next 12 months

81% of respondents view serialization in my organization", 81% view it as an important compliance objective" or "an objective beyond compliance" or both; 10% responded that it is a business priority. When asked to identify the number one business reason for implementing quick and inexpensive compliance while 9% reported they had no opinion. When asked to identify the number one business reason for implementing serialization, the top answer given was "to enhance our reputation with customers, followed closely by "detecting counterfeiting," "greater inventory control," and "streamlining the returns process."

Value Proposition of Supply Chain Integrity

Business Benefits in Addition to Regulatory Compliance

- Global Counterfeiting exceeds **\$50B**
- Impacts **3.4B prescriptions** annually in US
- As much as **1%**, or **34M** doses could be counterfeit
- Systems to authenticate product
- Protect brand integrity
- Recall Management
- China effect – Heparin, Melamine, Lead

Product Integrity

- \$2B+ / year and climbing at 10% rate
- Controlling/Validating returns
 - Systems to detect counterfeits
 - Assess and authorize valid returns

Returns

Channel Integrity

- Diverted product impacting profitability
- Parallel trade
- Inventory shrinkage and damage control
- Identification/reporting of suspect shipments

Regulatory Compliance

- US State by State regulations
- FDA Amendments / Globalization Acts
- European Commission Pedigree / Authentication
- Serialization initiatives in Turkey, Italy, Belgium, etc.
- European Federation of Pharmaceutical Industries & Associations (EFPIA)



Supply Chain Integrity – Returns Repudiation

- \$2B+ / year and climbing at 10% rate
- In US, estimated 5% of line volume is returned to the manufacturer*
- One large branded pharma alone spends \$400M per year on return credit
 - Estimates 50% are illegitimate
 - Counterfeit
 - Returned at higher price than invoice
 - Product not purchased from manufacturer
 - Expired product (“*distributor offloads before expiry date*”)
- Current industry order fulfillment data tracking cannot detect illegitimate returns
 - Lots span multiple days/weeks/months of production
 - No way to track return to original sales order, shipment or invoice
- **Serialization allows a link between the return receipt and the original shipment/invoice**

Returns

*Source: California Board of Pharmacy estimates 2008

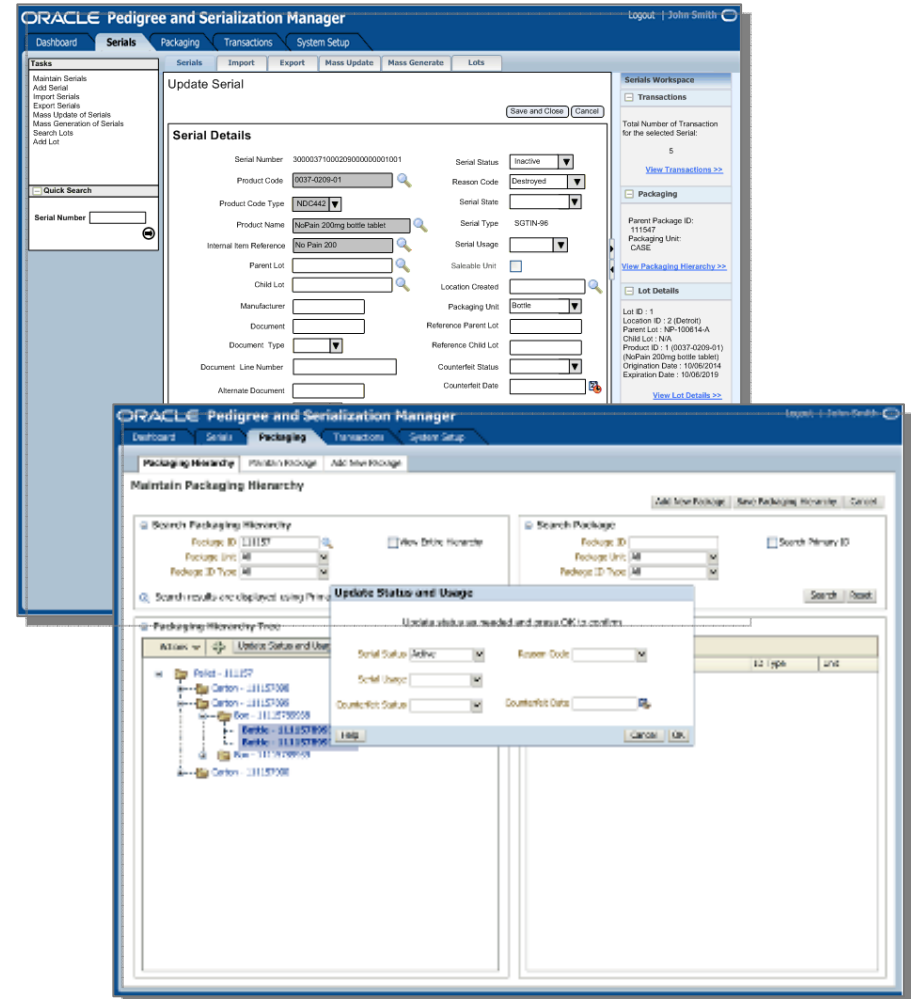
ORACLE

Oracle Pedigree and Serialization Manager

Ensure Supply Chain Integrity



- **WHAT** – An integrated mass-serialization and pedigree application that enables companies to implement mass-serialization of drug products and share serialized product data.
- **HOW** – Mass serialization management based on US (CA, FL, Federal) and international standards (GS1 Healthcare), regulations and industry consortium initiatives (EFPIA). Accessibility to data through role based application user interface, portal, web services, and file exchange along with business analytics for counterfeit threat assessment.
- **RESULTS** – Protect public health; Achieve compliance with global electronic pedigree, serialization, track & trace and product authentication regulations and industry mandates through product (and ingredient) data sharing; Protect brand integrity; Cost savings through validation of returns.

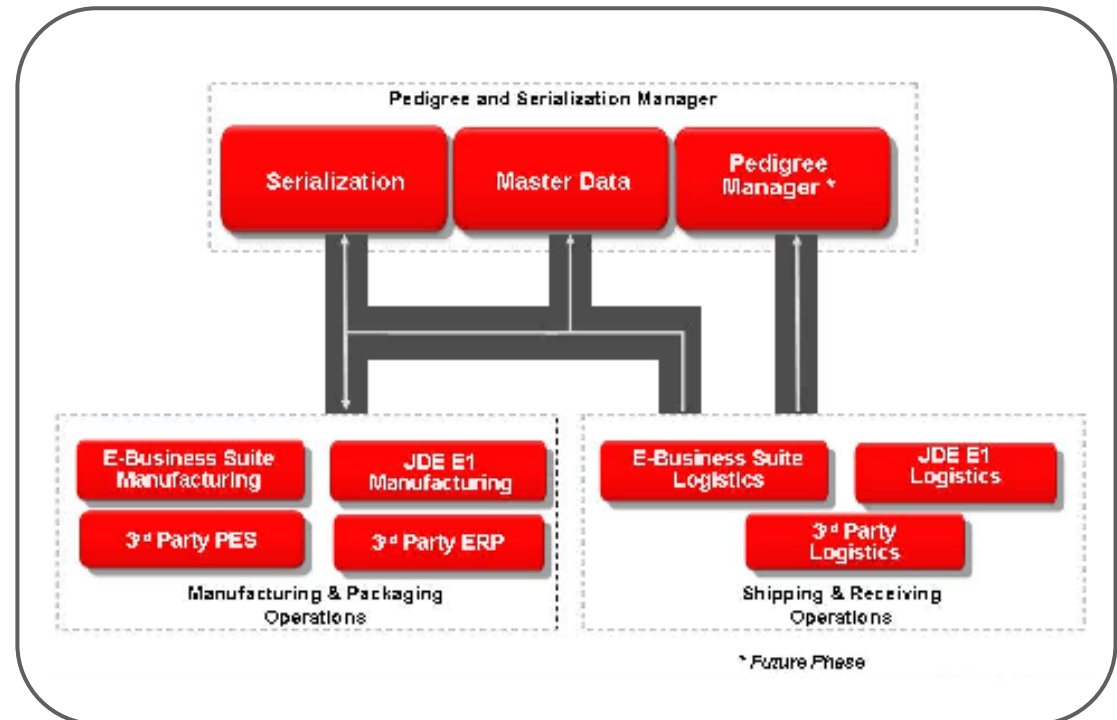


Deliver Out-of-the-Box Integration

Maximize Return on Investment & Reduce Complexity



- **WHAT** – A process integration pack to support integration of OPSM with Oracle and 3rd party manufacturing, packaging and logistics systems
- **HOW** – Populate OPSM with reference data from one or more existing back end systems and trigger serialization management from receipts, returns, shipments and packaging
- **RESULTS** – Integrated and reusable Oracle solution that delivers lower initial and ongoing TCO compared to EPCIS and pedigree-only solutions



Challenges of Existing Solutions

**EPCIS is a
generic
communications
framework &
data model, not
an application**



1 Custom Development Required

Customers have to build their own user interfaces, functional flows, system interfaces, labeling & serial generation logic

Customer1 *“The integration is bigger than any app we are integrating to”*

Customer2 *“Splitting solution into pedigree and EPCIS is not scalable”*

2 Not Industry Specific

EPCIS is built to store generic serial numbers, no concept of other pharmaceutical requirement such as lot control, Electronic Records & Signatures & other compliance requirements

3 Lack of Exception Management

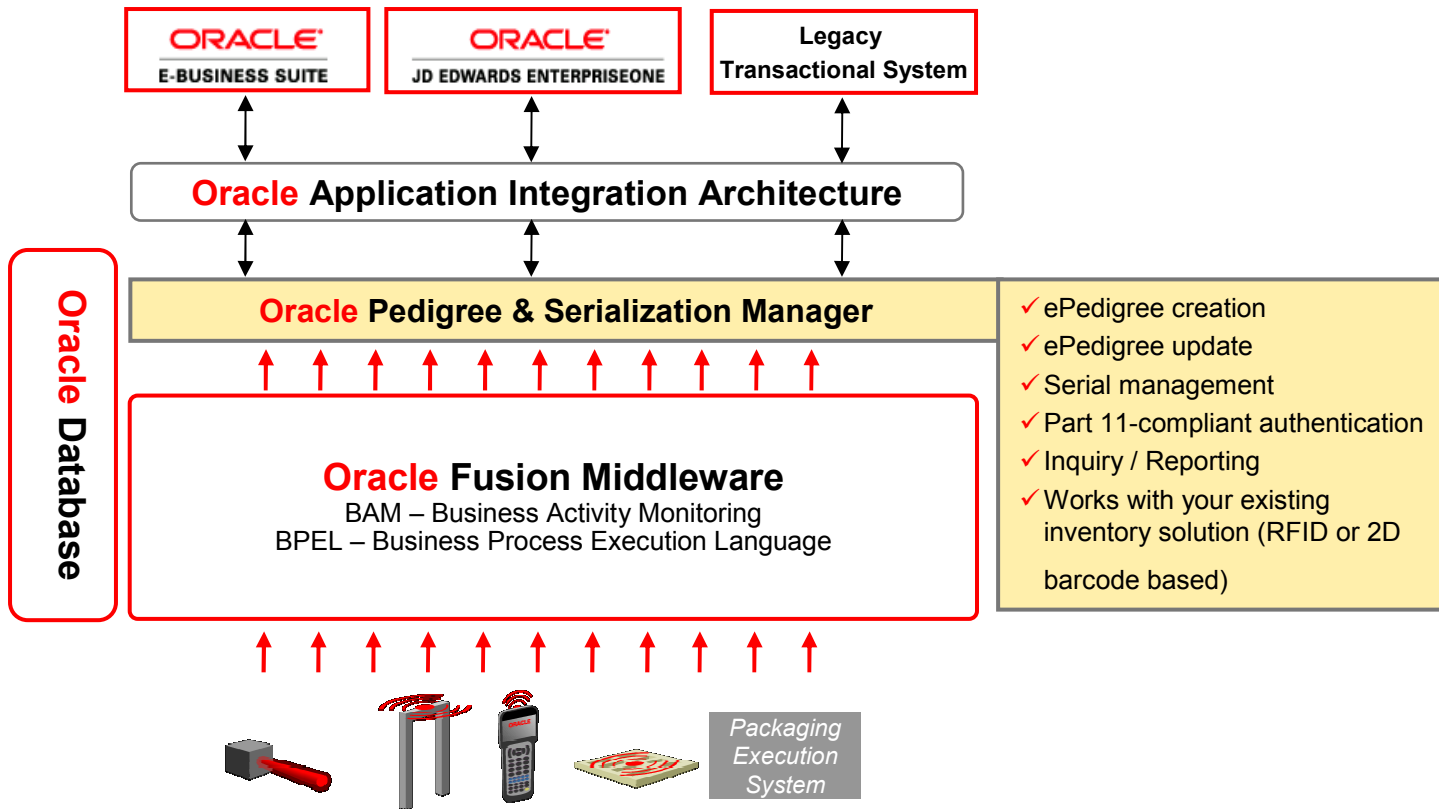
Not built for industry use cases, can't handle pharmaceutical exceptions – e.g., what if you don't receive what the pedigree says

4 Still Need a Pedigree System

Additional product and integrations for pedigree

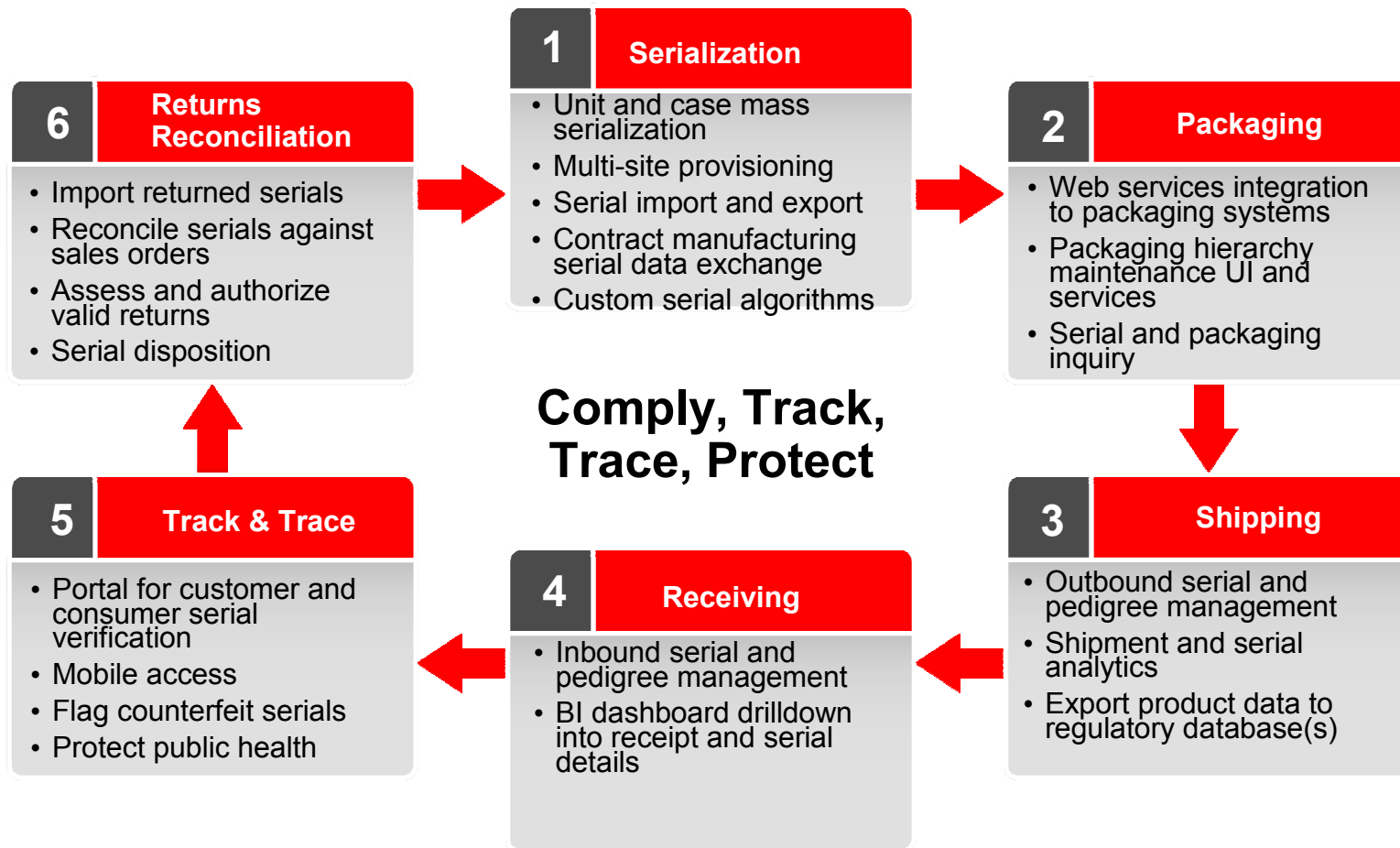
Oracle Pedigree & Serialization Manager

Interoperable Solution for Serialization & Pedigree Management



Drug Supply Chain Integrity

Serialization and ePedigree Management Application



Oracle Pedigree and Serialization Manager

Built with Users and Other Systems In Mind

User Interface

System Setup

- System Parameters
- Locations
- Products
- Serial Ranges
- Lots

Serials Workspace

- Find Serials
- Maintain Serials
- Inactivate Serials
- Serials Mass Update
- Export Serials
- Flag Counterfeits

Packaging Workspace

- Find Package
- Pack / Unpack
- Associate Serials to Package
- Assign Package Ids
- Packaging Level Serial Disposition

Transaction Workspace

- Find Transactions
- View Serials Transaction History
- Transaction Details
- Manage Exceptions
- Associate Serials
- Export Serials

Operational Dashboards

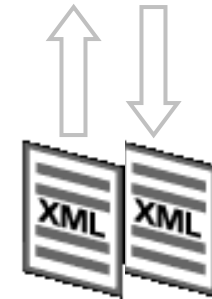


Web Services

	Generate Serials
	Create Serials
	Update Serials
	Inactivate Serials
	Get Serials
	Send Serials
	Pack
	Unpack
	Add Shipment
	Add Return
	Cancel Return



OPISM



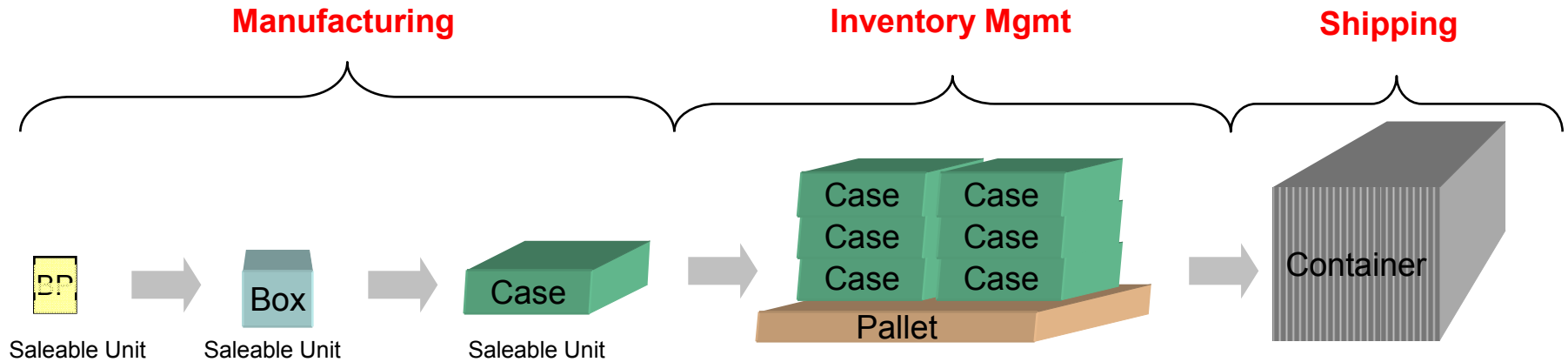
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Partner / Consumer Serial Validation Portal



- Manufacturers get additional views into where their product is consumed
- Customers can verify serial authenticity
- Customers can check for holds, expiration or recalls by lot or serial

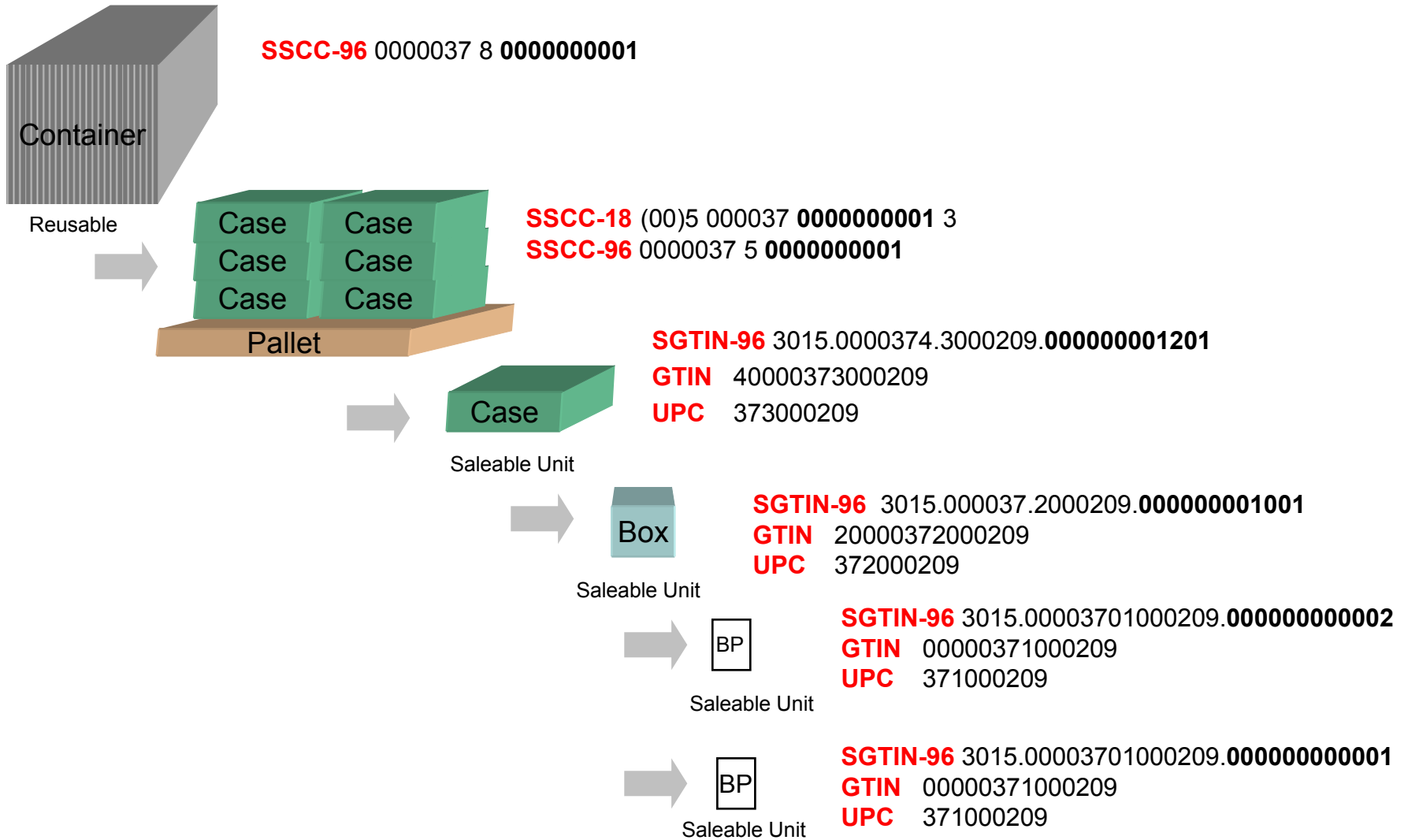
Serialization / Packing



- - Product Packaging - -

1	3.000037.1000209.000000000001	SGTIN-96	Blister Pack / Bottle / Vial	Serialized Product	
2	2.000037.2000209.000000001001	SGTIN-96	→ Box	Serialized Product	
3	2.000037.3000209.000000001201	SGTIN-96	→ → Case	Serialized Product	
4	(00)5 000037 0000000001 3	SSCC-18	→ → → Pallet	Serialized Packaging	
5	000037.5 0000000001	SSCC-96	→ → → → Container	Serialized Packaging	

Multiple Product Packaging IDs



Why Supply Chain Integrity Management?

It is Important

- Consumer Safety
- Brand Protection
- Problems are always Urgent

It is Universal

- Multi Industry
- Pharma, CG, Food & Beverage, High Tech
- Multi Enterprise
- Manufacturers, Distributors, Retailers

It is Hard

- Multi Instance IT Structures
- Lack of lot & serial control in many industries
- High volume -> requires scalability



Oracle Pedigree & Serialization Manager

Purpose-built for and with the pharma industry

Serialization and pedigree management
in a single solution

Delivering regulatory compliance
and business value

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