



California State Board of Pharmacy

1625 N. Market Blvd, N219, Sacramento, CA 95834

Phone: (916) 574-7900

Fax: (916) 574-8618

www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
E-PEDIGREE COMMITTEE MEETING
MINUTES**

DATE: June 24, 2013

LOCATION: Department of Consumer Affairs
First Floor Public Hearing Room
1625 N. Market Boulevard,
Sacramento, CA 95834

**COMMITTEE MEMBERS
PRESENT:** Randy Kajioka, PharmD
Rosalyn Hackworth, Public Member
Stanley C. Weisser, Rph

**COMMITTEE MEMBERS
NOT PRESENT:** Ryan Brooks, Public Member
Tappan Zee, Public Member
Amy Gutierrez, PharmD
Shirley Wheat, Public Member
Deborah Veale, Rph

**STAFF
PRESENT:** Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Judi Nurse, Supervising Inspector
Joshua Room, Supervising Deputy Attorney General
Desiree Kellogg, Deputy Attorney General
Carolyn Klein, Staff Manager
Laura Hendricks, Staff Analyst

Note: The webcast for this meeting is available at:
<http://www.pharmacy.ca.gov/about/meetings.shtml>

Call to Order

Chair Randy Kajioka called the meeting to order at 9:36 a.m.

Chair Kajioka announced 2 hours of continuing education credit would be available for attending the entire meeting.

Chair Kajioka conducted a roll call. Committee members present: Dr. Randy Kajioka, Rosalyn Hackworth and Stan Weisser. Committee members not present: Dr. Amy Gutierrez, Shirley Wheat, Ryan Brooks, Deborah Veale and Tappan Zee.

Note: Mr. Weisser temporarily appointed himself to the committee.

I. Next Scheduled Meetings of the E-Pedigree Committee for 2013

Chairperson Kajioka announced the remaining e-Pedigree Committee dates for 2013.

- September 26: Southern California
- December 10: Likely San Francisco

II. Presentation by TechN'Arts

On January 1, 2010 Turkey implemented a unit serialization e-tracking system for prescription drugs, somewhat similar to California's requirements. Mr. Taha Yayci provided a presentation via Skype on an overview of the requirements of Turkey's system, and how the system has operated since implementation. The presentation is available on the Board's website:

www.pharmacy.ca.gov/meetings/agendas/2013/13_jun_e_ped_presentation.ppt

Discussion

Mr. Yayci stated that from 2005 to 2009 a group worked to convince Turkey's politicians of the country's drug supply problems and to get the required legislation in place. It then took one year to get the technology in place - the system implementation took place in January 2010. The system has been fully functioning for three years.

The committee asked if inference was used in Turkey's system.

Mr. Yayci answered that solving the problem of inference was one of the biggest problems in implementing the system. Their solution was the creation of "Package Transfer Service (PTS)" which is a centralized file sharing platform that contains hierarchal data of which container holds each sellable unit and can be shared between each stakeholder in the system.

Mr. Yayci noted that wholesalers rate manufacturers based on their reliability and quality of service. If a manufacturer has a high rating then a wholesaler will not need to open a packager to scan each sellable unit inside. However, if they have a low rating, than a wholesaler will open each package and scan each sellable unit to ensure that the inference is correct.

Chair Kajioka noted that this is similar to the board's "trusted relationship."

Chair Kajioka asked Mr. Yayci to present at the July 2013 Board Meeting.

Mr. Yayci responded that he would like to attend the meeting in person. The board will work with him to coordinate presenting either in person or via Skype.

The committee asked if there were complaints from the industry about an increase in workload.

Mr. Yayci answered at first there was a lot of push back from the industry. To address this multiple workshops were held to discuss problems and concerns. However once the system was in place, the industry found it to be beneficial as it prevented diversion and counterfeits from entering the supply chain.

Ms. Herold asked if there were companies that could not sell drugs because they couldn't meet Turkey's deadlines.

Ms. Yayci answered that at the beginning of the project the required technology was not available for the system to work. It took six months from the January 2010 implementation date to get all of the technology in place, this resulted in the temporary slowdown of the healthcare system.

There were public comments.

III. Discussion Regarding Comments Submitted by the Board of Pharmacy in Response to Federal Legislation in April 2013

In April different versions of federal legislation to provide supply chain security were introduced in both the House of Representatives and the Senate. In May, the House passed its version. In the Senate, the Senate HELP Committee has passed its bill but the full Senate has not voted on this matter yet. If the Senate passes the bill pending there, the matter will go to a conference committee to resolve the differences between the two different approaches.

At the request of President Weisser, the board submitted comments on both versions of the legislation. These letters are provided in the meeting materials.

Discussion

Chair Kajioka asked if there were any updates on federal legislation in this area.

Mr. Room responded that the full Senate has not voted on the bill yet, but it is expected to be heard in the coming weeks.

Mr. Room noted that the letter to the House of Representatives was absent from the meeting materials. He added that the letter to the House expressed a general opposition to the House bill in preference to the Senate Bill. The letter has been added on the board's website.

Chair Kajioka provided a brief summary of the letter sent to the House of Representatives as follows.

- The House bill does not protect Californian's to the degree the board feels is necessary
- There is strong board support for having one standard for all 50 states to avoid variances
- The board strongly supports strengthening the supply chain to protect consumers on a national level

- The board is concerned that California’s law has an implementation date of 2015-2017, however the federal bill would push implementation out by 10 years

Mr. Room noted that another letter was sent to the House in November 2010 that was extremely detailed in outlining concerns that board had with the bill in its approach to supply chain security. The letter sent in April did not go into as much detail; however, it did reference the letter sent in November. Mr. Room added that another area of concern the board expressed in the letter was how counterfeit drug investigations by the regulatory agency would be accomplished.

Mr. Weisser encouraged the public to review the letter once it was provided on the website.

Mr. Room commented that some changes have been made to the bill in response to the board’s initial comments - including clarifying language on how counterfeit drugs would be provided to regulatory agencies for investigation.

Mr. John Valencia, representing a variety of manufacturers, asked if federal legislation would preempt California’s law and if the board would have the authority to take additional measures if the bill was passed.

Mr. Room answered that both the House and Senate bills have explicit preemptive language on certain subject areas, one of those being anything related to serialization and track and trace. The bills differ on national wholesale licensure standards. The House bill specifically preempts any additional state regulation of those entities, the Senate bill sets a floor but allows states to have additional requirements.

IV. Update on the Status of Pending CALIFORNIA Regulations on Requirements for the Serialized Numeric Identifier, Reporting the 50 Percent of Products Serialized by January 2015 and the Remaining 50 Percent by January 2016, and “Grandfathering” Parameters for Unserialized Products in the Supply Chain – 16 California Code of Regulations Section 1747. -1747.1

At the February Board Meeting, the board held a regulation hearing and approved regulation requirements for the following items. The specific language is provided in the meeting materials.

1. The serialized numeric identifier (section 1747)
2. The process for advising the board how a manufacturer will reach the 50 percent of its products that will be sold in California after January 1, 2015, and the remaining 50 percent by January 1, 2016 (section 1747.1)
3. How to designate unserialized product that may exist in the supply chain after the staggered implementation dates (section 1747.1).

Discussion

Chari Kajioaka noted that this subject has been discussed at multiple meetings and asked if the committee had any questions or comments.

Ms. Herold noted that the regulations have been undergoing review by the State and Consumer Services Agency since the beginning of April. She added that it has not yet gone to the Office of Administrative

Law (OAL) for review. Once received, OAL has the equivalent of 30 working days to either approve or deny it. The board hopes the process will be complete by September.

Mr. Room commented that both he and Ms. Herold have provided presentations to the industry on this subject, and they continue to receive questions on the application of these regulations and the general underlying requirement that manufacturers have 50% stock serialized by January 1, 2015. He added that as far as he is aware there have been no questions or comments provided that would prevent the regulation from continuing to be secured.

There was no public comment.

V. Discussion on GS1 Healthcare US's Implementation Guideline Applying GS1 Standards to US Pharmaceutical Supply Chain Business Processes, Release 1.0

At the board's last e-pedigree meeting, GS1 presented their new implementation written guideline. This guideline has been aigenized for this meeting to ensure interested parties are aware of its availability.

Although it takes about 100 pages to lay out the standards, Ms. Herold commented that the material is valuable in providing considerable background about tracking and tracing. The guidelines were provided for review in the meeting materials.

Discussion

There were no comments from the committee or the public

VI. Presentation by GS1 on Using EPCIS to Support E-Pedigree Requirements

Mr. Bob Celeste, senior director at GS1 Healthcare, provided a presentation to show how EPCIS can be used to support California pedigree requirements. The presentation has been attached at the back of these meeting minutes.

Discussion

Mr. Weisser asked Mr. Celeste what he thought of the presentation by Turkey earlier in the meeting.

Mr. Celeste answered that GS1 Global worked with Turkey on the successful implementation of their track and trace system. He added that it is important to work towards a standardized way of tacking products through the supply chain on a global scale.

Mr. Room asked if there are GS1 subscription costs.

Mr. Celeste answered that the cost for a manufacturer is about \$0.10 per product line (not per each). To get a Global Locator Number (GLN) it costs \$50. GS1 manages the system globally to ensure there are not repeated identifiers anywhere in the world.

Mr. Kajioka asked if there is an annual fee per product line.

Mr. Celeste answered that the annual fee is about \$0.01 per product line.

Mr. Room clarified that a Global Locator Number (GLN) identifies a geographic location. So a pharmacy would only need one GLN were a wholesaler may need multiple GLNs.

Mr. Celeste responded that a GLN can actually identify one geographic location or one entity. So a wholesaler might choose to only use one GLN despite having multiple geographic locations.

Chair Kajioka asked if there was a way to tell if a product unit code had already been used in the system. For example: If a pharmacist scanned a code then the next day another pharmacist scanned a different product that had the same code - would it be flagged as counterfeit?

Mr. Celeste answered that currently it would not, and it is a problem with pedigree.

Mr. Room commented that the board has always understood that all it can do is raise the barrier and create complications for those trying to compromise the supply chain. The immediate notification of a code being used twice requires a level of technology that is currently not available.

Mr. Celeste added that massive counterfeiting would be very difficult to do with the pedigree system.

Chair Kajioka asked if an inspector could go into a pharmacy and use the system to find were a specific bottle of medication had been in order to determine if there was fraud.

Mr. Celeste answered that the pharmacy should be able to access the system to immediately and verbally provide the inspector with the containers movement through the supply chain, though it could take some time to pull the full written report.

Mr. Room noted that looking at one bottle's information would not reveal to an inspector that there were no other bottles sitting on a different pharmacy's shelf with the same serial number. However, if the fraud was taking place in the pharmacy the inspector could do an inventory of the entire drug stock to see if they had duplicate serial numbers in their stock. Likewise, if the fraud was taking place at the wholesale level, it is possible to look at the history of all the products leaving the wholesaler to find duplicate serial numbers.

Mr. Weisser asked Mr. Celeste if decommissioning a serial number would help to flag fraud.

Mr. Celeste answered that if a serial number is decommissioned it essentially does not exist anymore. This makes moving a decommissioned item to be properly destructed difficult to do, even when it is being done for a completely legitimate reason.

Mr. Room added that what would be preferable to have certain "not to be dispensed again" codes rather than having the number be decommissioned entirely.

Mr. Room noted that when the board developed the language for the law in 2003, this type of system did not exist. The current language more closely meshes with a system where the entire supply chain history is provided with every transaction in the chain. In the system that Mr. Celeste described, each transaction only transmits the information from the immediate trading partner. The board needs to decide if this constitutes receipt of pedigree.

Chair Kajioka reiterated that the system allows for an entity to know exactly to whom they bought/sold an item to, although the entity cannot see further up or down the chain.

Chair Kajioka agreed it that it does not make sense to use language that was written 10 years ago and may have become outdated. He instructed board staff to identify end of life scenarios and proposals for the committee to vet-out.

Chair Kajioka commented that this has been a long process because the board's first goal is always consumer protection. However they did not want to create technological barriers for the industry that would prevent the dispensing of medications.

No public comment.

The committee recessed for lunch at 11:45 a.m. and resumed 1:03 p.m.

VII. Presentations and Questions from the Pharmaceutical Supply Chain on Their Readiness to Meet California's Staggered E-Pedigree Implementation Schedule

Time was set aside at this meeting to provide interested parties with the opportunity to provide information or presentations to the committee about implementation matters or simply to ask questions.

Discussion

A presentation on questions from the industry was provided by Mr. Bill Fletcher from PharmaLogic Solutions. The presentation has been provided following the meeting minutes.

Ms. Herold noted that many questions have been received on e-pedigree implementation and the board's staff is working on posting a Q+A section on the board's website.

Mr. Fletcher reported that many companies base their 50% serialization on projections of future sales. The industry would like to know what the ramifications would be if they do not meet their projections or if they exceed them.

Ms. Herold answered that the board is looking for long term compliance. If a company makes a good faith effort to be compliant and can show the board that their projections were solid, the board will be willing to work with the company to meet the 50% serialization requirement.

Mr. Kajioka added that the board was purposefully flexible in the definition of 50% calculation in the law.

Mr. Fletcher noted that the flexibility in defining 50% is what has lead to the confusion within the industry.

Ms. Herold responded that under the pending regulation requirements, prior to January 1, 2015 someone with the authority to bind the company must commit, under penalty of perjury, in the company's statement to the board how it will meet the 50% serialization requirement. If the board determines that the projection is totally unrealistic the board had the ability to reject it.

Mr. Fletcher asked what a manufacturer should do with a pedigree for a product they have produced with a serial number prior to wholesalers being required to accept pedigrees (July 1, 2016).

Mr. Room confirmed this.

Mr. Fletcher asked to clarify that starting in 2015 a manufacturer can produce products that have a pedigree even when there is no wholesaler ready to accept pedigrees.

Mr. Room answered while this is not ideal there is no legal problem. The intent behind the staggered implementation dates was to allow for testing of the system and prevent delays when the full implementation date is reached. Mr. Room added that the board views 2015 to July 1, 2016 as the "good faith" period during which manufacturers can establish their 50 percent threshold and being sending product through the supply chain so they can work out any problems in the system. During this time period the board will be most willing to work with manufacturers on issues rather than making it an enforcement issue.

Mr. Fletcher reported that in the fourth quarter of 2014 manufacturers will be producing products that will not actually leave their facilities until 2015 when the 50 percent requirement will take effect. The manufacturers would like to know if they will still be allowed to sell the products in California in 2015 if it was supposed to be part of the 50 percent but was not able to be serialized.

Mr. Room answered that he feels people are overly concerned about this provision, the board understands that manufacturing takes place over a period of time. The goal of this provision is to ensure that manufacturers have a plan in place to have all of their products fully serialized to be sold in California by 2016. It is important that they be as forthcoming with the board as possible and show that they are making a good faith effort to meet the requirements, given that some of the product was produced prior to January 1, 2015.

Mr. Fletcher added that this is a large undertaking and companies are seeing this provision as black and white. In the course of trying to plan for the 50%, the issue of what to do with their current inventory is a concern.

Mr. Room responded that in his opinion a company should perhaps target 60% serialization so that issues such as inventory would not be as big of a problem.

Chair Kajioka stated that the board wants to see forward progress and not have companies with only 2% of their products serialized by 2016.

Mr. Fletcher asked if SKU was an acceptable measure for the 50 percent requirement.

Mr. Room answered that the law allows for this.

Mr. Fletcher asked it was acceptable for a company to use product family as their 50 percent requirement.

Mr. Room answered that product family would be an acceptable way to measure the 50% serialization requirement.

Mr. Fletcher reported that some manufacturers are concerned that trade information will be going all the way down the supply chain if they create a pedigree for an entire pallet. So they have adopted a policy of creating an electronic pedigree per case so that when a wholesaler distributes that case, only the pedigree for the case would move to the next recipient.

Mr. Room commented that the law only requires tracking of the unit. Tracking above the unit is done for convenience and logistical reasons. Therefore the manufacturer could have pedigrees for each unit if they choose.

Mr. Fletcher asked the board to look at using a number higher than 48 for inference as proposed in a new pending regulation, as many companies package products in cases of 100 items or more. He also reported that inference on the pallet level is common practice in other industries and recommended that the board consider this.

Mr. Room responded that as written, the regulation would only apply inference to sealed, homogeneous cases. There is no inference applicable to pallets, however several comments received by the board have advocated for inference applied to pallets.

Mr. Fletcher reported that he receives many questions on inference in general. Particularly in regards to why the board gets so carried away with inference when a unit will always be scanned before it is dispensed - so any counterfeit drug would be caught before it reaches the consumer.

Mr. Room answered that this law was written based on the model created by the FDA as part of its counterfeit drug taskforce in 2003. California relied on the FDA's expertise to determine what the best model would be to prevent counterfeit and adulterated products from getting into the supply chain. The intent was to create a closed system where the participants in the supply chain have the ability to intervene at any point and prevent further transmission of counterfeit or adulterated drugs. The ability to intervene would not be there if the members of the supply chain were not scanning individual units, or at least inferring individual units, at every stop in the chain.

Mr. George Pennebaker, pharmacist, commented that he feels that the board has moved away from its original intent to prevent counterfeit drugs from reaching the consumers.

VIII. Discussion to Develop Regulation Requirements to Permit Inference as Provided by California Business and Professions Code Section 4163

Since July 2012, the board has several times released written requests for specific comments needed to develop possible regulations to authorize inference. The board received only a few comments in response to these requests for information, and few of the comments received were appropriately responsive to the board's inquiries. The comments provided by the supply chain can be obtained from the December 4, 2012 Meeting Materials of the Enforcement Committee:

<http://www.pharmacy.ca.gov/about/meetings.shtml#enforce>

At the March Enforcement and E-Pedigree Meeting, draft language was released for discussion purposes to develop the regulation language for inference. A copy of this proposal was provided in the meeting materials.

Following the March meeting, the board received additional comments specific to the language released in March. These comments were also provided in the meeting materials.

Discussion

Chair Kajioka asked Mr. Room to provide the primary issues that have been raised in the comments received by the board.

Mr. Room provided that the board would need to make a decision in the near future about what kind of aggregate containers it is comfortable applying any sort of inference to. Each time an inference is implied it is requiring a little less than that law, in the sense that you are not scanning individual units. So each instance needs to be supported by data that shows the inference is enhancing, rather than harming the overall security of the supply chain.

Mr. Weisser asked if enough comments were received to determine if a large portion of the industry shares a similar opinion on inference.

Ms. Herold responded that they received comments from associations that represent players in the supply chain. The intent of allowing for comments at this time is to make the regulation more meaningful at the front end. Ms. Herold added that the board needs to make decisions on inference and certification; however, she did not feel the committee meeting was the best setting to do so. She offered to integrate the comments received into the regulation so it would be easy to see the comments on each point of the language.

Mr. Room added that the draft language was provided to encourage comments and was not intended to be the final regulatory proposal. The board still needs to make decisions on the concepts before it is ready to line edit.

Chair Kajioka directed board staff to prepare a document integrating the language and the comments received for review by the committee.

Mr. Weisser commented that if the document could be provided at the next E-Pedigree meeting in September, then a recommendation could be made to the board at the October Board Meeting.

Ms. Herold noted that it may be better to have part of the discussion at the July Board Meeting to get a general consensus on where the board would like to go. Otherwise it would almost certainly mean the committee recommendation could not be made to the board until its meeting in January 2014.

Mr. Room added that he recommends not re-writing the regulation based on the comments received, without the input of the full board.

Chair Kajioka offered that the language provided was a good starting point and some good comments were received. An integrated report would allow the committee to make a stronger recommendation to the board.

Ms. Herold and Mr. Room offered that the language and the comments could be combined in a report to the board.

Ms. Herold added that the general opinion seem so be that the industry wants inference- perhaps in a more board sense than the board feels comfortable with.

Mr. Kajioka commented that you need to be able to certify the integrity of the product at each step in the chain in order to validate that it is safe to dispense to the consumer and to determine where a problem may have occurred.

Mr. Room expressed his gratitude to those who took the time to submit detailed comments.

No public comment was recieved.

IX. Discussion Concerning Possible Regulation Requirements on the Certification Process Needed to Comply with California's E-Pedigree Law

At the March Enforcement and E-Pedigree Meeting, the board distributed possible regulation language for the certification of each sale and purchase into the e-pedigree record.

A copy of the certification proposal was provided in the meeting materials. Also included in this section is proposed language for a regulation to specify board access to e-pedigree information during inspections.

Written comments submitted following the March meeting that pertain to these proposals were made available as part of the comments provided in the meeting materials.

Discussion

Mr. Room commented that the largest issue that the board needs to resolve with this proposal is what the party is actually certifying. In other words, to what level of information are they verifying or confirming as true or correct for the next recipient of that product.

Mr. Room suggested that a document integrating all the comments received be created.

Chair Kajioka directed board staff to prepare a document integrating the language and the comments received for review by the board.

No public comment was submitted.

X. Discussion Concerning Possible Regulation Requirements on the Use of Drop Shipments in an E-Pedigree System

The board has also begun work on the process by which drop shipments will be addressed in the e-pedigree system. The reference in California's Business and Professions Code with respect to drop shipments is provided below.

4163.1. Drop Shipment by Manufacturer

- (a) For purposes of Sections 4034 and 4163, "drop shipment" means a sale of a dangerous drug by the manufacturer of the dangerous drug whereby all of the following occur:
 - (1) The pharmacy, or other person authorized by law to dispense or administer the drug, receives delivery of the dangerous drug directly from the manufacturer.

- (2) The wholesale distributor takes ownership of, but not physical possession of, the dangerous drug.
 - (3) The wholesale distributor invoices the pharmacy or other person authorized by law to dispense or administer the drug in place of the manufacturer.
- (b) The board may develop regulations to establish an alternative process to convey the pedigree information required in Section 4034 for dangerous drugs that are sold by drop shipment.

In February, the board released a request for comments on drop shipments. One comment was received before the March Enforcement Committee Meeting and was provided in the meeting materials.

During the March committee meeting, the committee saw a PowerPoint presentation about drop shipments prepared by HDMA. An excerpt of the minutes of this meeting and the HDMA PowerPoint were provided in the meeting materials.

Board staff has not drafted a regulation proposal. The proposal submitted by industry as part of the February request for comments is:

Proposed Draft: Limitation on Reach of Drug E-Pedigree Requirements in the Instance of “Drop Shipment” Sales of Dangerous Drug Products in California (Authority: Bus. & Prof. Code Sec. 4163.1)

“For the purposes of Business and Professions Code Section 4163.1, when a manufacturer utilizes the “drop shipment” means of sale for a dangerous drug product as defined by that section, only those entities involved in the physical handling, distribution, or storage of a dangerous drug product, are required to provide or receive the “pedigree” required by Section 4034. Any entity, including but not limited to a wholesale distributor, that is not involved in the physical handling, distribution, or storage of the dangerous drug product sold by means of “drop shipment,” is not required to provide or receive a pedigree for that dangerous drug product, [even if such entity holds legal title to the dangerous drug product]. For purposes of this section, facilitating the distribution of a product by providing various administrative services, including processing of orders and payments, [even if holding title,] shall not, by itself, be construed as being involved in the physical handling, distribution, or storage of a product.”

Discussion

Mr. Room commented thus far the board has struggled with the topic of drop shipment and has not reflected a high level of satisfaction of any of the presentations or answers it has received on the subject.

Mr. Room reported that there are three main ways of approaching drop shipment as follows:

1. Not treat them any differently, and require that you have full pedigrees for all drop shipments.
2. Still require pedigrees to be reflective of all owners of a drug for a drop shipment, but somehow allow for either time tolerances or paperwork tolerances that would better accommodate pedigree requirements to the logistics of how drop shipments are actually handled in the supply chain.
3. Anyone who is not involved in the actual handling of a drug being dropped shipped would not have pedigree appending requirements for a wholesaler who does not have to certify their participation in the pedigree transaction.

The comments provided by John Valencia on behalf of his clients reflect the third approach to drop shipments.

Mr. Room added that a drop shipment must have the three characteristics described in Business and Professions Code Section 4163.1, one of which is the shipment must be directly from a manufacturer to a pharmacy or other dispenser.

Mr. Weisser commented that the drop shipment system has been around for a long time and usually goes directly from the manufacturer to the pharmacy or practitioner for patient use.

Mr. Valencia, representing two specialty manufacturers, requested that the committee make a recommendation on the proposed language so that the full board can move forward with its approval.

Mr. Room commented that perhaps the language needs to be modified slightly.

Mr. Valencia expressed that his clients would be happy to review and comment on any edits the board made.

Ms. Hackworth provided that she feels language needs to be added to handle how the product will move back up the supply chain.

Angela Blanchard from HDMA commented that they support moving forward with the proposed language provided by Mr. Valencia and are open to working on fine tuning the language.

Mr. Room stated that he would make several modifications discussed by the committee and bring it to the board meeting.

XI. Additional General Discussion

Dr. David Holness, CEO of PharmaDocs, commented that authentication may be a way to fill the gaps that exist in the track and trace system. PharmaDocs has such a system.

XII. Closing Comments

Adjournment

2:28 p.m.



GS1 STANDARDS

THE ROLE OF GS1

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

- **109** member service 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 IS BOTH GLOBAL & LOCAL



GS1 Global Office

Identification, creation, development and maintenance of standards and our foundational architecture, coordination with other international bodies, development of training programs...not-for profit organization ...

GS1 Member Organizations

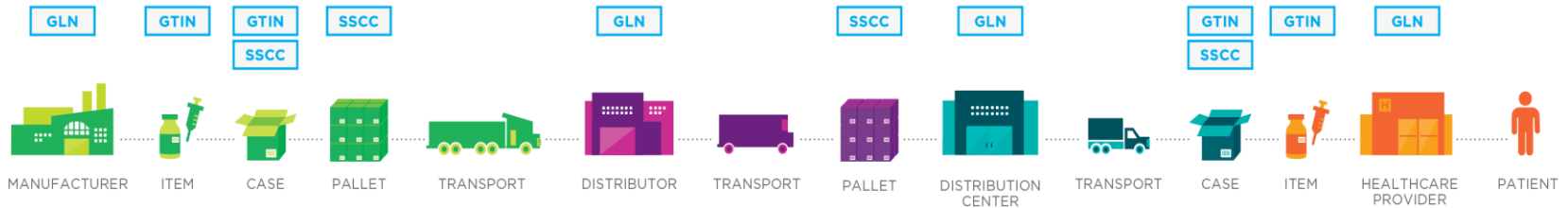
Local offices in 110 + countries around the globe, such as **GS1 US**
Implementation of standards, local regulatory adjustments, community management and relationship management with local governments and regulatory agencies...

GS1 STANDARDS IN HEALTHCARE



IDENTIFY: GS1 SYSTEM IDENTIFICATION NUMBERS

GLN Global Location Number **GTIN*** Global Trade Item Number* **SSCC** Serial Shipping Container Code **EPC*** Electronic Product Code™



CAPTURE: GS1 SYSTEM DATA CARRIERS

BARCODES

EAN/UPC



GS1-128



ITF-14



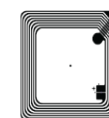
GS1 DataBar™



GS1 DataMatrix



EPC-ENABLED RFID TAGS



SHARE: GS1 INTERFACE STANDARDS FOR ELECTRONIC COMMERCE

MASTER DATA GLN Registry for Healthcare®, Global Data Synchronization Network™ (GDSN®) **TRANSACTIONAL DATA** eCom/EDI **PHYSICAL EVENT DATA** EPC Information Services



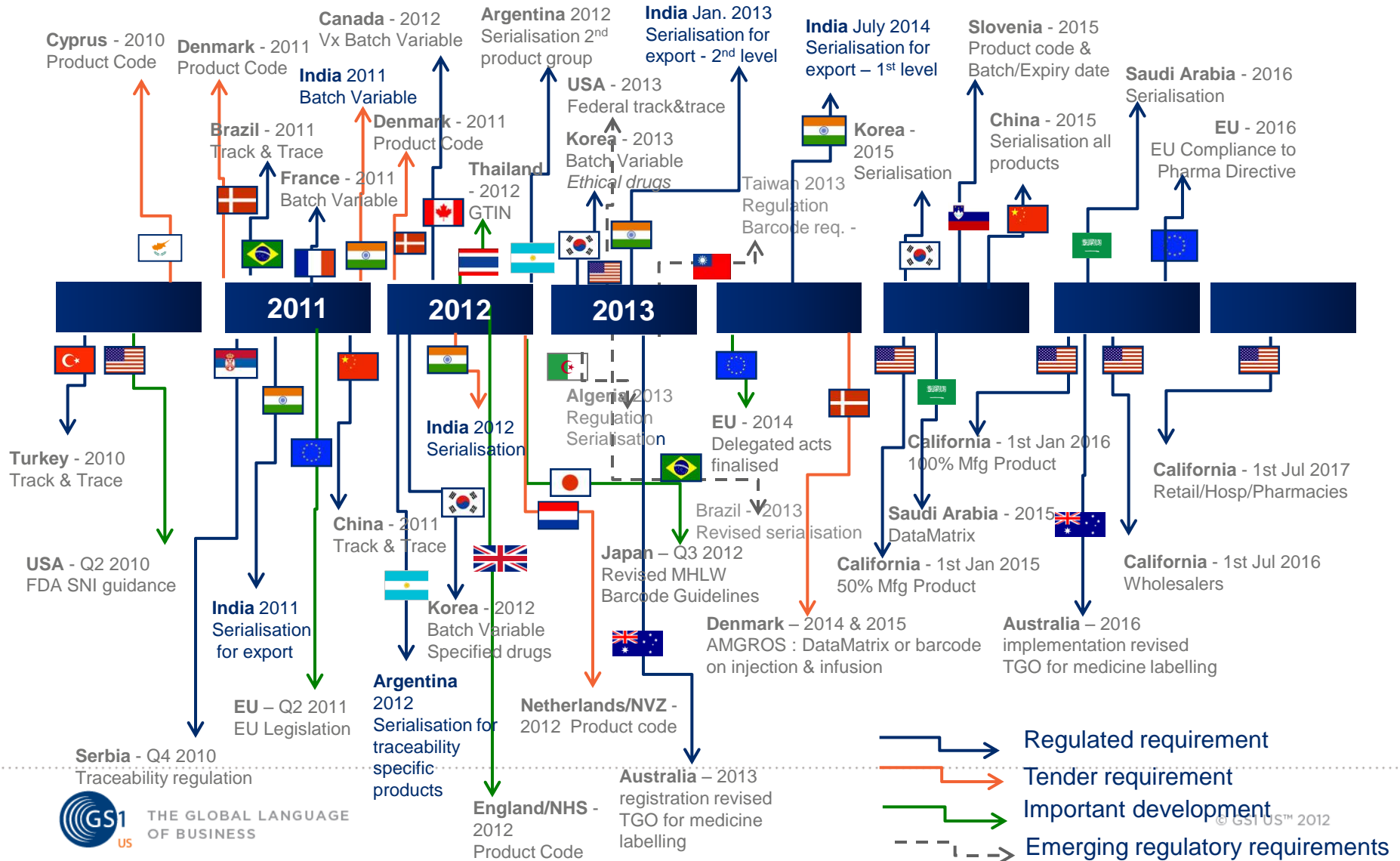
CONTENT

- Purpose
- The trouble with Pedigrees
- EPCIS based pedigree data
- Holding data vs having access to data
- A counterfeit in the middle of the supply chain
 - DPMS
 - EPCIS
- Massive counterfeiting
 - DPMS
 - EPCIS
- Pharmacist purchasing on grey market
- Inspection process considerations

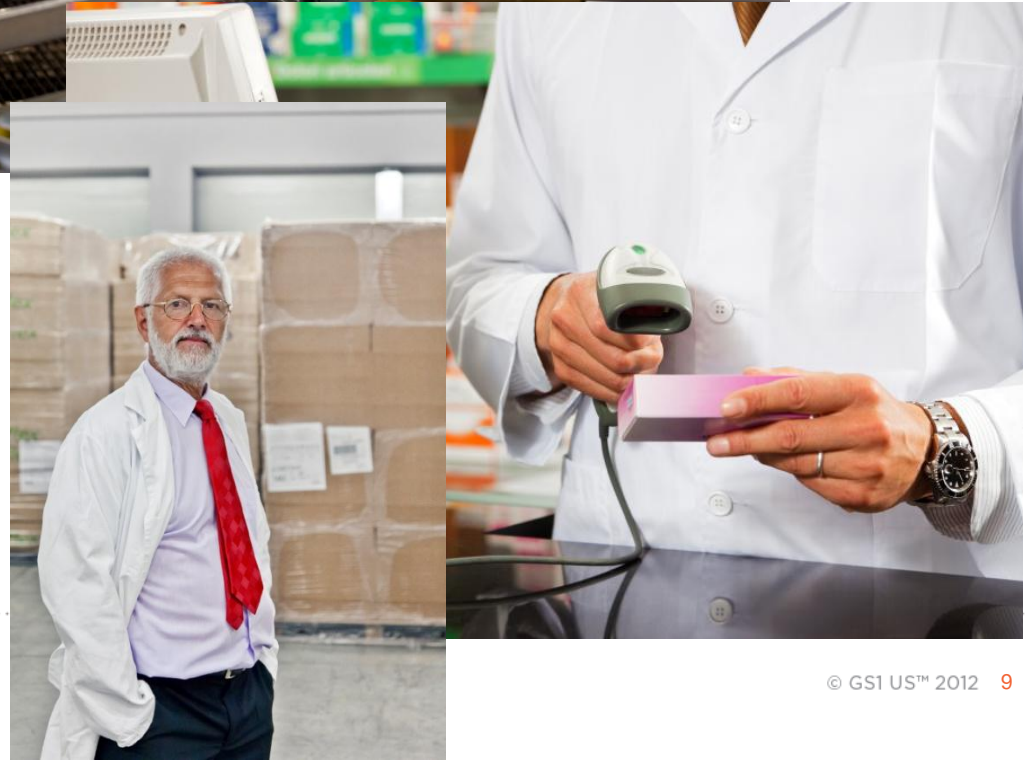
PURPOSE

Companies in the industry are making significant investments in hardware and software, Initially, we would like a signal that an EPCIS based solution looks viable. In the short term, we would like (as we did with the Pedigree Messaging Standard) a statement that would indicate that pedigree data delivered via an EPCIS platform is acceptable for compliance.

PHARMA – GLOBAL CODING & SERIALIZATION REQUIREMENTS



THE TROUBLE WITH PEDIGREES



In Order for Pedigree to work, we need a high level of automation.

THE TROUBLE WITH PEDIGREES

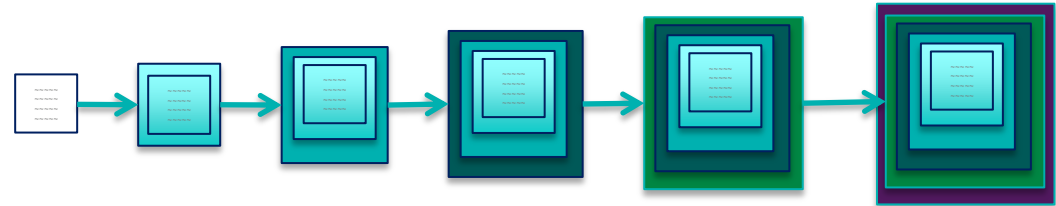


In regular transactions, products are ordered and information is transacted on the product ID rather than the full set of product data. This also applies to the company identifiers (Customer #, etc.).

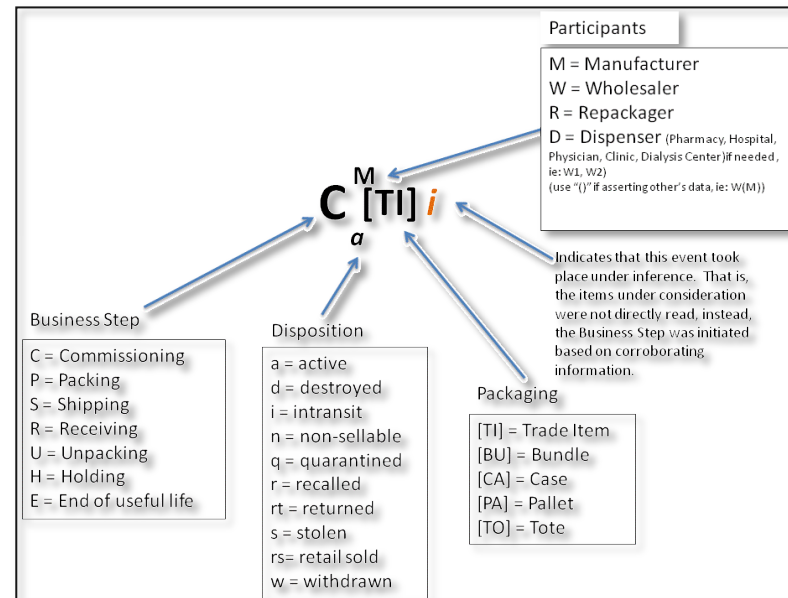


PEDIGREES VS EPCIS BASED PEDIGREE DATA

Pedigrees are document based. Where each trading partner adds their document to the last with no current mechanism for error corrections.



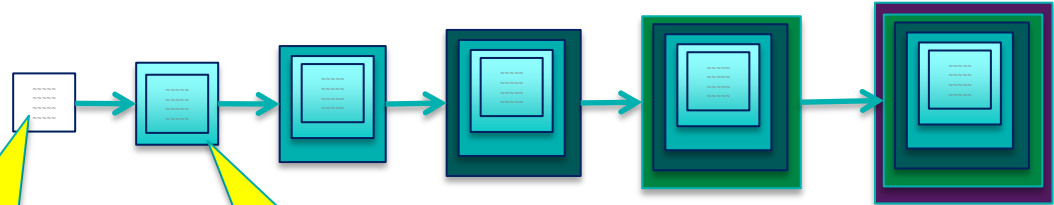
EPCIS is event based. Allowing more flexibility to describe what took place and allows error correction.



PEDIGREES VS EPCIS BASED PEDIGREE DATA

Pedigrees can contain data that is difficult to verify.

- By trading partners
- By inspectors



Manufacturer X's Pedigree:

Ship From: Manufacturer X,
123 Sunset Blvd, Sacramento
CA 95834

Ship to: Wholesaler Y, 562 El
Camino Real, Los Altos, CA
94022

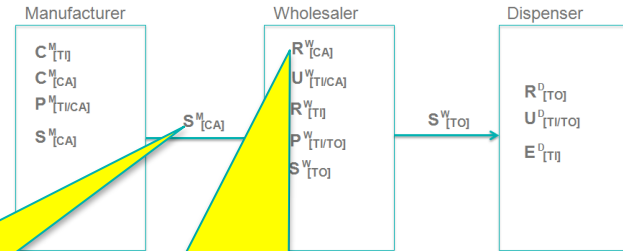
Wholesaler Y's Pedigree:

Ship From: Manufacturer X, 51
Main Street, Newark, DE, 19711

Ship to: Wholesaler Y, 562 El
Camino Real, Los Altos, CA
94022

PEDIGREES VS EPCIS BASED PEDIGREE DATA

EPCIS uses independently verifiable IDs



Manufacturer X's EPCIS data:

Transferred By ID:
GLN/0312345123459

Transferred To ID:
DEA/40695843

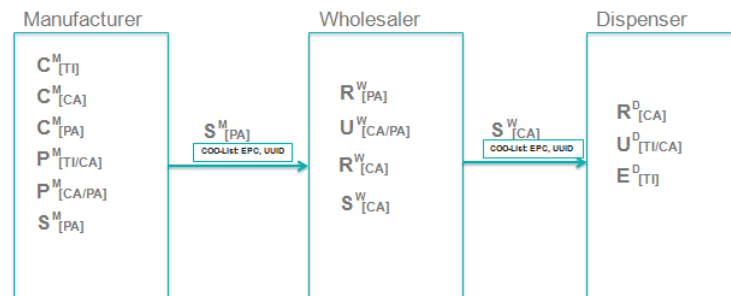
Wholesaler Y's EPCIS data:

Transferred By ID:
GLN/0312345123459

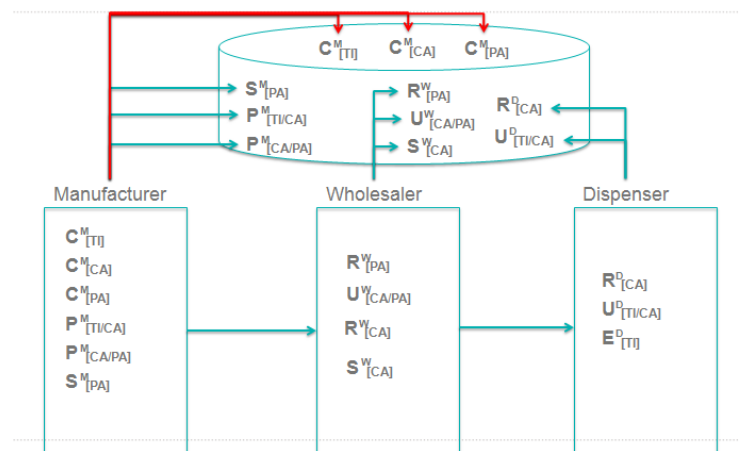
Transferred To ID:
DEA/40695843

EPCIS BASED PEDIGREE DATA

AVOIDING SENDING MASSIVE DUPLICATION OF DATA



EPCIS can be used in a number of architectural settings.



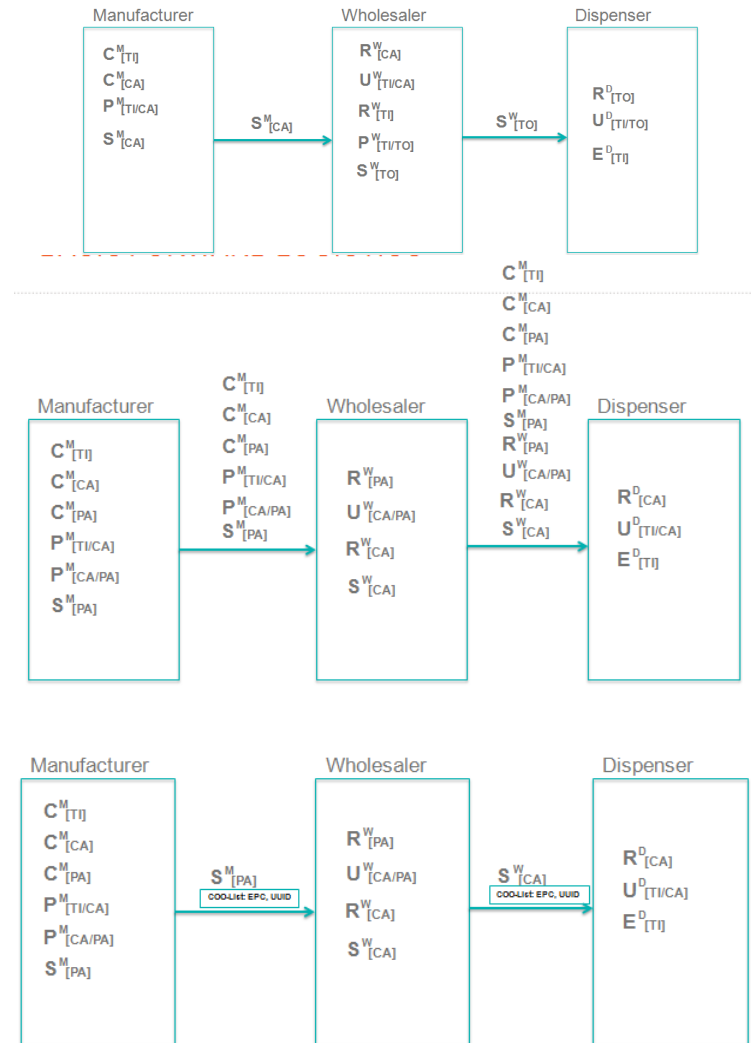
EPCIS BASED PEDIGREE DATA

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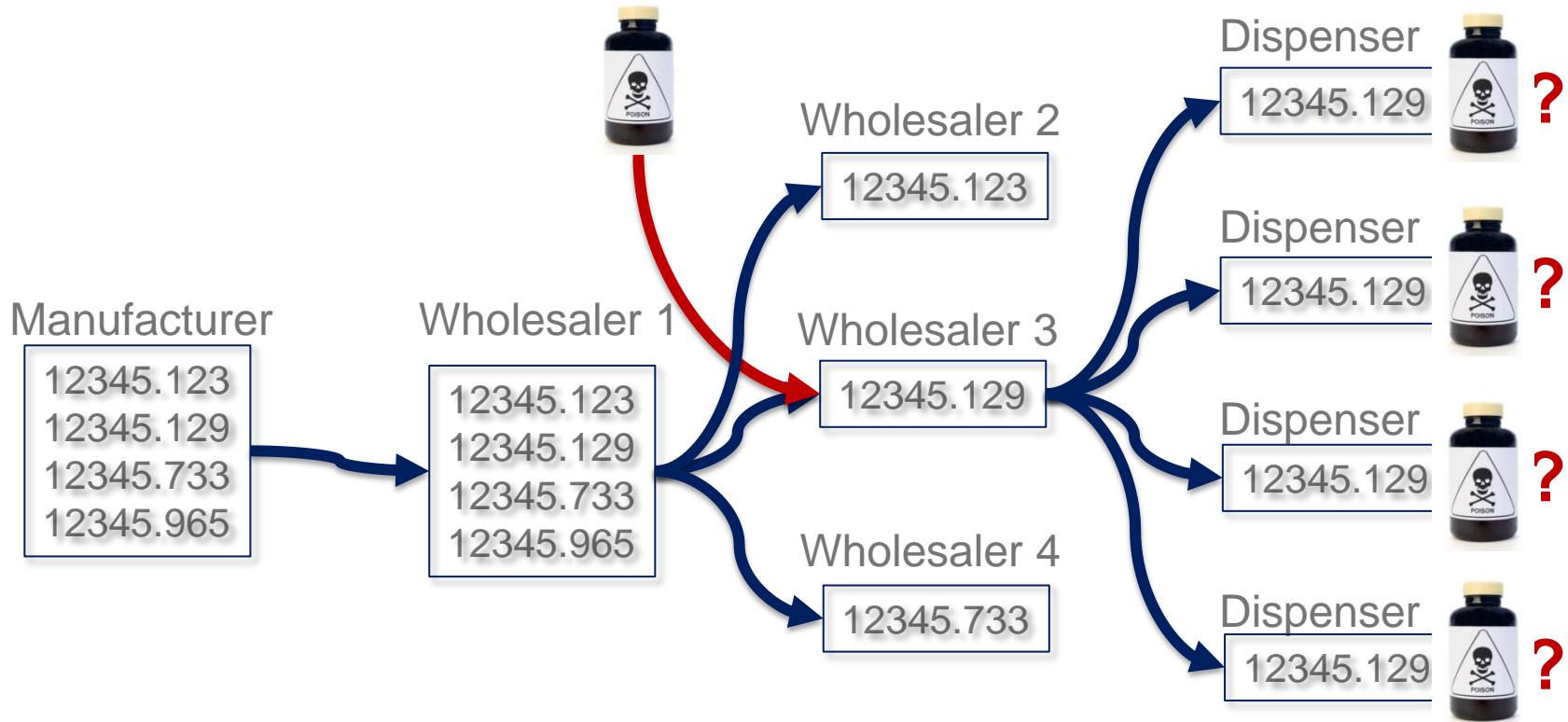
The Rx Guideline v1.0 describes how EPCIS can be used to share pedigree data via supply chain events in a 1 up / 1 down fashion.

We are trying to avoid entirely duplicating DPMS in EPCIS (passing all data redundantly).

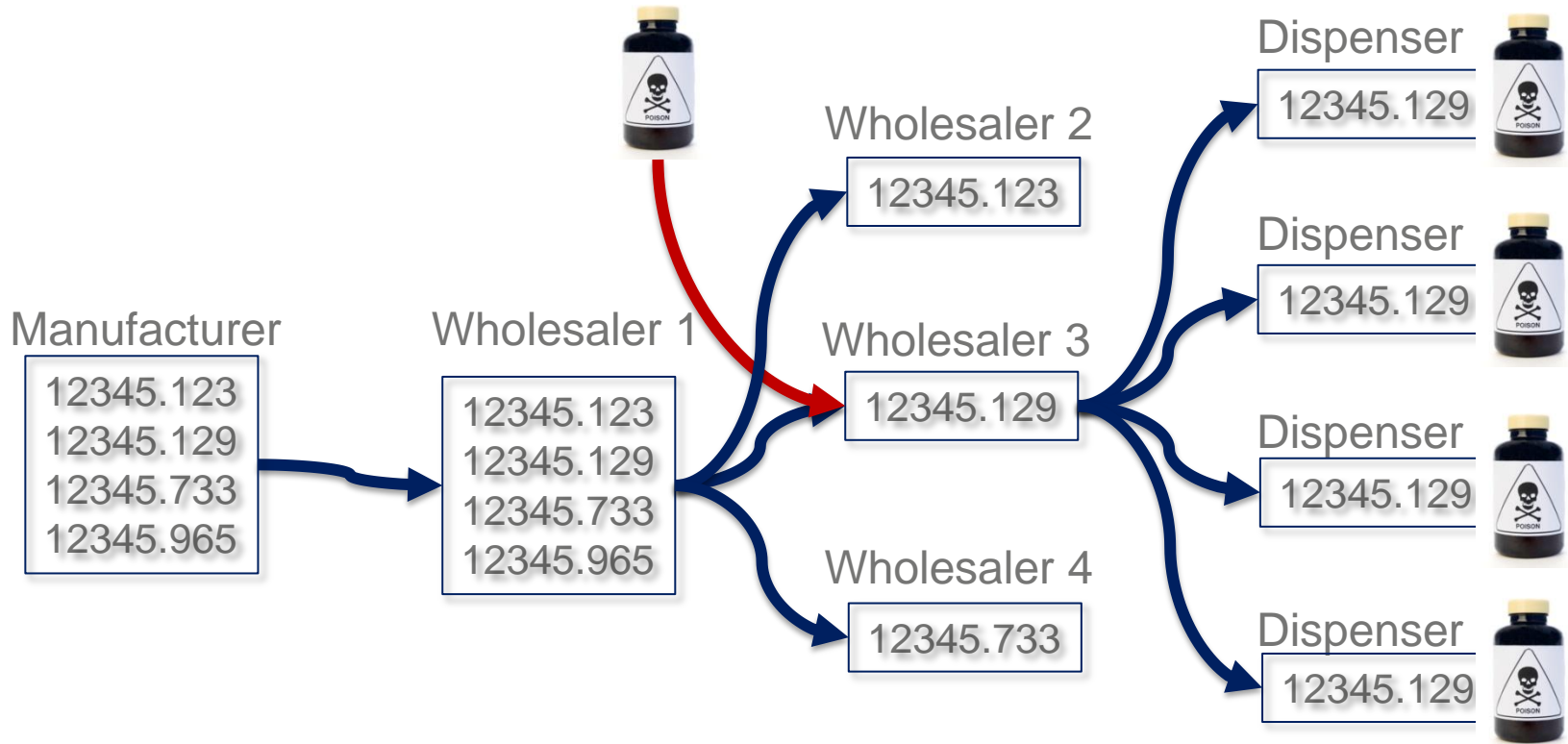
By including a “Breadcrumb trail” or Chain of Ownership list including a minimum set of data and provide the trail back to the manufacturer.



A COUNTERFEIT IN THE MIDDLE OF THE SUPPLY CHAIN

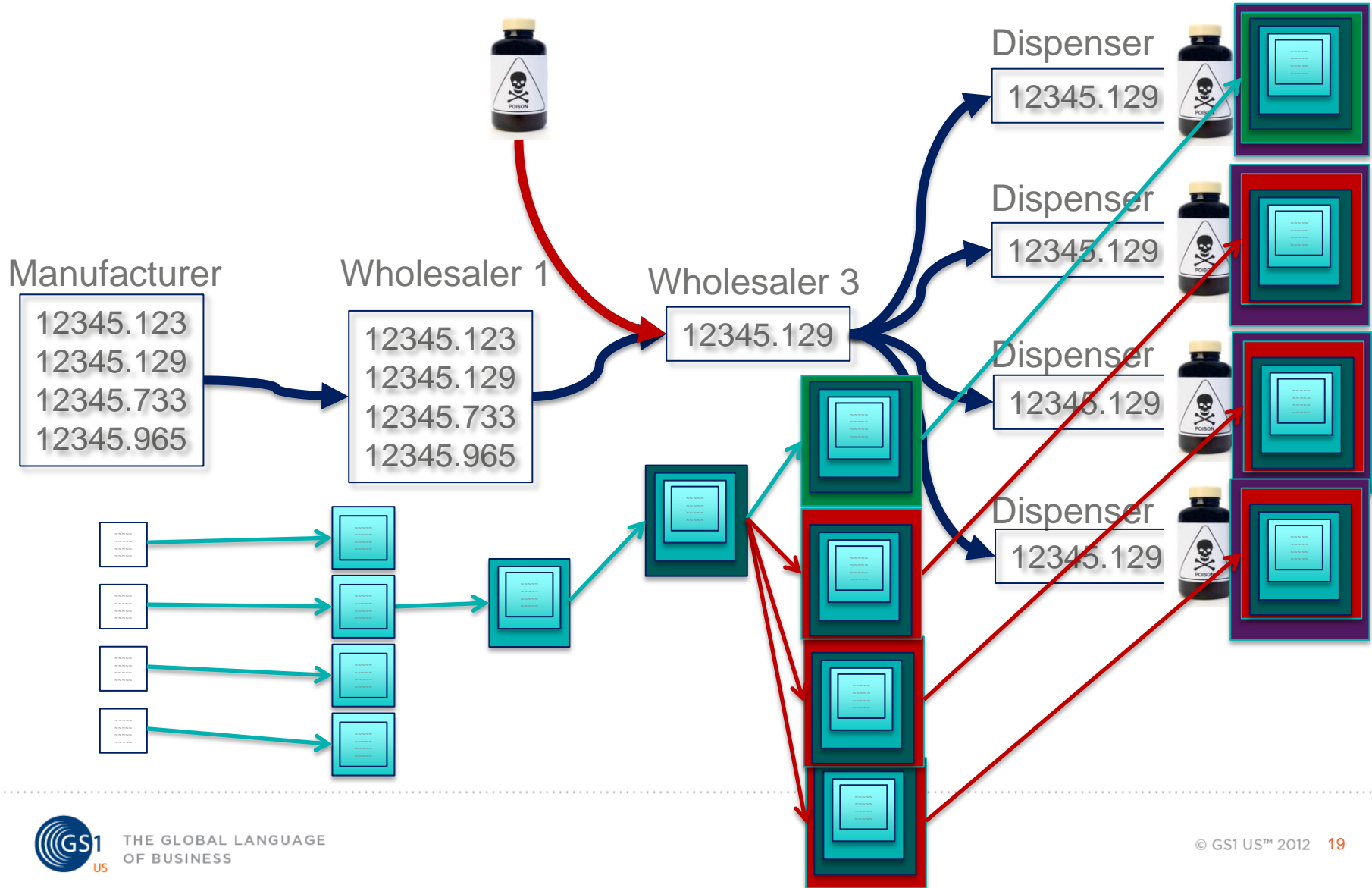


A COUNTERFEIT IN THE MIDDLE OF THE SUPPLY CHAIN



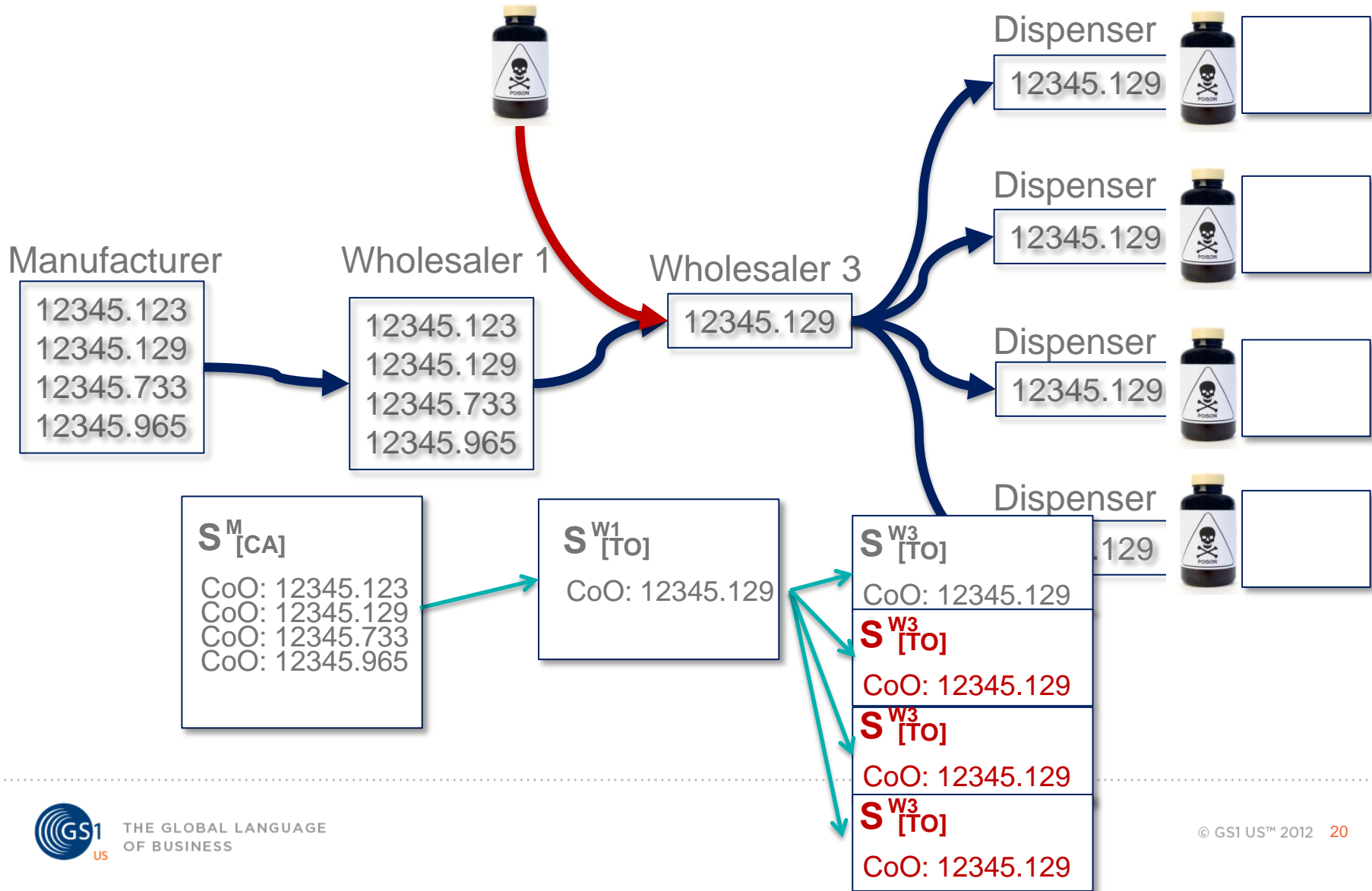
A COUNTERFEIT IN THE MIDDLE OF THE SUPPLY CHAIN

DPMS



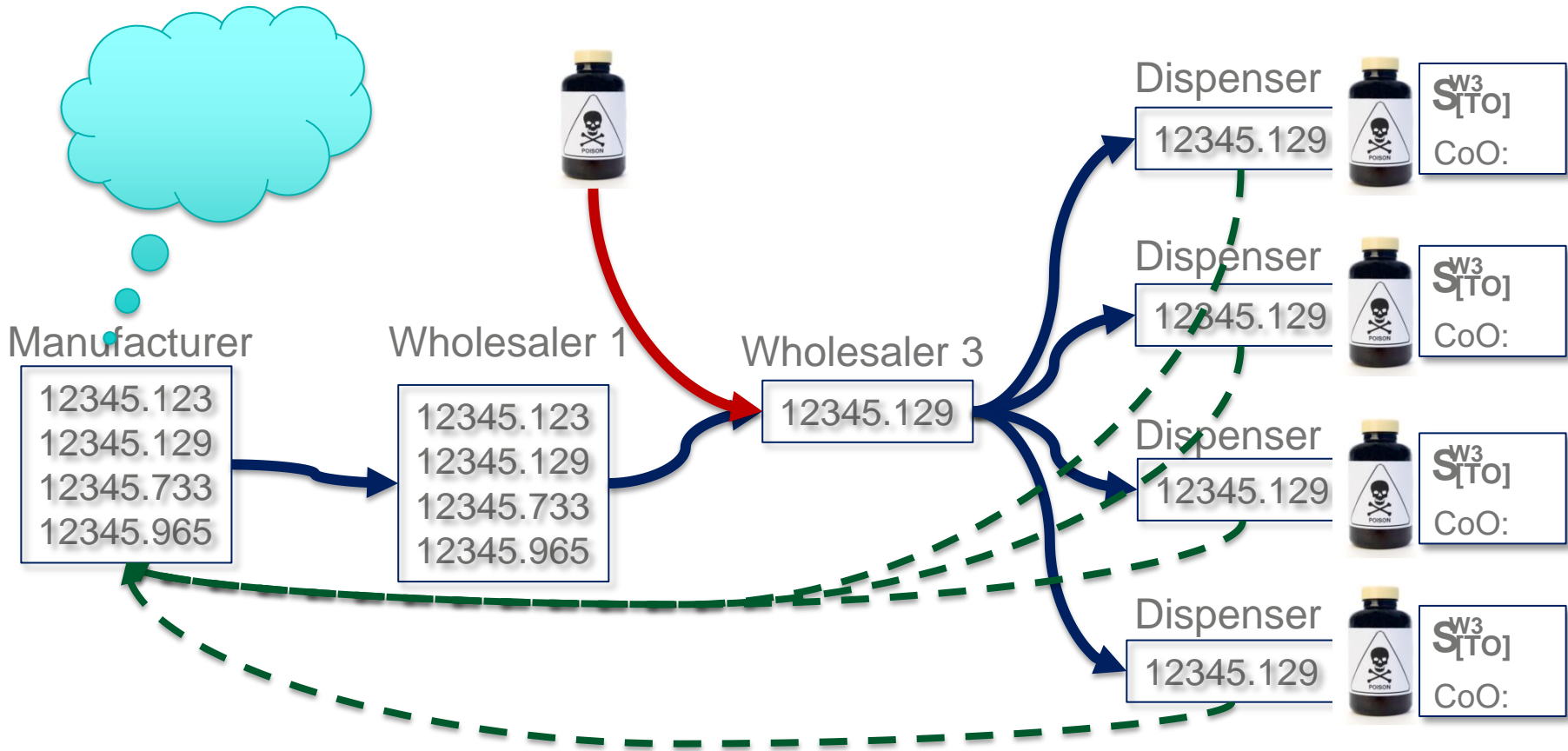
A COUNTERFEIT IN THE MIDDLE OF THE SUPPLY CHAIN

EPCIS

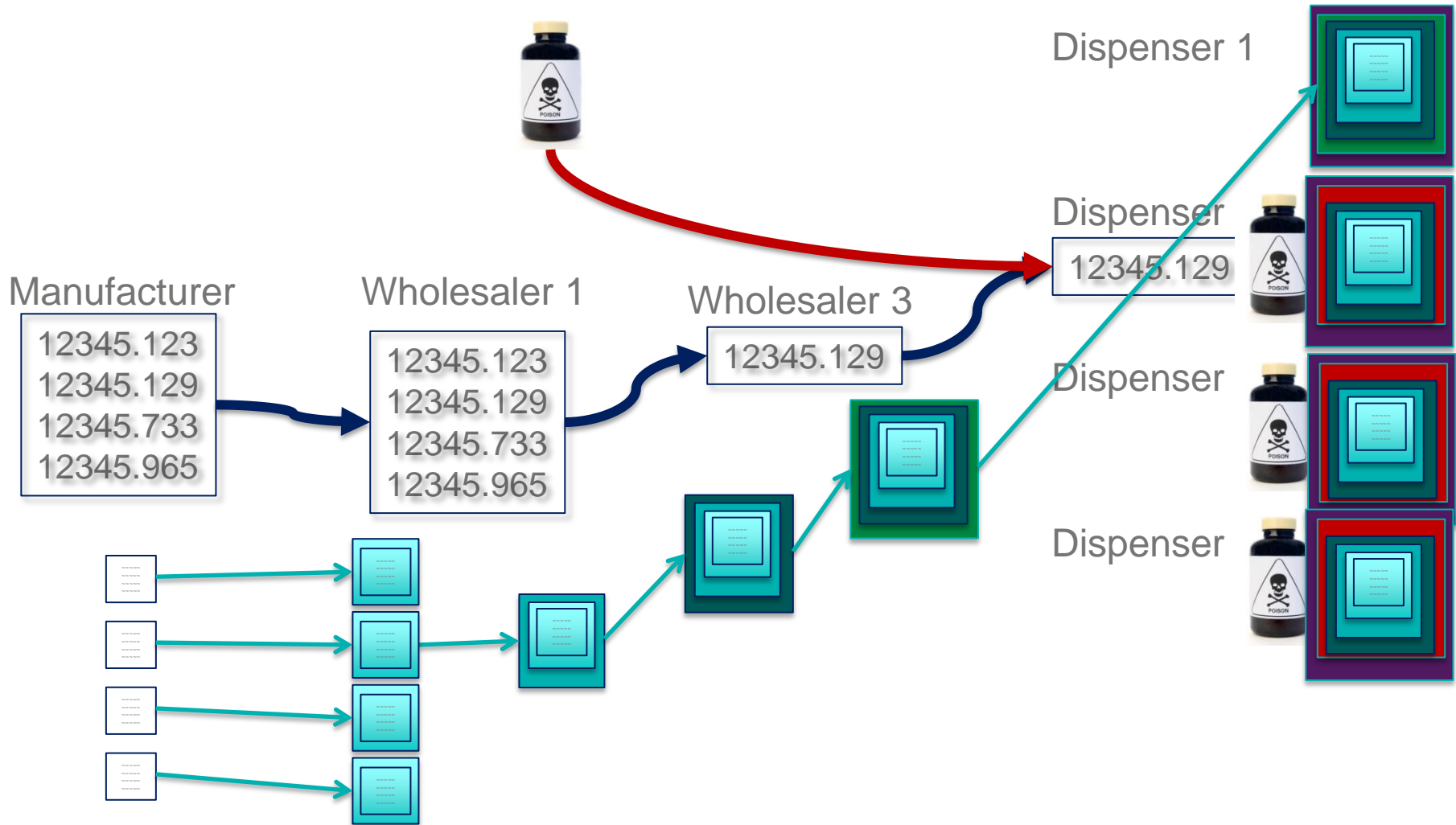


A COUNTERFEIT IN THE MIDDLE OF THE SUPPLY CHAIN

EPCIS



A PHARMACIST PURCHASING OFF THE GREY MARKET





THE GLOBAL LANGUAGE OF BUSINESS

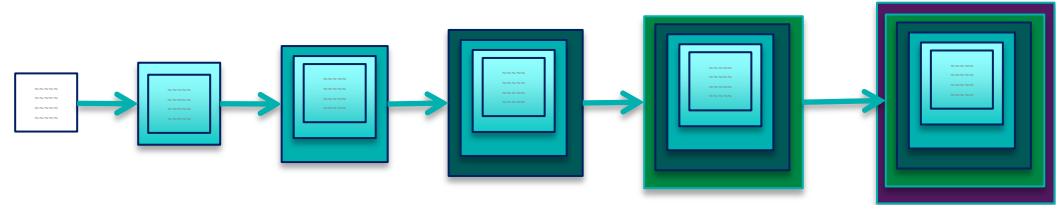
THE INSPECTION PROCESS



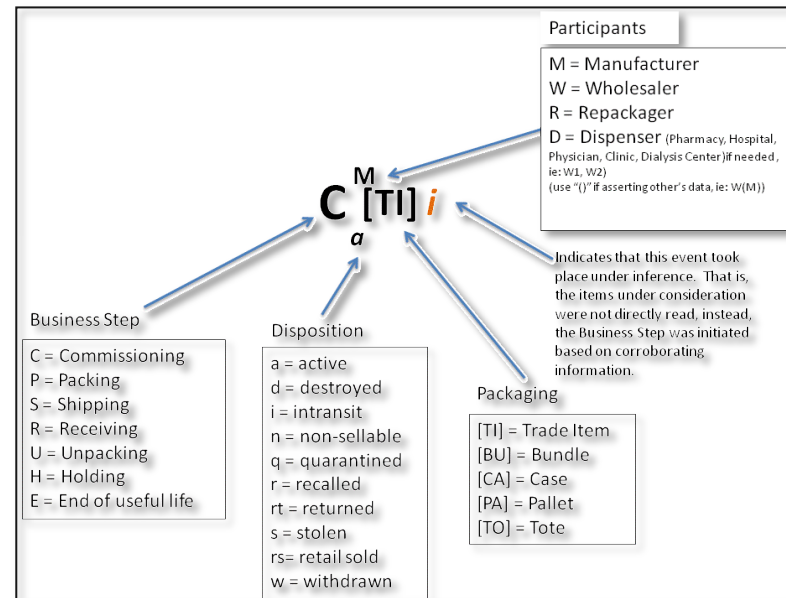
INSPECTION PROCESS

THE INSPECTOR WILL ENCOUNTER THE SAME ISSUES AS THE SUPPLY CHAIN

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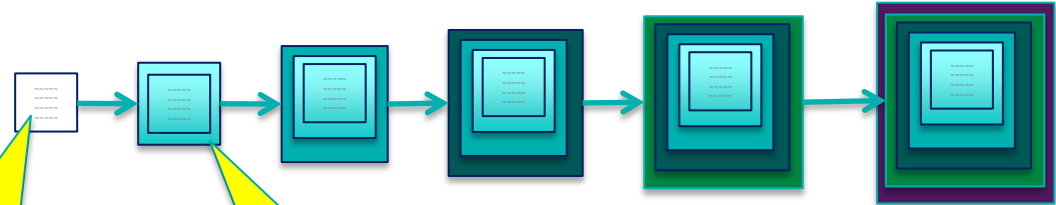


INSPECTION PROCESS

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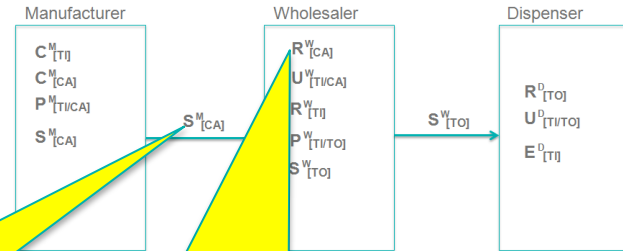
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DEA/40695843

Wholesaler Y's EPCIS data:

Transferred By ID:
GLN/0312345123459

Transferred To ID:
DEA/40695843

INSPECTION PROCESS

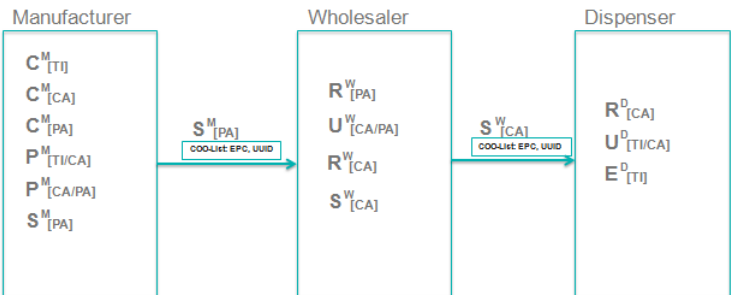
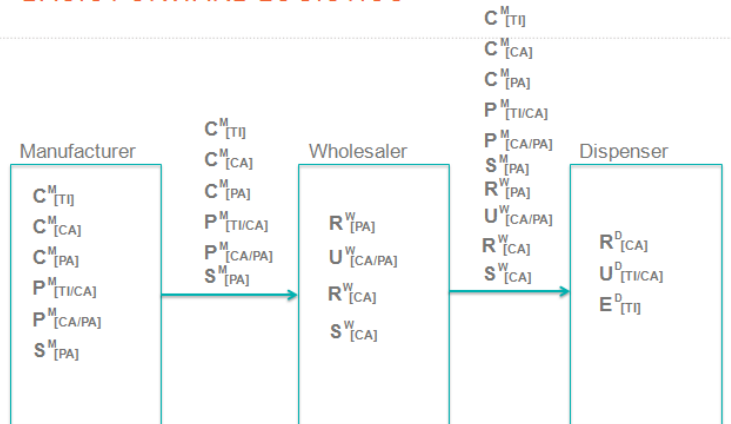
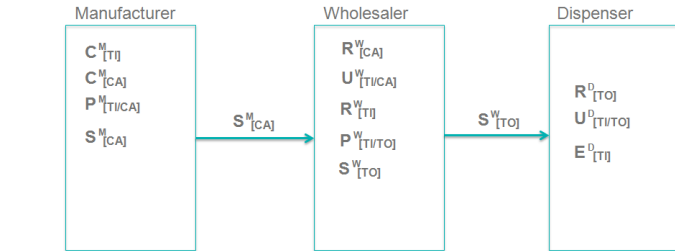
THE INSPECTOR WILL ENCOUNTER THE SAME ISSUES AS THE SUPPLY CHAIN

The Rx Guideline v1.0

describes how EPCIS can be used to share pedigree data via supply chain events in a 1 up / 1 down fashion.

We are trying to avoid entirely duplicating DPMS in EPCIS (passing all data redundantly).

By including a “Breadcrumb trail” or Chain of Ownership list including a minimum set of data and provide the trail back to the manufacturer.



SUMMARY OF EPCIS ADVANTAGES

- Provides comparable security to other business transactions
 - Orders, Invoices, Advance Ship Notices
 - Includes capability to manage exceptions
- Tested in pilots
 - Pfizer / McKesson
 - Abbott / McKesson / VA (via GHX)
- More effective than DPMS
 - Less master data errors
 - Provides auditable data
 - Better suited to supply chain use
- Flexible standard format
 - Valuable information is accessible for other business uses
 - Allows trading partners to expose data only about the actual products traded
 - Can support many architectures (Distributed/Central/Semi-Central)
 - Allows trading partners to choose the amount of data provided to them
 - Publishable set of standard messages and queries

CONTACT INFORMATION

CORPORATE HEADQUARTERS
Princeton Pike Corporate Center
1009 Lenox Drive, Suite 202
Lawrenceville, NJ 08648 USA

T +1 609.947.2720

E rceleste@GS1US.org

www.GS1US.org

Connect with the GS1 US community on





THE GLOBAL LANGUAGE OF BUSINESS

REFERENCE SLIDES



EPCIS BASED PEDIGREE DATA

AVOIDING SENDING MASSIVE DUPLICATION OF DATA



A Pedigree currently calls for:

Trading partners to send full sets of data on the product, companies or locations, certifiers and production run (exp date and Lot#).

PRODUCT DATA

NDC OR GTIN REPRESENT THE FULL SET OF PRODUCT DATA

- NDC: 1234-5678-90
 - Name: Product FG, 100 ct 10MG Tablets
 - Desc: 100ct bottle of Product FG, 10MG Tablets
 - Strength: 10, UOM: MG
 - Dosage Form: Tablet
 - Container Size: 100, UOM: ct
- NDC: 1234-5678-90
 - Name: Product FG, 100 ct 10MG Tablets
 - Desc: 100tab bottle of Product FG, 10MG Tablets
 - Strength: 10, UOM: MG
 - Dosage Form: Tablet
 - Container Size: 100, UOM: ct

COMPANY DATA

GLN, SGLN, DEA, ETC.

Address Types:

- Business Location
- Transferred By
- Transferred To
- Ship From Location
- Ship To Location

Attributes:

- Name:
- Street Address:
- City:
- State:
- Zip:
- Country:

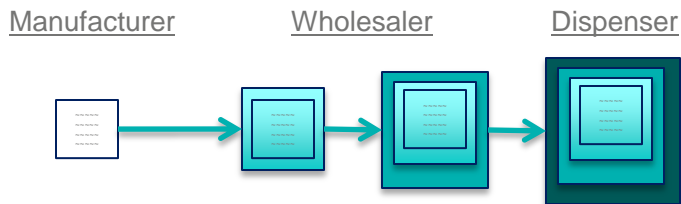
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A Pedigree currently calls for:

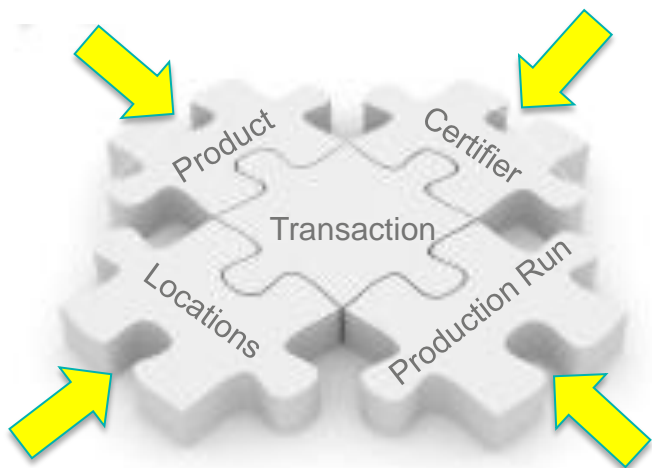
Trading partners to send full sets of data on the product, companies or locations, certifiers and production run (exp date and Lot#).



... and for each subsequent trading partner to append their own pedigree data.

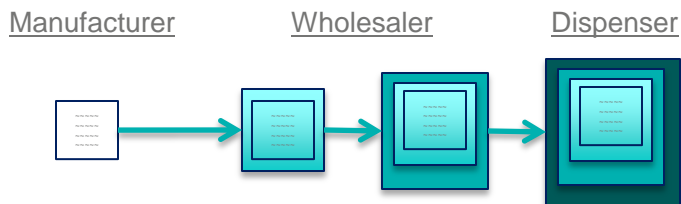
EPCIS BASED PEDIGREE DATA

AVOIDING SENDING MASSIVE DUPLICATION OF DATA



The result is that ...

The majority of data in a pedigree is repeated again and again, for each trade item in a shipment (ex: each bottle in a case or pallet).



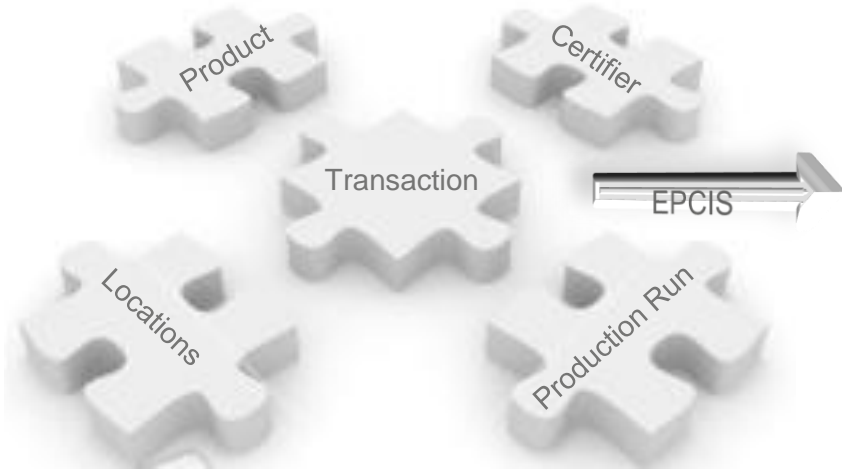
... this repetition is magnified as each trading partner adds their data to the pedigree.

Burdening the partners that are most likely least able to manage large amounts of data.

Challenging for inspection purposes.

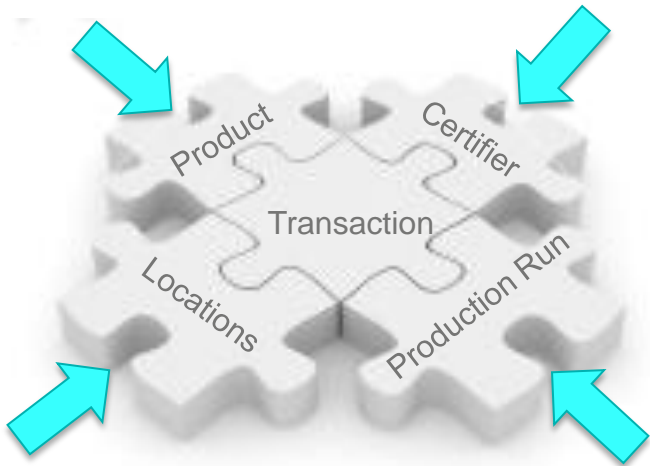
EPCIS BASED PEDIGREE DATA

AVOIDING SENDING MASSIVE DUPLICATION OF DATA



Using EPCIS,

The repeated data can be shared and managed separately ...



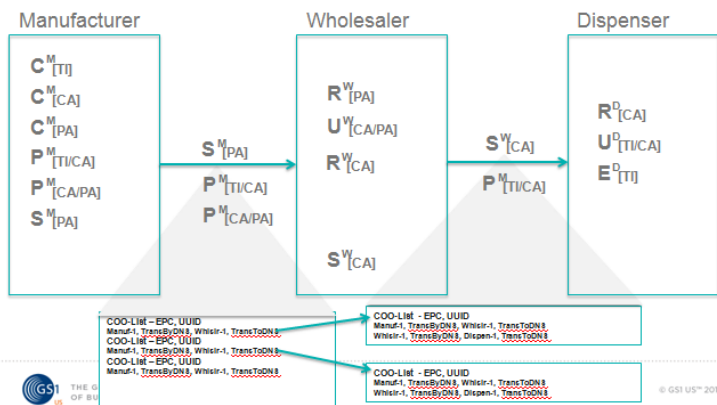
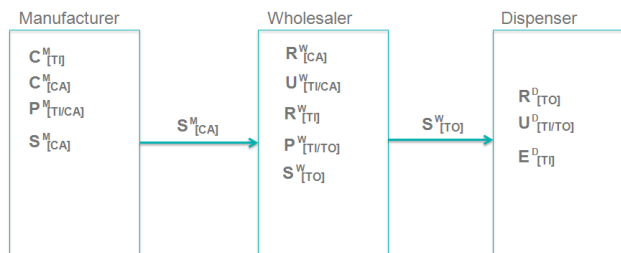
... and the associated data can be accessed when needed.

EPCIS BASED PEDIGREE DATA

AVOIDING SENDING MASSIVE DUPLICATION OF DATA

EPCIS events ...

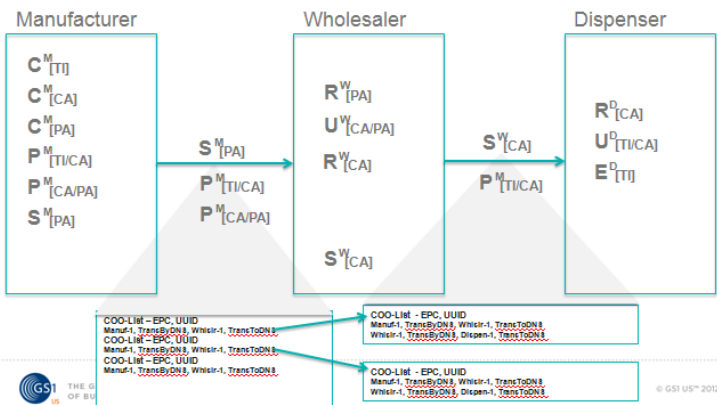
Can be used to collect pedigree data and share it with trading partners in a 1-up/1/down model



Can be extended to provide a Chain of Ownership List”.

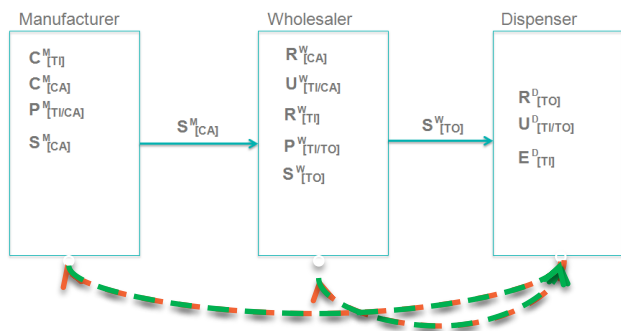
EPCIS BASED PEDIGREE DATA

AVOIDING SENDING MASSIVE DUPLICATION OF DATA



Using the Chain of Ownership List ...

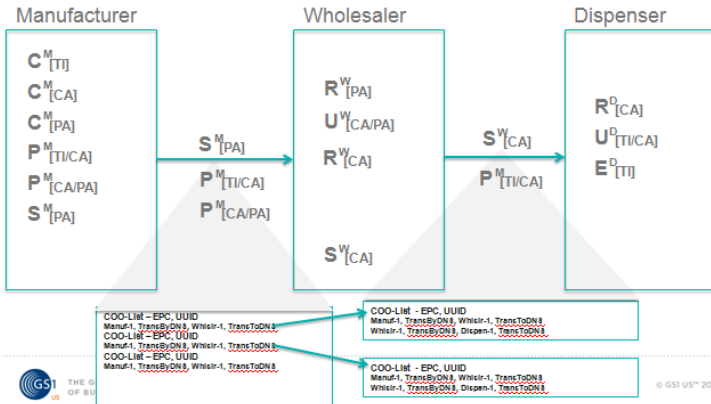
Companies have an immediate view into where an item has been in the supply chain.



... and, if needed, pull forward the full set of pedigree data.

EPCIS BASED PEDIGREE DATA

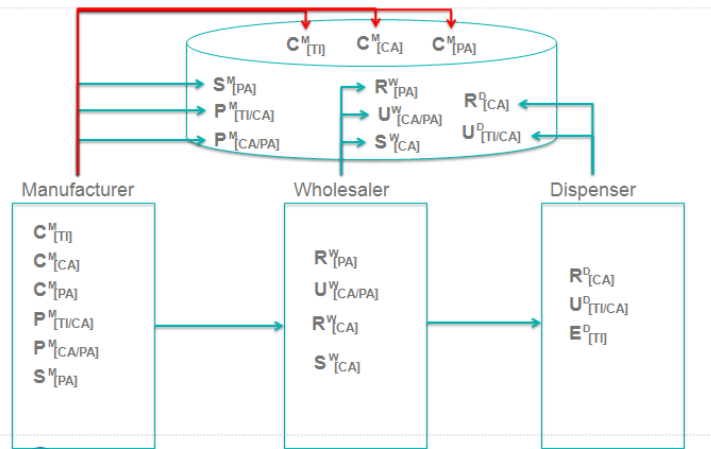
AVOIDING SENDING MASSIVE DUPLICATION OF DATA



EPCIS events can be used with ...

Distributed Architectures (each company holds their own data).

... and, Central and Semi-Central Architectures (each company contributes their data to one or more locations).

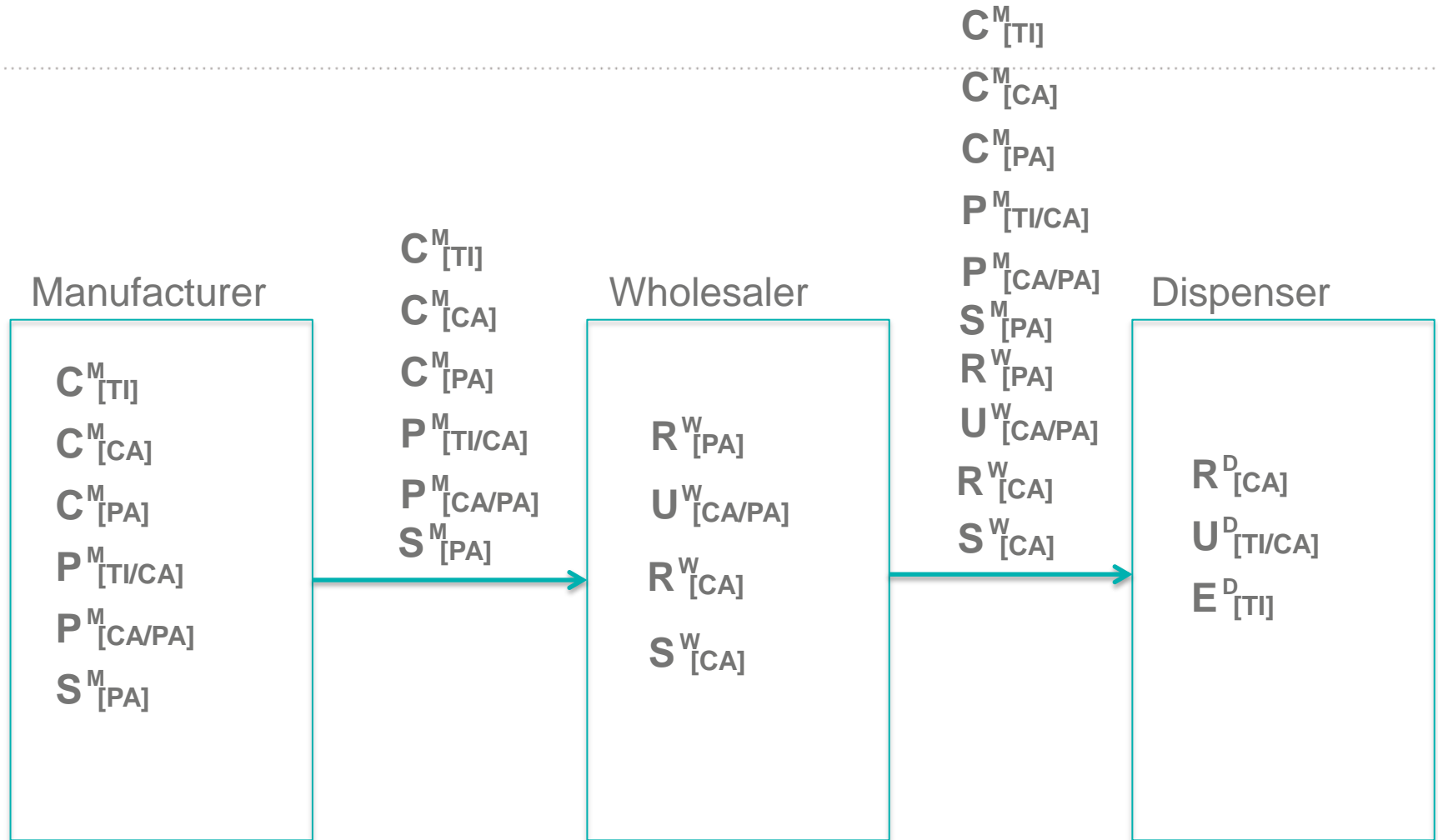


SERIALIZATION / TRACK & TRACE

THE CHALLENGE IS:

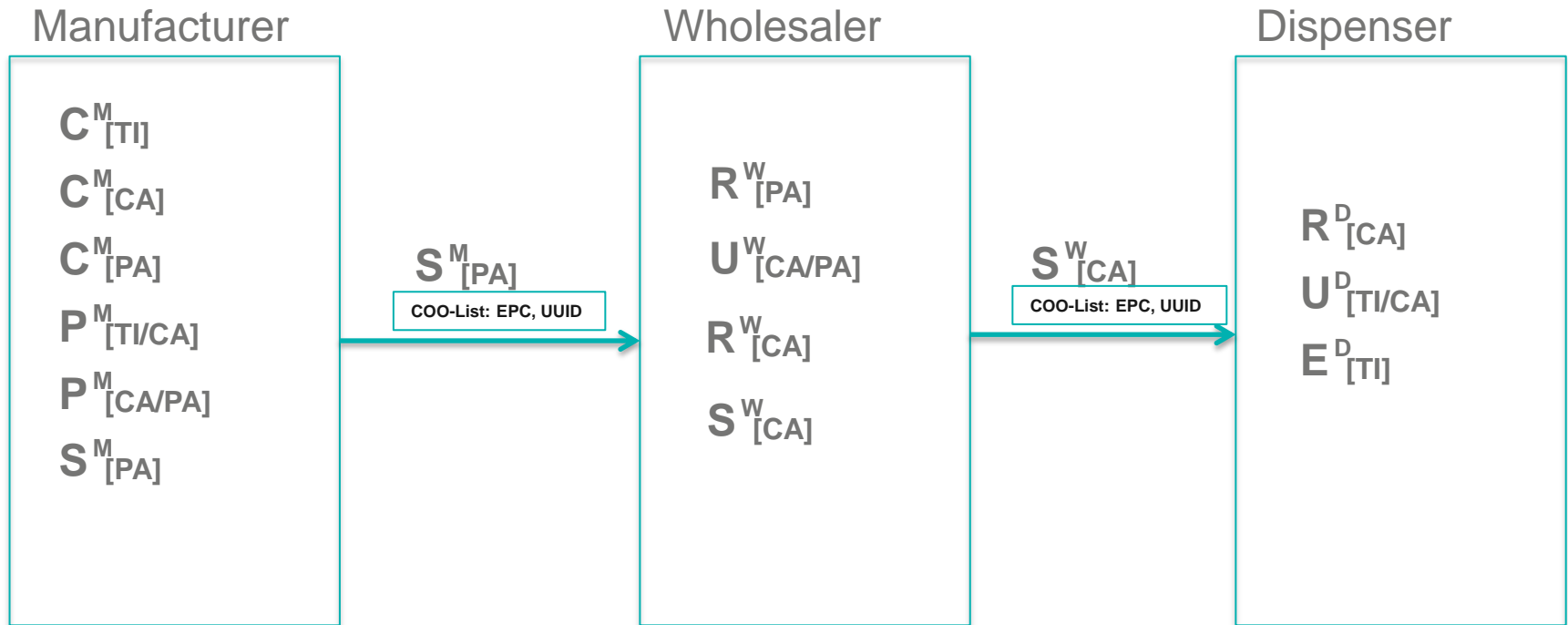


THE EQUIVALENT OF RECREATING DPMS IN EPCIS



EPCIS BASED PEDIGREE DATA

THE USE OF CHAIN OF OWNERSHIP LISTS



EXAMPLE:

CHAIN OF OWNERSHIP LIST DATA

COO-List: urn:epc:id:sgtin:030001.0012345.10000001003, urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6

•Key1

- **TransBy:GLN/** 0300011111116
- **TransByDNS:** www.Manuf-1.com
- **TransTo:DEA/** 12386549
- **TransToDNS:** www.Wholesaler-2.com

•Key2

- **TransBy:DEA/** 12386549
- **TransByDNS** www.Wholesaler-2.com
- **TransTo:GLN/** 0312311111114
- **TransToDNS:** www.Dispenser-1.com



CALIFORNIA STATE
BOARD OF PHARMACY

Scenarios for complying with California Board of Pharmacy (BoP) e-pedigree



Introduction

- Serialization/Traceability projects with 18 global life sciences companies.
 - Over 30 years of industry experience.
 - Plus dozens of projects with life sciences companies and validated systems spanning 20 years.
 - Over 10 years working with many of the world's largest companies on logistics and supply chain systems.
- Consultant specializing in solutions for global drug serialization, traceability and supply chain, including:
 - strategy,
 - requirements,
 - vendor selection,
 - pilots and
 - Implementation
- I don't sell hardware or software.
- Member GS1 US Healthcare.
- Certified GS1 Professional.





Today's Presentation

- Provide scenarios for selecting 50% of products for 2015 per 4163.5. (Pedigree Requirement Implementation Date).
- Discuss inference quantity of 48 items.
- The objective is to provide the basis for a future document from the State of California Board of Pharmacy (BoP) with scenarios to help avoid misunderstandings.





Unforeseen downturn

- The manufacturer submits its report in December 2014 in good faith.
- An unforeseen event prevents the company from meeting its commitment to California because products it thought would make up the 50% did not sell as well as expected.
- What is the ramification?





Pedigree goes nowhere

- The manufacturer produces serialized goods and ships them to wholesaler.
- Wholesaler is not yet required to accept pedigree.
- What does the manufacturer do with the pedigree before the wholesaler begins to accept pedigree?
- Will the BoP expect to observe a serialized item in California in 2015 and ask to see the manufacturer's pedigree?





Inventory

- Manufacturer produces products in early 2014 that may not be shipped from their warehouse until early 2015.
- If those items are among the 50% designated for serialization in 2015, can they still be shipped into California because they were packaged and in inventory at the manufacturer before 2015 even if not serialized.





Unit volume

- Specialty Manufacturer of high price low volume products selects to designate the 50% based on Unit volume.
- For all items shipped into California, 50% of the items sold in 2015 will be serialized and 50% will not be serialized.
- The company will ship all products as un-serialized for the first 6 months of 2015 and will ship serialized goods for the remainder of the year to ensure the total 2015 volume includes 50% serialized items.
 - May be applicable to specialty biologics.





Product package (SKU) type

- Company has 100 Stock-keeping Unit (SKU).
- It will designate 50 SKU for serialization
- The 50 SKU makeup 1% of sales into California?
---- OR ----
- The 50 SKU makeup 1% of volume?





Drug product family.

- The manufacturer has 10 Brands (Product Family)
- The company will designate 5 brands to be completely serialized before 2015.
- The 5 brands makeup 1% of sales into California?
---- OR ----
- The 5 brands makeup 1% of volume?





SKU Volume selection

- Manufacture identifies specific Stock-keeping Unit (SKU) that make up 50% of its annual unit projected volume into California.
 - They commit to serializing all of the defined SKU before January 1, 2015,
 - They report the SKUs to California in December 2014.
- Sales in 2015 are not what was expected and the actual sales into California for the SKUs was only 10% of annual volume.





Inventory of un-serialized goods

- Manufacture identifies specific Stock-keeping Unit (SKU) that make up 50% of its annual unit projected volume into California.
 - if they have inventory of un-serialized goods in the defined SKUs in inventory on December 31, 2014, can those un-serialized goods still be shipped into California.





Trade Information

- A manufacture ships 50 cases per pallet.
- When they ship to a wholesaler they will send 50 separate e-pedigree files, one for each case.
- This is done to avoid sending the information relating to the full pallet shipment through the supply chain.
 - Since the Drug Pedigree Messaging Standard (DPMS) pedigree is a nested file containing the original shipment.





Inference quantity

- Some companies package cases of 100 items or more.
- A more practical limit may be 200 items in a single sealed container.
- Although the vast majority of shipments of pallets of goods beyond the first recipient from a manufacturer are rare, the rule implies that pallets of cases can never be inferred, so wholesalers must always scan cases on pallets.





Inference

- Since all items will be scanned in their saleable unit form before dispensing,
 - Why not allow any size of container? If the items are not what are recorded on the pedigree, they will have to be returned and will not be dispensed.
 - How would a patient be harmed if all items are scanned before being dispensed?
 - How would the Board of Pharmacy (BoP) investigation be hindered if items in a sealed case do not match the pedigree? The provider of the items would be responsible and the items would not be dispensed until scanned into inventory and pedigree confirmed.





Feel free to contact us.

Questions? Need More Information?



Pharma Logic Solutions, LLC

social@pharma-logic.com

www.pharma-logic.com

William Fletcher

Managing Partner

wfletcher@pharma-logic.com

www.linkedin.com/in/williamfletcher

(609) 961-1441 or (215) 680-9161