



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

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

DATE: March 21, 2012

LOCATION: Hilton San Francisco Airport
600 Airport Boulevard
Burlingame, CA 94010

COMMITTEE MEMBERS

PRESENT: Randy Kajioka, PharmD, Chair
Greg Lippe, Public Member, Treasurer
Anil Badlani, RPh
Tappan Zee, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Janice Dang, Supervising Inspector
Joshua Room, Deputy Attorney General
Carolyn Klein, Legislation and Regulation Manager
Tessa Miller, Staff Analyst

NOTE: The webcast for this meeting is available at:

http://www.dca.ca.gov/publications/multimedia/pharm_20120321.wmv

Call to Order

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

Chair Kajioka conducted a roll call. Board Members Anil Badlani, Tappan Zee, and Greg Lippe were present.

Board Member Ryan Brooks was in attendance in the audience for part of the meeting.

I. **PRESENTATION AND DISCUSSION ON THE USE OF OFF-SHORE ENTITIES TO INPUT PATIENT TREATMENT AND REFILL AUTHORIZATIONS FOR CALIFORNIA PHARMACIES**

Background

Last year, the board directed a pharmacy to stop using an off-shore data entry service to input patient data.

After this order, the board received a request from an attorney representing the pharmacy and requested an appearance before the board to more fully discuss this matter.

Presentation

An Vong, Pharmacist-in-Charge, Skilled Nursing Pharmacy (SNP) provided a presentation on the benefits of remote data entry of refill prescription orders.

Dr. Vong discussed the benefits that SNP believes it gains from using offsite services for non-clinical clerical data entry.

Stacie Neroni, Hooper, Lundy and Bookman, P.C., confirmed that SNP is not currently using off shore entry, but would like to in the future.

Discussion

Joshua Room, Deputy Attorney General, advised that the committee to focus its discussion on the general topic of off-shore data entry.

The committee discussed the information presented and indicated that, as advised by Mr. Room, no action can be taken at this time.

Chair Kajioka stated that the issue of remote data entry may be brought to the full board for further discussion and consideration in the future.

No public comment was provided.

The board recessed for a break at 10:06 a.m. and reconvened at 10:15 a.m.

II. DISCUSSION ON THE IMPLEMENTATION OF CALIFORNIA'S ELECTRONIC PEDIGREE REQUIREMENTS FOR PRESCRIPTION MEDICATION

a. Discussion about the Presence of Counterfeit Avastin in California Physician Offices

Presentation

Executive Officer Virginia Herold provided a presentation on counterfeit drugs. A copy of this presentation is attached, following this meeting summary.

Ms. Herold reviewed the appearance of counterfeit drugs in the supply chain and discussed a recent incident involving Avastin.

Ms. Herold stated that pursuant to Business and Professions Code section 4034(h), a manufacturer, wholesaler or pharmacy that has reasonable cause to believe it is in possession of counterfeit drugs must notify the board within 72 hours of discovery.

There was no committee discussion or public comment.

b. Presentation and Discussion of a Proposal for Federal Legislation by the Pharmaceutical Distribution Security Alliance

Presentation

Vince Ventimiglia, representing the Pharmaceutical Distribution Security Alliance (PDSA), provided a presentation to propose the development and enactment of the Pharmaceutical Traceability Enhancement Code (RxTEC) Act of 2012, a federal policy proposal for the domestic pharmaceutical distribution system. A copy of this presentation is attached, following this meeting summary.

Mr. Ventimiglia introduced other PDSA representatives in attendance and provided an overview of PDSA. He discussed that RxTEC is a federal approach that replaces the patchwork of state laws to improve the security and efficiency of the pharmaceutical distribution chain.

Discussion

Chair Kajioka provided comment on California's e-pedigree requirements and implementation schedule.

Mr. Room provided comment on the discussion draft of the RxTEC Act and sought clarification regarding the tracking and identification of product throughout the system.

Mr. Ventimiglia discussed that the RxTEC system would use lot-level reference systems, while a serialized code would be placed but not read or tracked at the unit-level. This would improve the safety of the supply chain today.

Discussion continued regarding the RxTEC system. The committee evaluated the system's enactment and the implementation of e-pedigree requirements.

No public comment was provided.

c. Presentation by Connie T. Jung, RPh, PhD, Acting Associate Director for Policy and Communications, Center for Drug Evaluation and Research, US Food and Drug Administration

Presentation

Dr. Jung provided a presentation on the need for protection of products in the drug supply chain. A copy of this presentation is attached, following this meeting summary.

Dr. Jung provided an overview of the supply chain and reviewed efforts by the FDA to protect the integrity of the supply chain to ensure patient safety. She indicated that the FDA has established the new Office of Drug Security, Integrity and Recalls (ODSIR) to address this issue.

Dr. Jung discussed attributes of the track and trace system and reviewed possible system models. She advocated for a national, uniform track and trace model, with an authentication system with tracking at the unit level. This would be a far more beneficial system than one which does not require tracking at the unit level.

Discussion

Chair Kajioka sought additional information regarding whether authentication should be done at the ownership level or the possession level.

Dr. Jung stated that this has not yet been determined as the requirement in this area has not been finalized. She provided comment on the importance of chain of custody for all products in U.S. distribution and discussed that pharmacies should know where product has been shipped and stored before it reaches the pharmacies.

No public comment was provided.

The board recessed for a break at 12:15 p.m. and resumed at 12:28 p.m.

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

Kimberly Fleming, Senior Manager, Product Security, EMD Serono, Inc.

Ms. Fleming provided an overview on EMD Serono and the company's efforts to combat diversion and counterfeit product in the U.S. She reviewed "must have's" for product security including track and trace, authentication and packaging, collaboration and communication, and supply chain security. She indicated that EMD Serono had serialized several of its product lines, and will be ready to meet California's deadlines for e-pedigree requirements.

Ms. Fleming discussed the Secured Distribution Program that EMD Serono has developed to maintain the integrity of EMD Serono's products that are at risk for diversion and/or counterfeit. She indicated that the ultimate goal is patient safety and stated that products are tracked via unique box serial numbers from the point of manufacture to the point of final dispensation. Ms. Fleming stated that these steps are necessary because their products have been counterfeited. In one case, within four months of bringing a new product onto the market patients were discovered with counterfeit product.

Discussion

Mr. Lippe referenced the \$5.8 billion Euros in revenue earned by EMD Serono in 2010 and asked how much the serialization system costs.

Ms. Fleming indicated that although she is unsure of the exact number, the cost for the global process is several million Euros.

Mr. Room asked how much product is currently serialized.

Ms. Fleming indicated that the highest volume products are not serialized at this time.

No public comment was provided.

Robert Celeste, Director, Healthcare, GS1 US

Mr. Celeste provided an overview on GS1 and efforts to implement global standards to improve the efficiency and visibility of supply chains globally and across countries. A copy of this presentation is attached, following this meeting summary.

Mr. Celeste discussed the use of the global trade identification number (GTIN) and other standards and serialization worldwide. He announced that GS1 will be releasing an implementation guideline for applying GS1 standards to U.S. pharmaceutical supply chain business processes. The guideline is tentatively scheduled to be released on the GS1 Web site in April 2012.

There was no committee discussion or public comment.

3. Other Companies, Associations and Other Entities Wishing to Address the Committee on E-Pedigree Issues

Gabrielle Cosel, PEW Charitable Trust

Ms. Cosel reviewed findings from a report released by PEW on protecting consumers from the risks of substandard and counterfeit drugs. She stated that many stakeholders support a strong national standard rather than separate state requirements.

Ms. Cosel discussed the Pharmaceutical Distribution Security Alliance (PDSA) proposal currently being considered by Congress and stated that this proposals fall short as it calls for tracking of drug product at the lot level. It also would prohibit aggregation which would result in no tracking at the package level. Also, the PDSA proposal does not require the pharmacy or any other party to verify the authenticity of the drugs.

Ms. Cosel stated that PEW supports a national serialization and authentication standard.

Ms. Cosel indicated that PEW is currently working on efforts to strengthen oversight and controlled systems for the manufacturing of drugs.

Marjorie Powell, Pharmaceutical Research and Manufacturers of America (PhRMA)

Ms. Powell stated that the California Board of Pharmacy has been the catalyst to bring all the parties within the pharmaceutical supply chain together to enact an interoperable electronic pedigree system. She stated that PhRMA member companies are in the process of implementing unit level serialization numbers on products and developing data systems to manage and share unit level information. Ms. Powell provided an overview on other efforts and pilot tests in this area and emphasized the need for a uniform national system. She stated that PhRMA will continue to work with PDSA on the draft legislation.

Ms. Powell offered support to the board in drafting regulations in this area. She encouraged the board to consider increased licensing standards nationwide and increased penalties for violations in this area.

Ms. Herold encouraged participation and input from industry during the regulation process for California's requirements.

The board recessed for a lunch break at 1:34 p.m. and reconvened at 2:37 p.m.

e. General Discussion

There was no additional discussion.

f. Discussion and Possible Action to Develop Regulation Requirements Specifying a Unique Identification Number for Prescription Medication Pursuant to California’s E-Pedigree Requirements

Mr. Room reviewed the following language regarding the specification of a unique identification number.

Unique Identification Number

Pursuant to Business and Professions Code section 4034, the "unique identification number" established and applied to the smallest package or immediate container by the manufacturer or repackager shall conform to the Standardized Numerical Identifier (SNI) set forth in the Guidance for Industry published by the U.S. Food and Drug Administration (FDA) in March 2010, consisting of a serialized National Drug Code (NDC) identifier (or equivalent product identifier for dangerous drugs for which no NDC has been assigned) combined with a unique numeric or alphanumeric serial number that is no more than twenty (20) digits or characters in length.

Ms. Herold recommended that the board promulgate this regulation as part of a regulation package.

No public comment was provided.

MOTION: Recommend that the board hold the proposed language to specify a unique identification number for prescription medication pursuant to California’s e-pedigree requirements to be pursued with other e-pedigree regulations as part of a regulation package.

M/S: Lippe/Zee

Support: 4 Oppose: 0 Abstain: 0

g. Discussion and Possible Action to Develop “Grandfathering” Provisions for Non-Pedigreed Dangerous Drugs Pursuant to Section 4163.2 of the Business and Professions

Mr. Room reviewed proposed language to specify the methodology to be used by manufacturers, wholesalers, repackagers, and pharmacies to identify drugs already in the supply chain that are not serialized but could be sold after the e-pedigree requirements take effect. A copy of this language is attached, following this meeting summary.

Public Comment

Diane Arico, representing Novartis Pharmaceuticals, sought clarification regarding the implementation requirements in subdivision (a) of the draft language.

Mr. Room reviewed the implementation requirements in Business and Professions Code section 4163.5(b). He clarified that before January 1, 2015, each manufacturer of a dangerous drug distributed in California must identify those dangerous drugs representing a minimum of 50 percent of its drugs that will be serialized and the remaining 50 percent must be serialized by January 1, 2016. Wholesalers have until July 1, 2016 to append the e-pedigree required information. Pharmacies and pharmacy warehouses have until July 1, 2017 to read and append pedigrees, making the system fully operational. He commented that this proposal deals with what happen to the non-serialized product that is in the supply chain when the requirements take effect, at each level, and thus could not be sold or distributed without an exemption.

MOTION: Recommend that the board hold the proposed language to develop “grandfathering” provisions for non-pedigreed dangerous drugs pursuant to Business and Professions Code section 4163.2 to be pursued with other e-pedigree regulations as part of a regulation package.

M/S: Lippe/Zee

Support: 4 Oppose: 0 Abstain: 0

h. Closing Comments

Chair Kajioka discussed the importance of addressing the counterfeit and diversion problem. He stated that the board will hold additional meetings to solicit input and develop strong requirements and standards to protect the public.

Ms. Herold announced that the board will hold its next Enforcement Committee and E-Pedigree Meeting in June 2012. The exact date and location will be posted on the board’s Web site.

III. PUBLIC COMMENT ON ITEMS NOT ON THE AGENDA/AGENDA ITEMS FOR FUTURE MEETINGS

No public comment was provided.

The meeting was adjourned at 2:51 p.m.

Specification of Non-Pedigreed Dangerous Drugs

Pursuant to Business and Professions Code sections 4163.2, 4163.4, and 4163.5, manufacturers, wholesalers, repackagers, and pharmacies may take the following actions to specify dangerous drugs that are not yet subject to the pedigree requirements set forth in sections 4034 and 4163 et seq. Other than as specified below, all dangerous drugs distributed in or through California are subject to the pedigree requirements set forth in those sections.

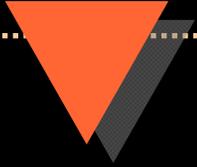
(a) By no later than December 1, 2014, any manufacturer seeking to limit application of the pedigree requirements to 50 percent of its drugs pursuant to Business and Professions Code section 4163.5 shall submit to the Board a declaration, signed under penalty of perjury by an owner, officer, or employee of the manufacturer with the legal capacity to bind the manufacturer, that specifies the dangerous drugs by name and product package (SKU) type representing 50 percent of its total as of January 1, 2015, as measured pursuant to section 4163.5, subdivision (d), that is ready for implementation of pedigree requirements as of January 1, 2015. The declaration shall identify the measurement from section 4163.5, subdivision (d) used to measure the 50 percent, shall illustrate the calculation(s) used to arrive at the 50 percent figure, shall identify those drugs by name and product package (SKU) type that are in the remaining 50 percent not yet subject to pedigree requirements, and shall specify the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed. Any manufacturer submitting a declaration to identify the 50 percent of its drugs that are subject to the pedigree requirements as of January 1, 2015 shall also, by no later than December 1, 2015, submit a declaration, signed under penalty of perjury by an owner, officer, or employee of the manufacturer with the legal capacity to bind the manufacturer, that specifies the remaining 50 percent of its dangerous drugs by name and product package (SKU) type ready for implementation as of January 1, 2016. The declaration shall identify the measurement from section 4163.5, subdivision (d) used to measure the 50 percent, shall illustrate the calculation(s) used to arrive at the 50 percent figure, shall

identify all drugs by name and product package (SKU) type that are ready for implementation, and shall specify the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed. The Board or its designee shall have discretion to determine whether any submitted declaration is compliant, and to reject and require re-submission of any non-compliant declaration(s) until fully compliant. Information contained in these declarations shall be considered trade secrets and kept confidential by the Board. Any failure to submit a first or second declaration conforming to these requirements by December 1, 2014 or December 1, 2015, or any failure to submit a fully compliant first or second declaration by January 31, 2015 or January 31, 2016, shall automatically make the entire drug stock of any manufacturer failing to do so subject to the pedigree requirements as of January 1, 2015, and no exemption shall be applied to any drugs owned or distributed by that manufacturer.

(b) By no later than August 1, 2016, any wholesaler or repackager seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the pedigree requirements pursuant to Business and Professions Code sections 4163.2 and 4163.4, shall submit to the Board a declaration, signed under penalty of perjury by an owner, officer, or employee of the wholesaler or repackager with the legal capacity to bind the wholesaler or repackager, that specifies the dangerous drugs by name and product package (SKU) type in the possession, ownership, or control of the wholesaler or repackager that were acquired prior to July 1, 2016, specifies the means and source of acquisition, and specifies the anticipated means of any subsequent distribution or disposition. The Board or its designee shall have discretion to determine whether any submitted declaration is compliant, and to reject and require re-submission of any non-compliant declaration(s) until fully compliant. Information contained in these declarations shall be considered trade secrets and kept confidential by the Board. Failure to submit a declaration conforming to these requirements by August 1, 2016, or failure to submit a fully compliant declaration by September 31, 2016, shall automatically make the entire drug

stock of any wholesaler or repackager failing to do so subject to the pedigree requirements as of July 1, 2016, and no exemption shall be applied to any drugs owned or distributed by that wholesaler or repackager.

(c) By no later than August 1, 2017, any pharmacy or pharmacy warehouse seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the pedigree requirements pursuant to Business and Professions Code sections 4163.2 and 4163.4, shall submit to the Board a declaration, signed under penalty of perjury by an owner, officer, or employee of the pharmacy or pharmacy warehouse with the legal capacity to bind the pharmacy or pharmacy warehouse, that specifies the dangerous drugs by name and product package (SKU) type in the possession, ownership, or control of the pharmacy or pharmacy warehouse that were acquired prior to July 1, 2017, specifies the means and source of acquisition, and specifies the anticipated means of any subsequent distribution or disposition. The Board or its designee shall have discretion to determine whether any submitted declaration is compliant, and to reject and require re-submission of any non-compliant declaration(s) until fully compliant. Information contained in these declarations shall be considered trade secrets and kept confidential by the Board. Failure to submit a declaration conforming to these requirements by August 1, 2017, or failure to submit a fully compliant declaration by September 31, 2017, shall automatically make the entire drug stock of any pharmacy or pharmacy warehouse failing to do so subject to the pedigree requirements as of July 1, 2017, and no exemption shall be applied to any drugs owned or distributed by that pharmacy or pharmacy warehouse.

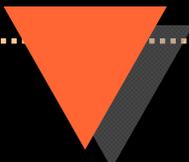


Counterfeit Drugs

California State Board of Pharmacy

Enforcement Committee

March 21, 2012

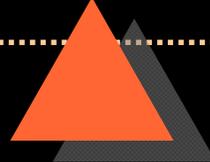


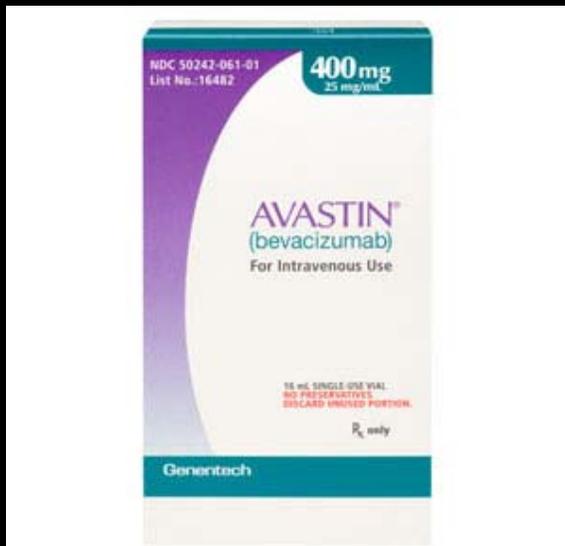
Statutory Mandate

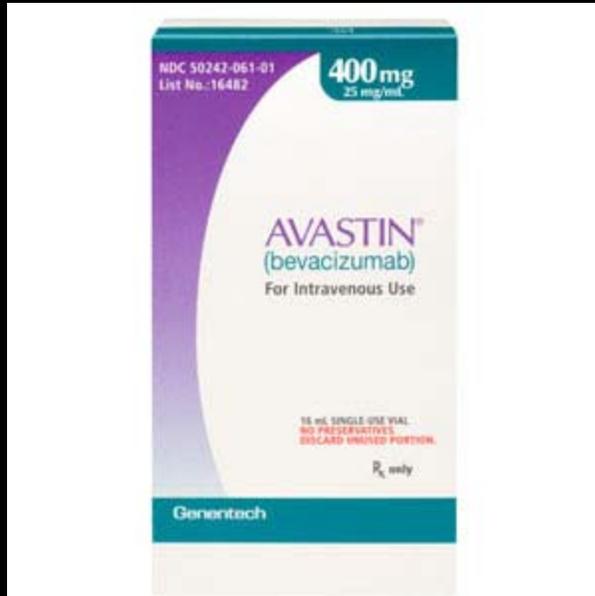
Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions.

Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

CA Business and Professions Code 4001.1







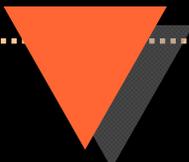






Counterfeit

Genuine



Reporting Counterfeits in CA

- If a manufacturer, wholesaler or pharmacy has reasonable cause to believe that a dangerous drug in, or having been in, its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler or pharmacy shall notify the Board within 72 hours of obtaining that knowledge. This subdivision shall apply to any dangerous drug that has been sold or distributed in or throughout CA

CA Business & Prof Code 4034(h)



California Board of Pharmacy

*Presentation by
The Pharmaceutical Distribution
Security Alliance (PDSA)*

March 21, 2012

The Mission

- PDSA's mission is to develop and help enact a federal policy proposal that enhances the security and integrity of the domestic pharmaceutical distribution system for patients, and to articulate a technical migratory pathway to implement such a policy
- Our primary goal is ensuring patients have uninterrupted access to safe, authentic, FDA-approved medicine

Who We Are

- Membership spans the entire spectrum of the U.S. pharmaceutical distribution system, including brand and generic manufacturers, large and small wholesale distributors, third-party logistics providers, and retail and community pharmacies
- More than 25 organizations are formal members of PDSA, while many other external stakeholders provide additional policy and technical support to the group

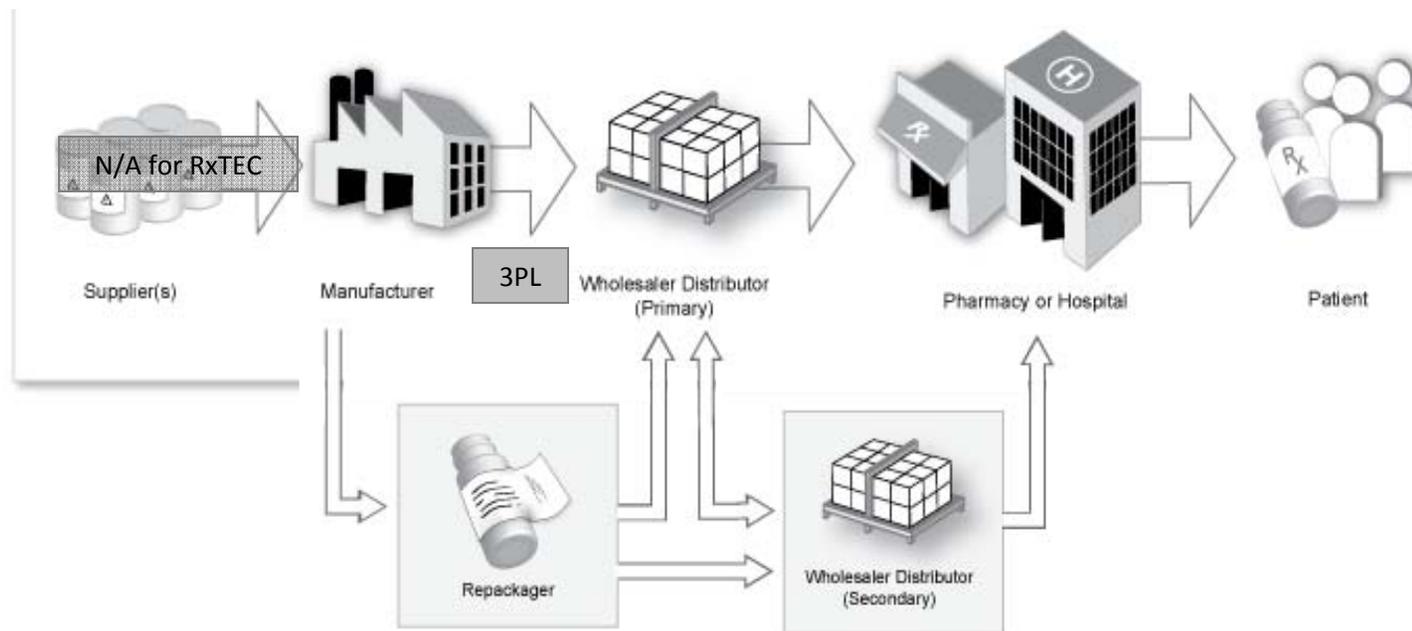
PDSA: Who We Are



PDSA: Why This Is Different

- **First time** that all sector participants in the pharmaceutical distribution chain:
 - Have engaged in robust discussion regarding pathways and proposal to advance prescription drug distribution supply chain security through a national policy framework
 - Have prepared a consensus policy approach to enhance supply chain security and safety
 - Are fully engaging, collectively, with bipartisan and bicameral Congressional leaders in support of legislative action
 - Are *asking* for more regulation

The Current Pharmaceutical Distribution Chain



The pharmaceutical distribution chain as adapted from a diagram by the U.S. Food and Drug Administration

Why a Federal Approach?

- Public health experts agree that while incidents of counterfeiting and drug diversion are less common in the United States than in other parts of the world, they are a serious concern
- While California and a handful of other states have passed enhanced wholesale distribution requirements and/or pedigree legislation, currently there is no uniform national system to prevent or identify possible suspect products
- This state patchwork creates opportunities for bad actors to "shop" for states with the lowest safety requirements in order to enter the gray market or infiltrate the legitimate supply chain
- Illegal online "pharmacies" take advantage of loopholes in federal law to evade law enforcement
- A federal solution would raise the bar for industry participants in all 50 states, address current loopholes, and aide deterrence – all greatly enhancing supply chain safety and security worldwide
- Such a uniform national system would enable regulators, law enforcement and industry participants to harmonize their processes on a global basis, yielding costs savings and investment efficiencies for all parties

The PDSA Proposed System

***The Pharmaceutical Traceability
Enhancement Code (RxTEC) Act of 2012***

- ✓ ***Prevention***
- ✓ ***Identification***
- ✓ ***Response***
- ✓ ***Assessment***

The RxTEC Act

Prevention – Identification – Response – Assessment

A Comprehensive Approach with Immediate Benefits

- | | |
|---|---|
| <ul style="list-style-type: none">➤ Establishes Strong National Standards: Immediately sets strong federal standards for wholesale distributors with state licensure authorities, strong standards and a new federal license for third-party logistics providers, and streamlined licensure requirements for manufacturers | <ul style="list-style-type: none">➤ Raises the Bar for Wholesale Distribution: Interim federal requirements for wholesale distribution during RxTEC system development to provide a strong, efficient, uniform system for product distribution in between states |
| <ul style="list-style-type: none">➤ Addresses Loopholes: New laws to combat illegal online drug sellers (aka “online pharmacies”), including requiring a “valid prescription” prior to dispensing, and creating a registry of all safe online sources | <ul style="list-style-type: none">➤ Aids Deterrence: Increases penalties for prescription drug counterfeiters |

The RxTEC Act

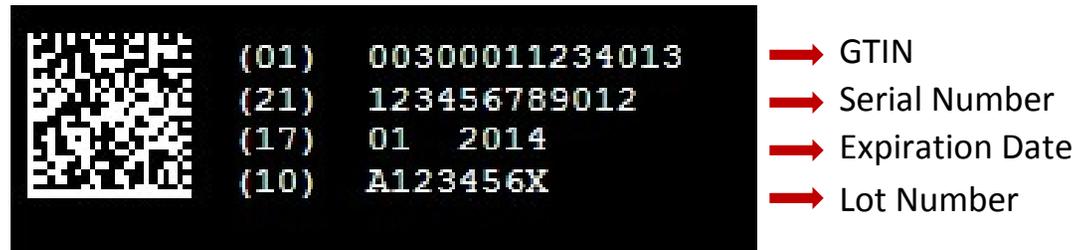
Prevention – Identification – Response – Assessment

- The cornerstone of the RxTEC Act of 2012 is the development of the RxTEC system through unit-level serialization and use of a new data carrier to improve product visibility throughout the pharmaceutical distribution chain

- The RxTEC system leverages lot-level business systems that may be in place today, while serializing at the unit-level and increasing the ability to identify suspect product at both the unit and lot level

- **Obligations under the Act:**
 - Requires manufacturers to apply the RxTEC data carrier that includes both unit level (SNI) and lot level data to individual saleable units of prescription drugs and to homogenous cases in both human and machine-readable formats
 - Requires manufacturers to maintain associations between serial numbers and lot numbers
 - Requires trading partners to have systems and process to support
 - verification of a suspect product as determined necessary by the Secretary for investigations
 - lot level tracing upon change of ownership
 - lot level recalls

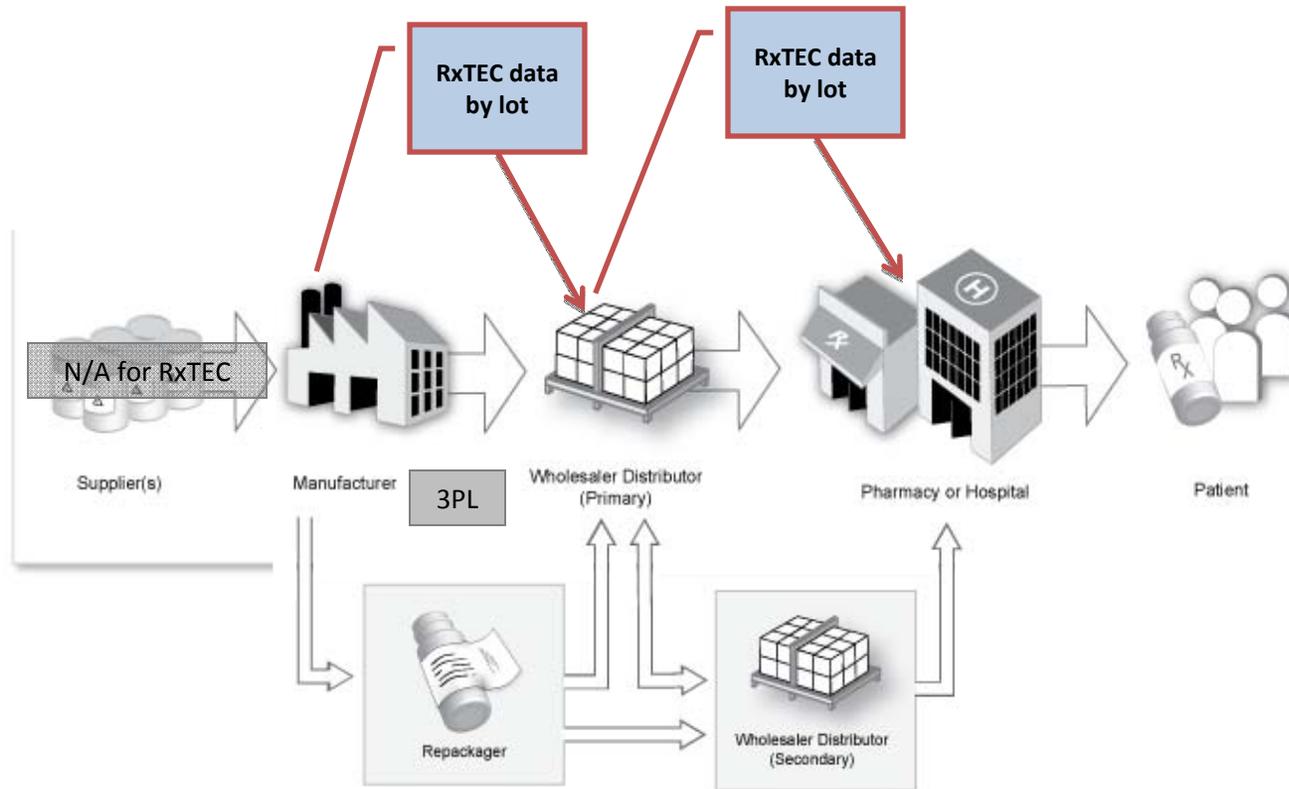
The Data Carrier – A Closer Look at RxTEC



- RxTEC is a data carrier that includes a Global Trade Item Number (GTIN), a serial number, expiration date and lot number
- This RxTEC data carrier would be applied on each individual saleable unit and homogenous case by manufacturers and repackagers
- Data will be in both human and machine-readable formats

The RxTEC Act

Prevention – Identification – Response – Assessment



The pharmaceutical distribution chain as adapted from a diagram by the U.S. Food and Drug Administration

The RxTEC Act

Prevention – Identification – Response – Assessment

- Provides new tools for identifying possible counterfeit or diverted product in the supply chain
 - The Secretary, state regulators, and manufacturers may verify the serial number of an individual saleable unit against a manufacturer's database to investigate a suspect product
 - Trading partners would be able to trace drug shipments upon change of ownership at the lot level

- Enables additional opportunities to check the legitimacy of products
 - Trading partners could also leverage RxTEC data in combination with their own business systems and processes to detect, prevent, or respond to threats in the distribution chain
 - Trading partners could also verify the serial number of an individual saleable unit against a manufacturer's database

The RxTEC Act

Prevention – Identification – Response – Assessment

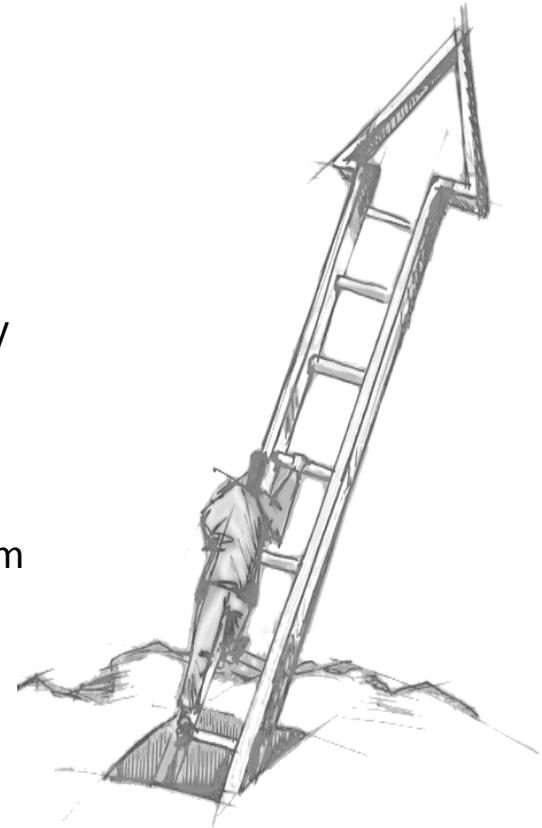
- Enables faster, more efficient response to identified counterfeit or diverted product
 - The Secretary and state regulators may obtain RxTEC data in the event of a recall or as determined necessary by the Secretary to investigate a suspect product
 - The Secretary and state regulators direct industry response to identified threats in the distribution chain
 - Trading partners would conduct a faster and more efficient recall by lot

The RxTEC Act

Prevention – Identification – Response – Assessment

Opportunities for Assessment and Enhancement

- The RxTEC Act provides critical building blocks that can be expanded as public health threats, interoperability standards, and technologies evolve
- Establishes the Pharmaceutical Distribution Chain Community
 - 21 members appointed by the Comptroller General
 - Provides regular consultation and advice to the Federal Government on pharmaceutical chain safety and security issues, including RxTEC implementation, best practices, pilot projects, and other insights
- Requires the Secretary to evaluate and report to Congress on
 - The RxTEC system's impact on health care delivery system and patient access to medicines,
 - RxTEC system's capabilities and scalability, and
 - Findings on whether additional electronic traceability requirements are needed to protect the public health
- This evaluation and report will help determine if further electronic traceability components are needed to ensure patient safety and secure the supply chain



ENACTMENT

2012.5

IMMEDIATE BENEFITS: New Standards, Enhanced Internet Security and Penalties

2013.5

COMMUNITY:
1st recommendation 12 months after enactment (annual thereafter)

2014

RxTEC REGULATIONS:
Final regulations promulgated 18 months after enactment

2017

MANUFACTURERS:
3 years after final regulations

FDA REQUEST AUTHORITY-
Manufacturers

REPACKAGERS:
4 years after final regulations

WHOLESALERS:
5 years after final regulations

2019

2020

DISPENSERS:
6 years after final regulations

2020

FDA REQUEST AUTHORITY- All participants

2020.5

FDA ASSESSMENT &
REPORT TO CONGRESS

2021

CONTINUED BENEFITS:
New Standards,
Enhanced
Internet Security
and Penalties

Overview of RxTEC Act Benefits

- Increases patient access to safe medicines
- Improves security of the pharmaceutical distribution chain
- Replaces the patchwork of state laws
- Increases efficiency throughout the pharmaceutical distribution chain
- Establishes a foundational technology -- creates “building blocks” not “road blocks” – that can evolve or be expanded based on public health needs and technological capabilities
- Is consistent with existing and emerging international requirements
- Lowers costs and regulatory burdens for all sectors when compared to compliance with existing and proposed laws

Thanks and Questions

PDSA contacts

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Libby Baney: libby.baney@faegrebd.com

Philip Bonforte: philip.bonforte@faegrebd.com

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U.S. Food and Drug Administration
Protecting and Promoting Public Health

www.fda.gov

Protecting the Drug Supply Chain



Connie T. Jung, RPh, PhD

Acting Associate Director for Policy and Communications

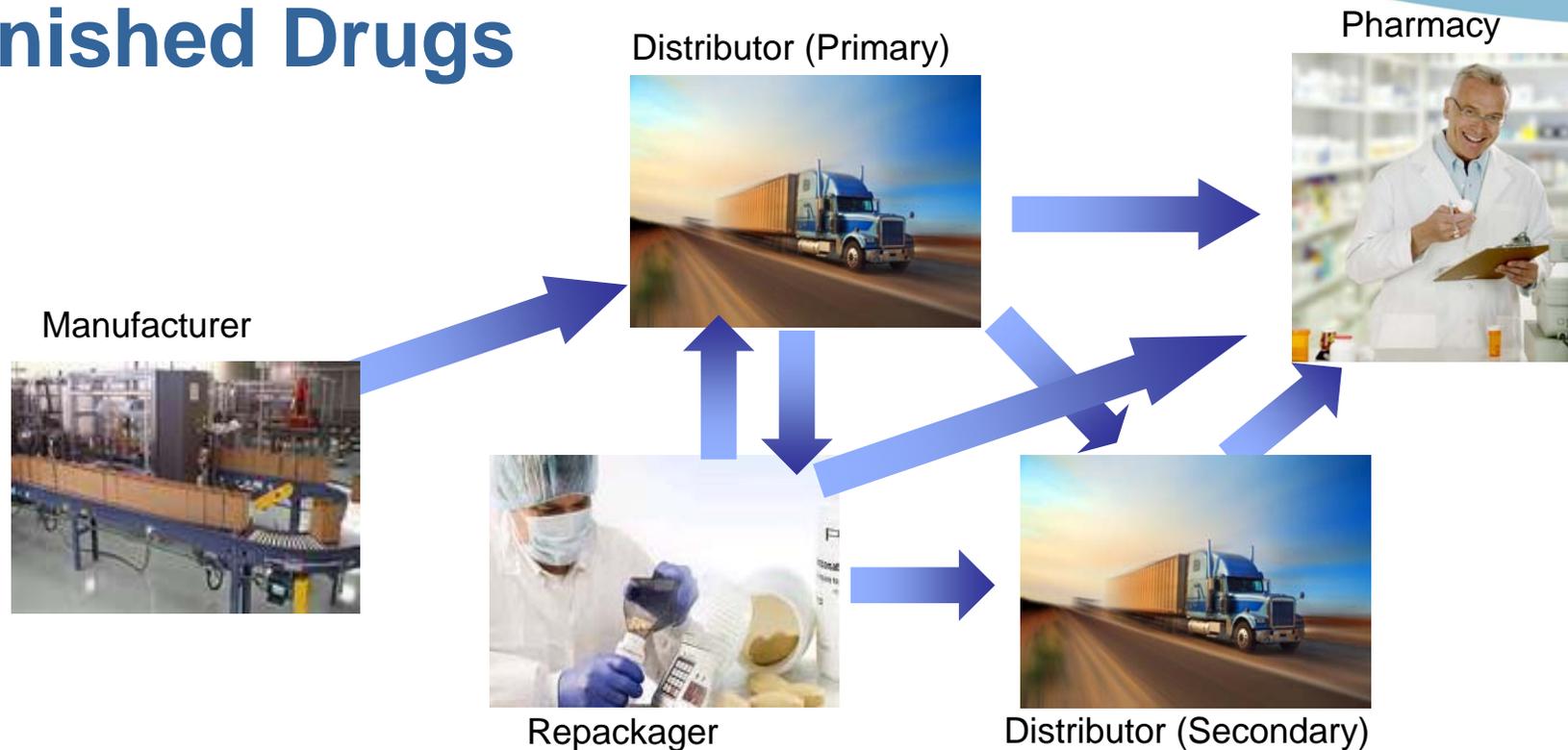
Office of Drug Security, Integrity, and Recalls

Office of Compliance/Center for Drug Evaluation and Research

U.S. Food and Drug Administration

CA State Board of Pharmacy - March 21, 2012

Supply Chain for Finished Drugs



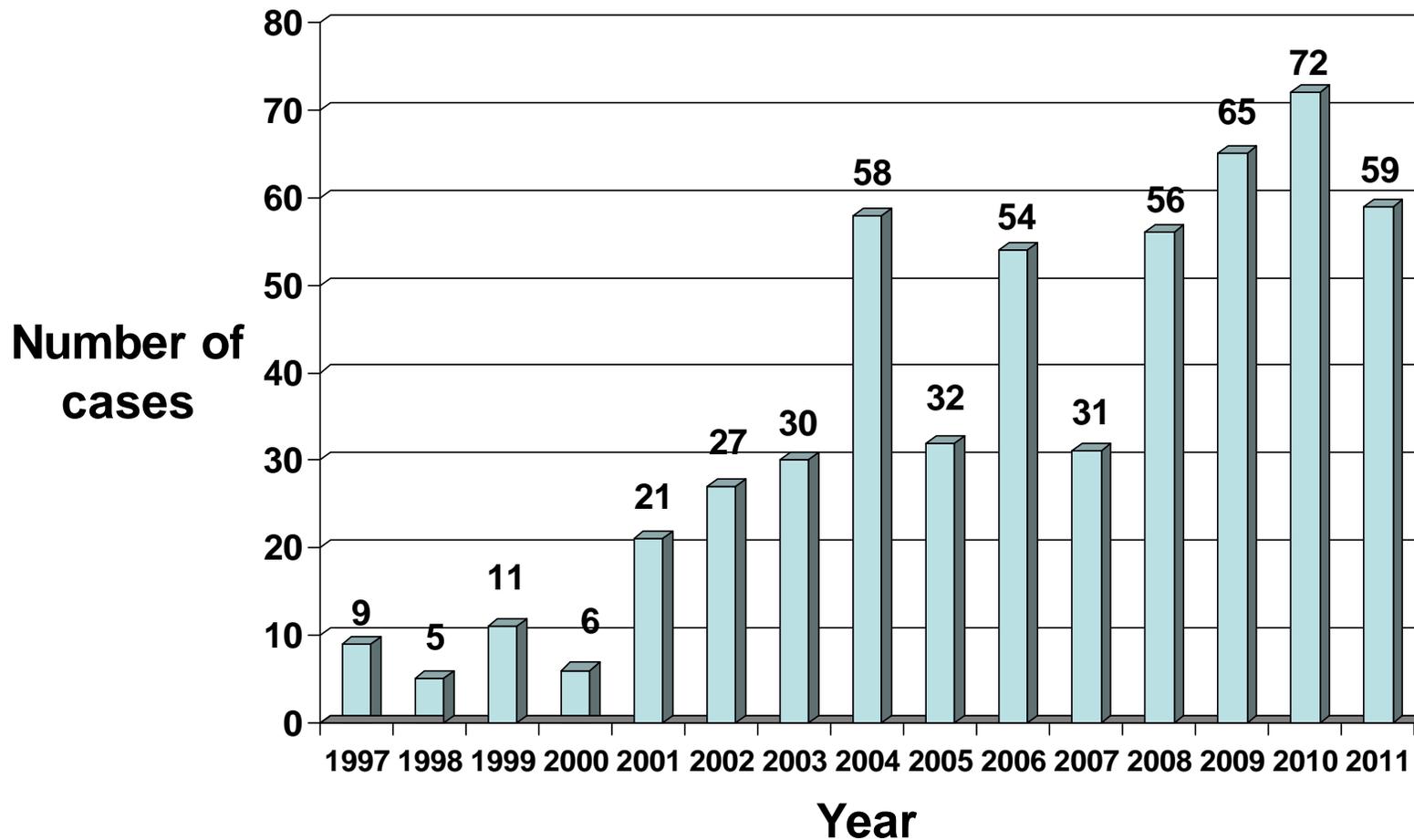
Complexity of the supply chain is increased by:

- Multiple participants
- Globalization of supply chains
- Criminal activities such as diversion, cargo theft, and counterfeiting
- Rules that vary by state

Example of vulnerabilities in the supply chain:

- Stolen products reintroduced
- Counterfeit/falsified drugs sold to suppliers
- Diverted drugs resold
- Other adulterated/misbranded drugs introduced

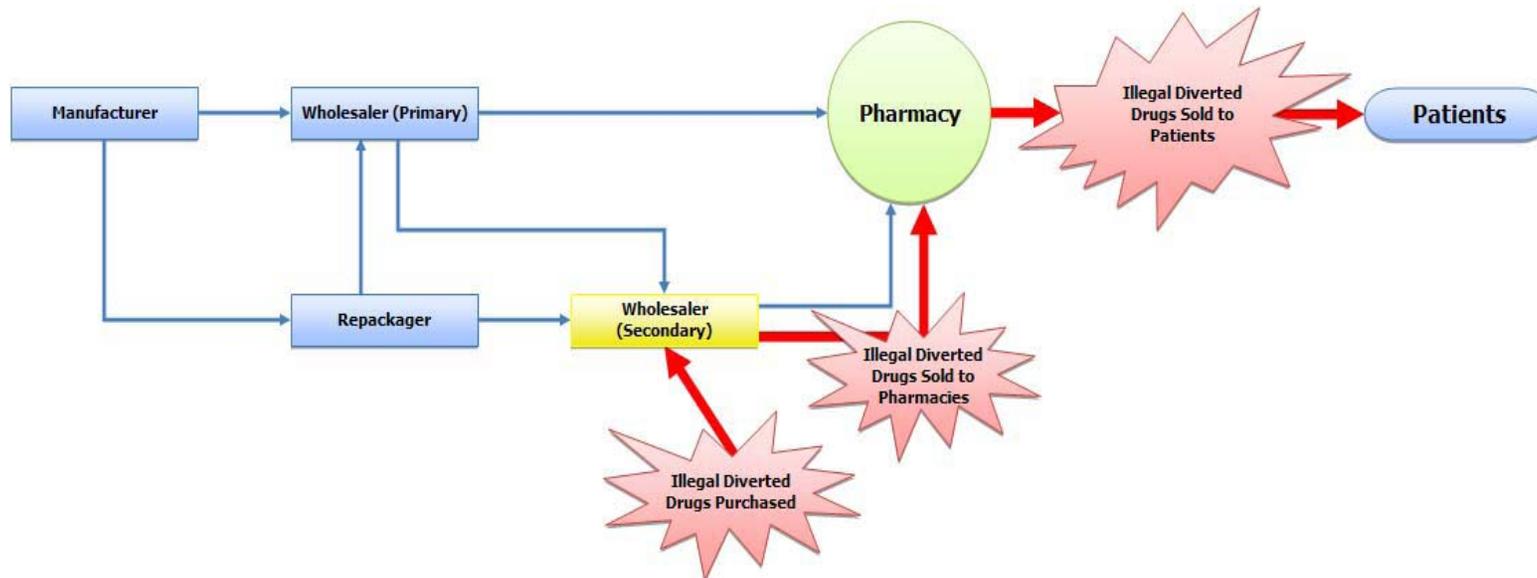
Counterfeit Drug Cases Opened by FDA's Office of Criminal Investigations per Fiscal Year



Preliminary Review of OCI Cases

Report Highlights

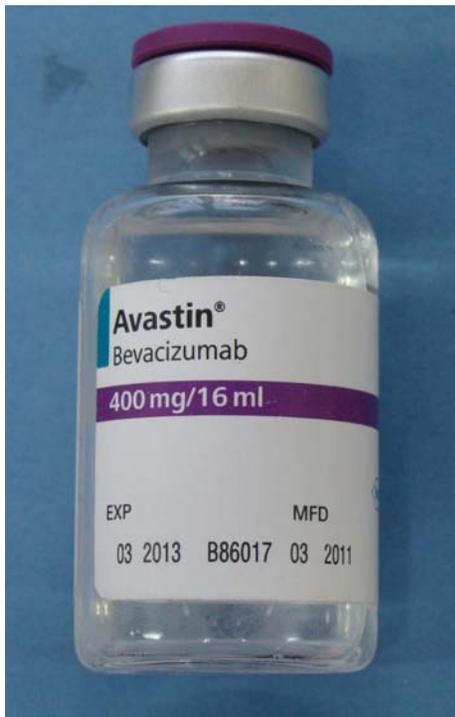
- Examples of diversion and counterfeit schemes



- Drug products involved (solid oral dosage forms)
- Type of entities involved (wholesalers, pharmacist, doctor etc.)

Compromised Integrity: Recent Supply Chain Threats

Counterfeit



- Counterfeit Roche Avastin
- No active ingredient
- Medical clinics notified
- Only Genentech Avastin is FDA-approved in U.S.
- Investigation ongoing

Authentic



Images from
Genentech, Inc.

Counterfeit/Falsified, Diverted or Stolen or Unapproved Drugs may be Dangerous



- May contain harmful ingredients
- May be ineffective (contain no or little drug)
- May cause adverse events (due to ingredients or wrong strength)
- May have lost potency (due to improper storage)
- May be expired
- May be produced under filthy conditions...etc.



What's FDA doing to protect public health?

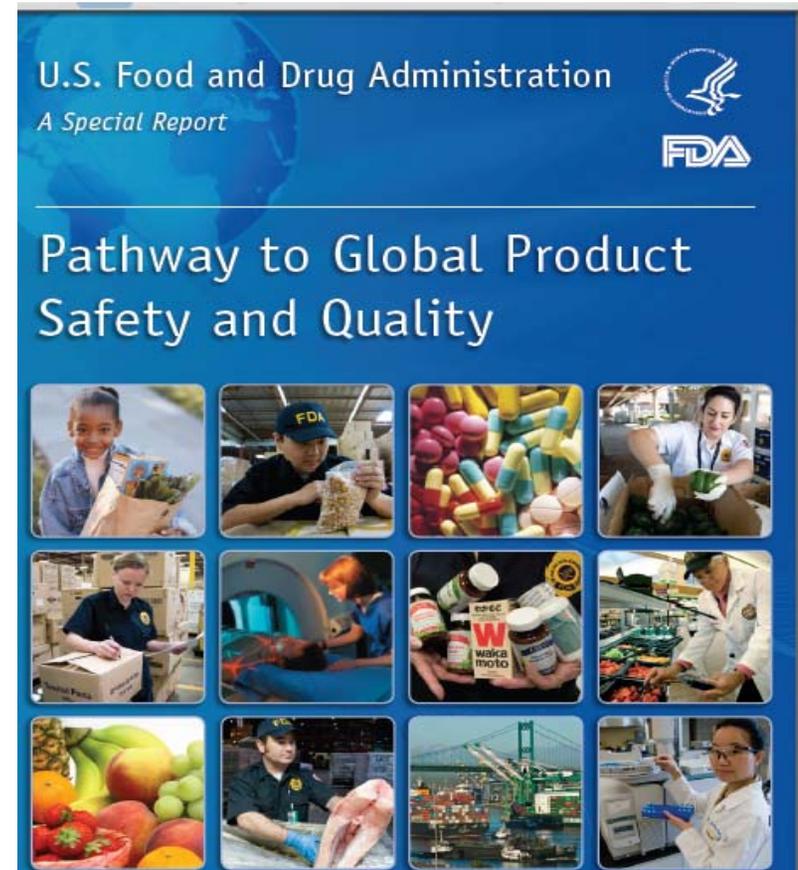
Building Supply Chain Integrity to Ensure Patient Safety (1)

- Transparency and accountability in the supply chain – up and down
- Better enforcement and regulatory tools
- Stakeholder responsibility
- Surveillance/monitoring
- Increased vigilance and awareness
- Educate consumers

(continued)

Building Supply Chain Integrity to Ensure Patient Safety (2)

- Collaboration/cooperation – domestic and international
- Harmonize/Converge internationally
- Share scientific and technical expertise with fellow foreign regulators
- Training programs in regulatory disciplines internationally
- Strengthen global detection, surveillance and assessment systems
- Support development of innovative information systems



New Office of Drug Security, Integrity, and Recalls (ODSIR)

- Enhanced and targeted resources
- Address increasing supply chain threats
 - Intentional adulteration, cargo theft, counterfeiting, diversion, other
 - Focus on life-cycle of the product from drug components through to the finished dosage form delivered to the patient
- New and coordinated approaches, policies and enforcement strategies

Recalls
Drug Shortages

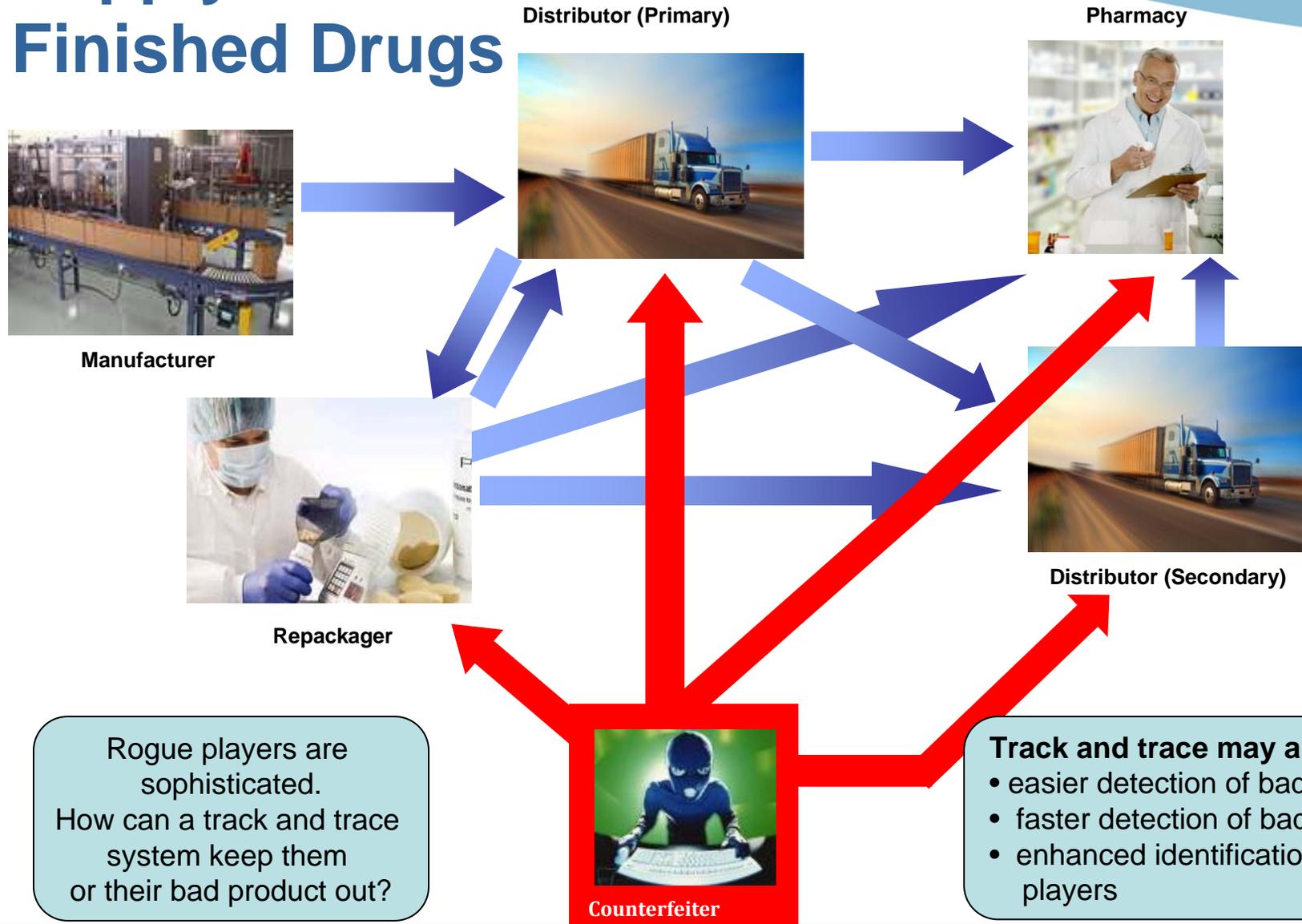
Imports
Exports

Drug Supply Chain Integrity

Transparency and Accountability

- **Know what is in the drug supply chain and who is handling the drugs**
- **Current: Pedigree**
 - documenting each sale or transaction of the product
 - knowledge of:
 - What drug? How much?
 - Who they bought it from and when
 - Who they sold it to and when
 - Other information
- **Future/Ideal: Track and Trace & Authentication**
 - National, uniform tracking and tracing & authentication at unit/package level
 - All supply chain stakeholders track and trace & authenticate
 - Authentication: Check unique serial number on each package & who sold it
 - Other possible security features (e.g., hologram, color-shifting ink, taggants)

Supply Chain for Finished Drugs



Rogue players are sophisticated. How can a track and trace system keep them or their bad product out?

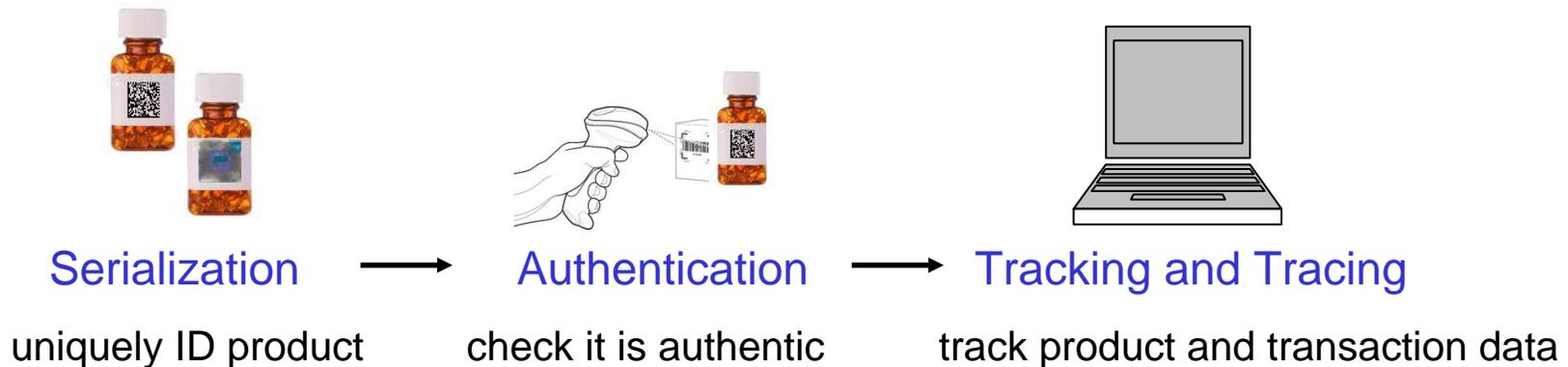
Track and trace may allow

- easier detection of bad products
- faster detection of bad products
- enhanced identification of rogue players

Counterfeiter

Development of Supply Chain Security Standards – Track and Trace

- Section 505D of the Federal Food Drug Cosmetic Act (2007)
- developing standards for tracking and tracing of Rx drug through the supply chain (who handled the product from the point of manufacture to point of dispense)
- Public Dockets (2008)
- SNI Guidance (2010) – standardized numerical identification, serialized NDC
- FDA Track and Trace Public Workshop (2011)



Development of Supply Chain Security Standards – Track and Trace

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

FINAL GUIDANCE

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)
March 2010

- package-level serialization
- SNI for most prescription products:
Serialized NDC (sNDC)

Example of a serialized National Drug Code (sNDC)

| NDC | SERIAL NUMBER |
|--------------|--------------------------|
| 55555 666 77 | + 1111111111111111111111 |

labeler code + product code + package code unique, up to 20 characters

- Serial numbers : numeric or alphanumeric, no more than 20 characters
- Machine- and Human-Readable
- Harmonized with internationally recognized standards

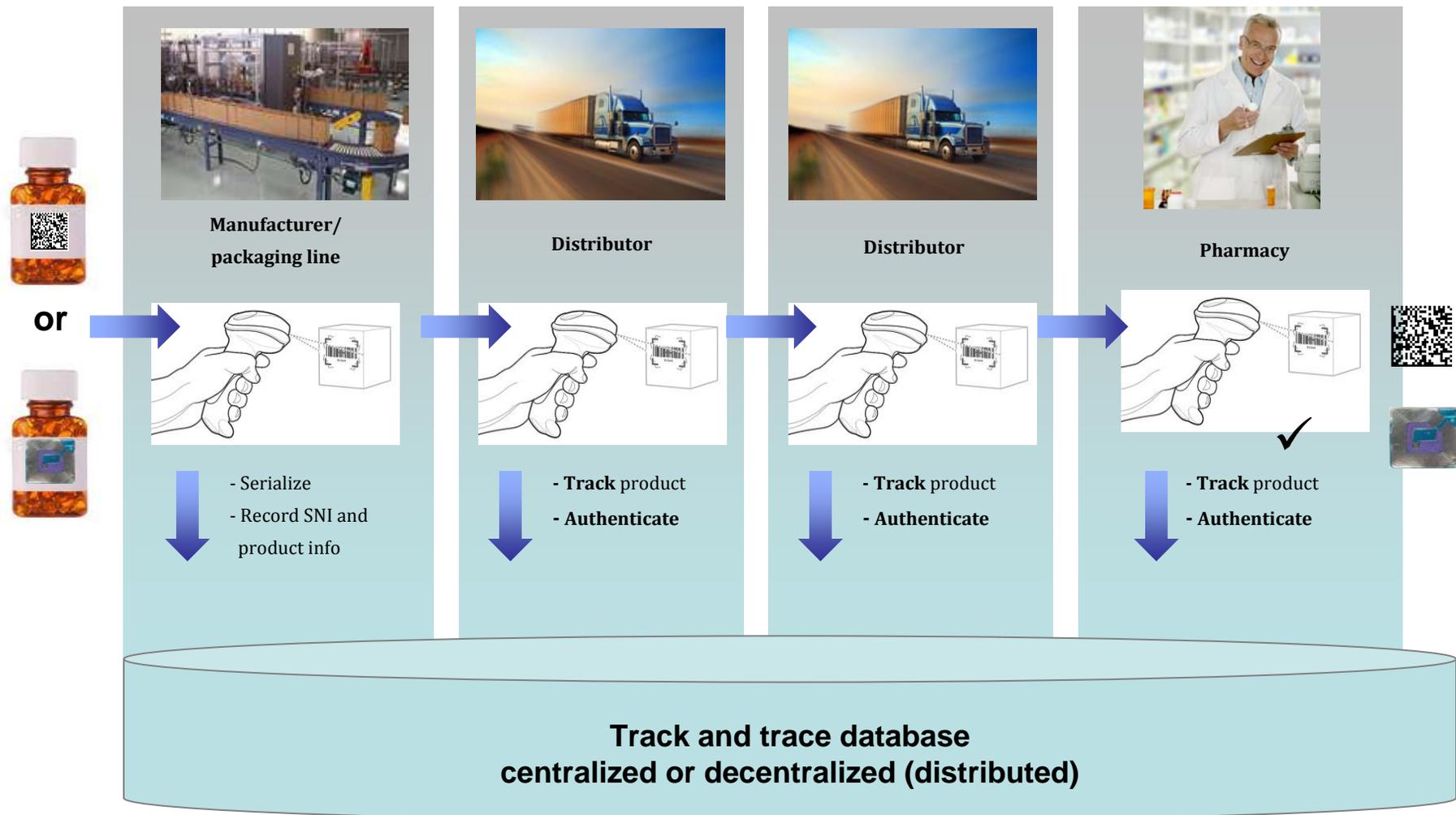
Development of Supply Chain Security Standards – Track and Trace

FDA Track and Trace Public Workshop (February 2011)

- Purpose of workshop – to obtain public input on the necessary elements to achieve effective authentication and the desirable attributes of a track and trace system
- 120 participants representing all stakeholders (manufacturers, distributors, pharmacy, carriers, standards organizations, solution providers)
- Workshop structure was very well-received by participants

<http://www.fda.gov/Drugs/NewsEvents/ucm239382.htm>

Overview of a Track and Trace System



Track and Trace System Goals to Protect the Drug Supply Chain

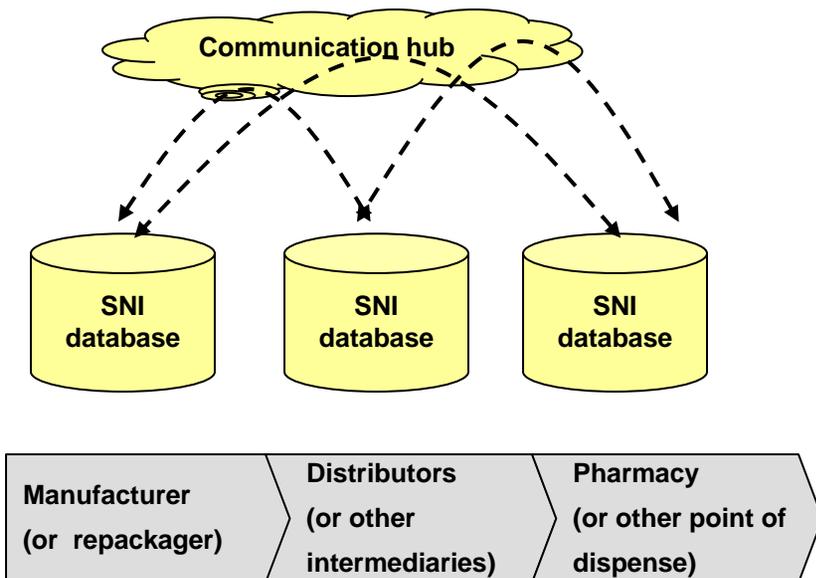
- Help to preventing the introduction of counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs
- Facilitating the identification of counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs
- Providing accountability for the movement of drugs by supply chain participants
- Improving efficiency and effectiveness of recalls

Potential System Attributes

- Capable of capturing data (SNI and status of the number)
- Interoperability - to enable supply chain participants to securely capture, store, and exchange track-and-trace data accurately and efficiently
- Authentication - SNI and distribution history of each package
- Appropriate Data Access and Utilization
- Secure
- Protects confidential commercial information and patient privacy (if applicable)

Possible System Models

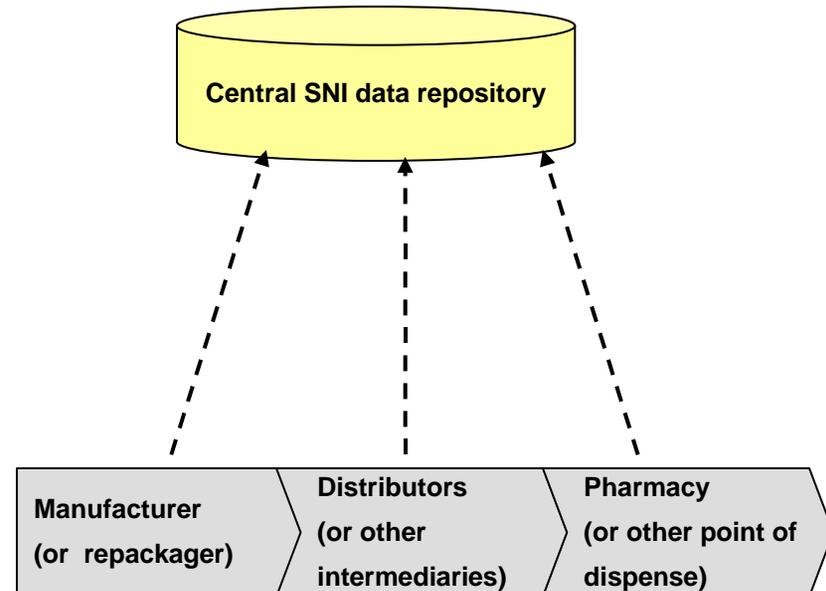
Decentralized (Distributed) Model



Description

- Participants record data into their own local database or data storage provider database
- Authentication and verification is performed by querying the each databases
- A communications hub connects different databases

Centralized Model



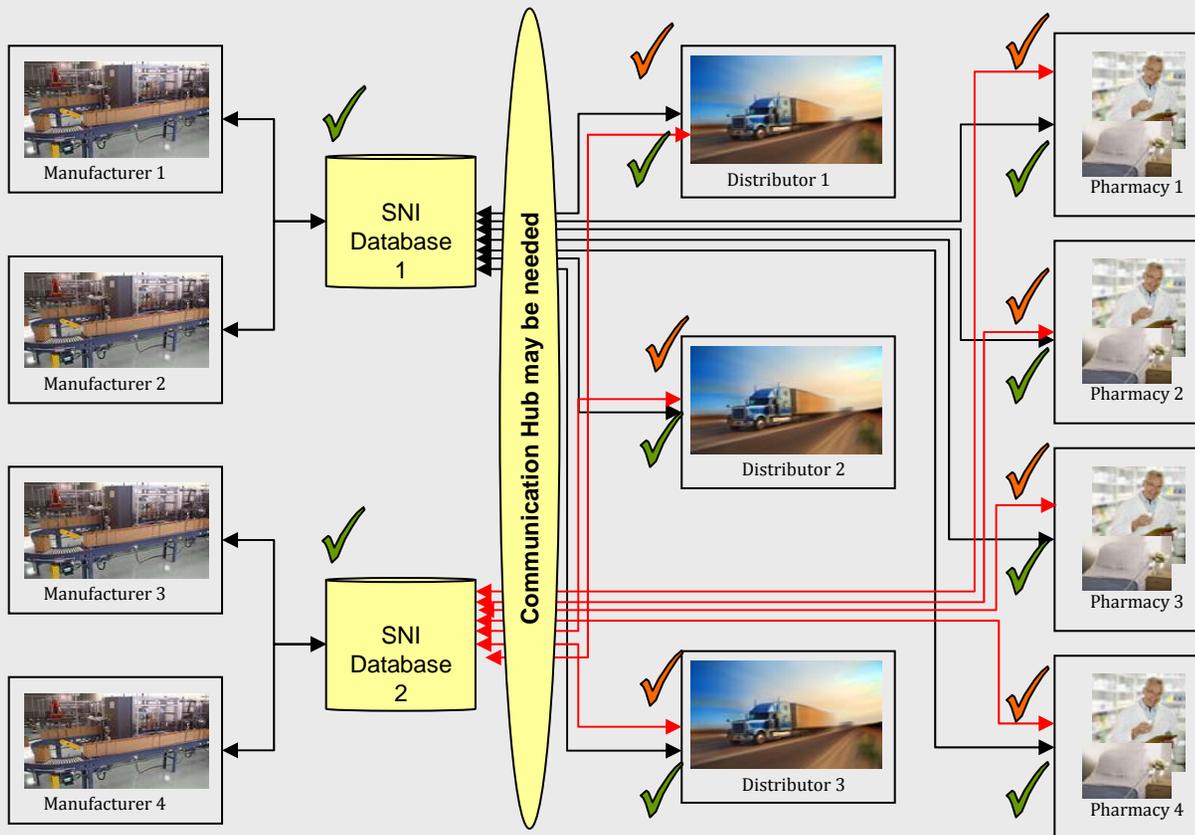
Description

- Participants record data into a central repository (database)
- Authentication and verification is performed by querying the central repository

Possible System Models

Semi-Centralized Model

• ILLUSTRATIVE EXAMPLE



- ✓ Verification of SNI
- ✓ Verification of distribution history

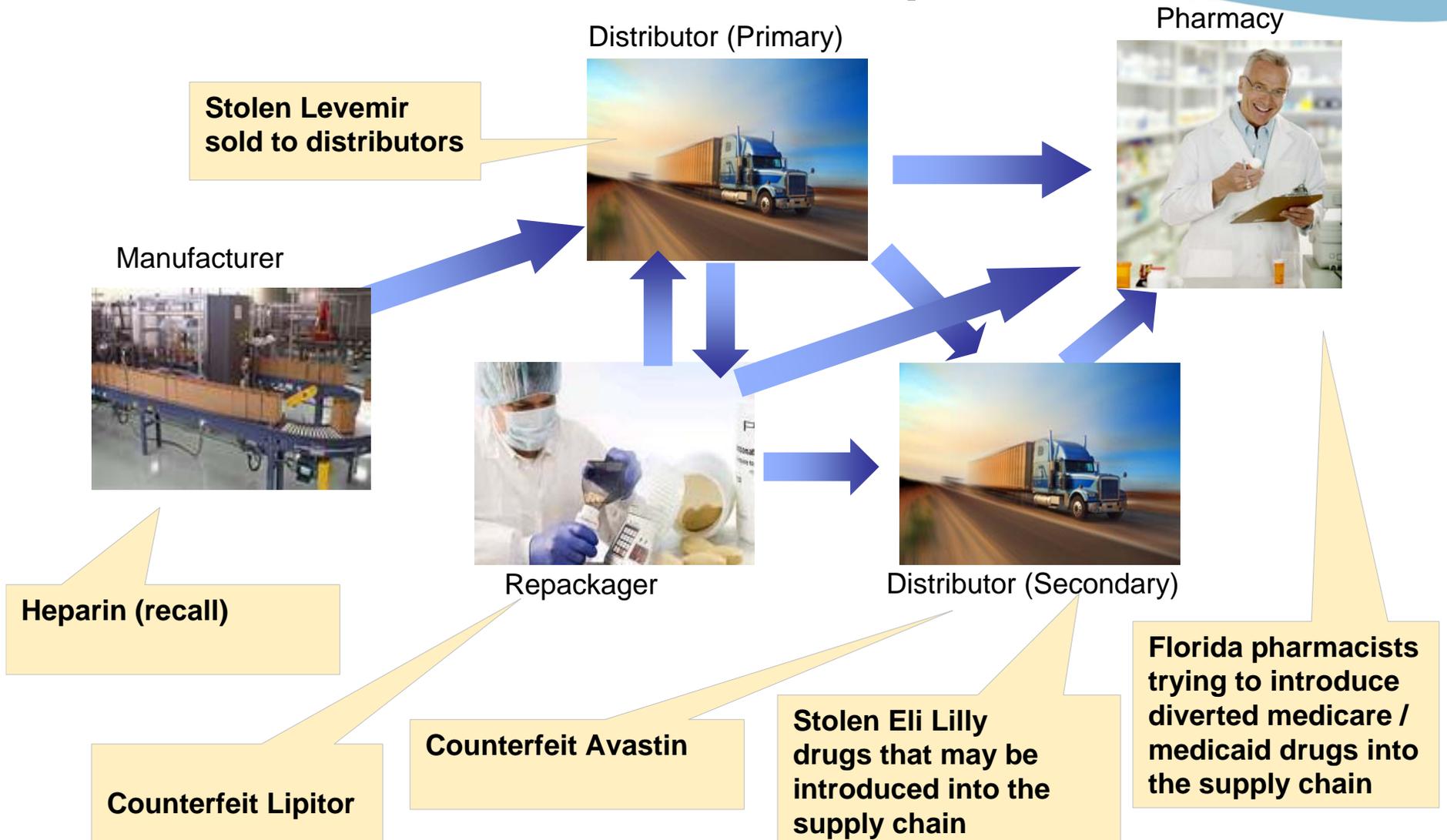
Pros

- Introduces options for companies of where to store their data; may lead to competitive service and pricing
- Enables interoperability by using one data format and communication across several main databases
- Enables full and rapid pedigree – all records for SNI are in one database

Cons

- Creates a large amount of data that should be expertly managed and stored
- Business intelligence submitted by each participant would be stored in the same database – would need good security

Where Track and Trace Can Help



Summary Points to Consider to Protect the Drug Supply Chain

- What drugs should be tracked and traced?
- How should those drugs be identified?
(SNI at the unit/package level)
- What info should be track and trace?
(SNI at the unit/package level)
- What to authenticate? (SNI and who sold/received package)
- Who should be actively tracking and tracing/authenticating?
(ALL members of the supply chain)

Summary Points to Consider to Protect the Drug Supply Chain

- How does unit/package level traceability build quality and integrity into the system to detect potentially dangerous products from entering into the drug supply and prevent further distribution of these dangerous product?
(a robust track and trace system would detect the problem product immediately when the product is introduced into the supply, assuming authentication at each step – is proactive, not just reactive to a problem)
- What would the system look like?
(Centralized, Semi-Centralized or De-centralized?)
- What data standards should be used for language, format and communication, utilization?



Thank you for your attention!

CDER/Office of Compliance/ODSIR Webpage

<http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/default.htm>

Counterfeit Medicines Webpage

<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/default.htm>

connie.jung@fda.hhs.gov



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
- **111** 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

WHY GLOBAL STANDARDS?



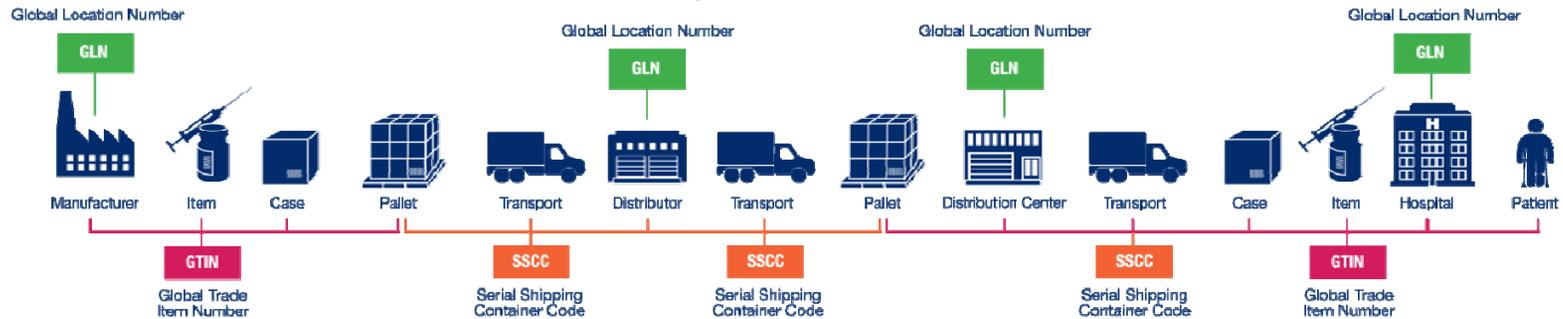
The package has:

- 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).

GS1 STANDARDS IN HEALTHCARE

Identify

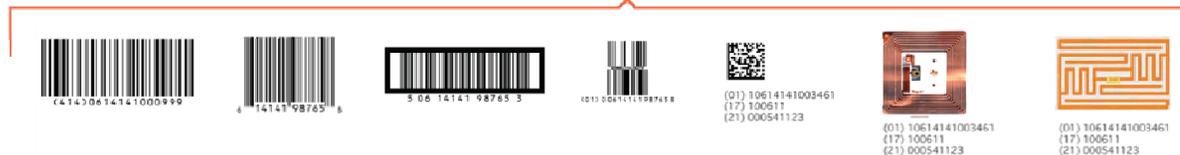
GS1 System Identification Numbers



Capture

GS1 System Data Carriers

Barcodes and EPC-enabled RFID tags



Share

Electronic Commerce Information Flow

Master Data (GLN Registry for Healthcare, GDSN) • Transactional Data (eCom) • Physical Event Data (EPCIS)

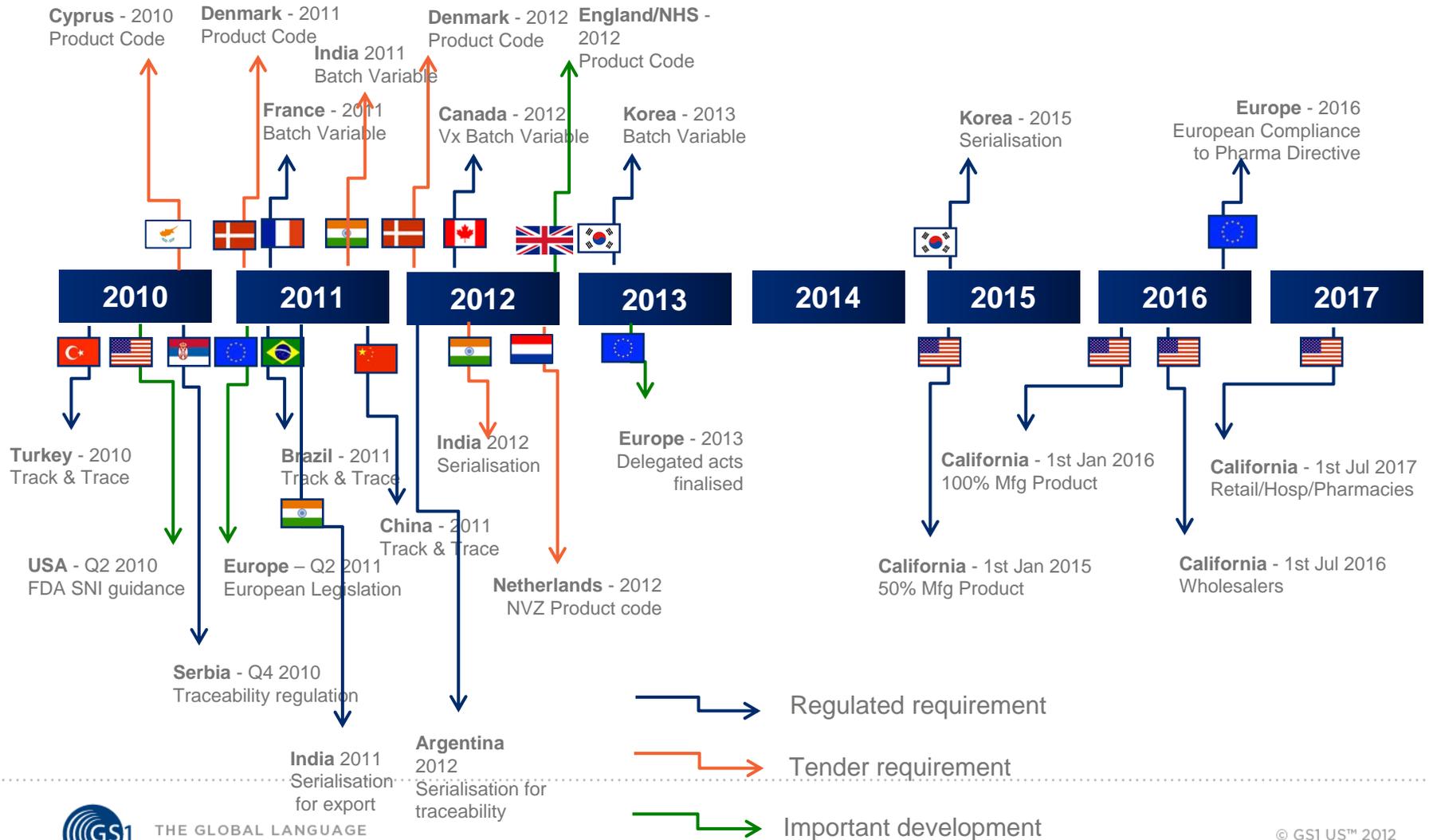




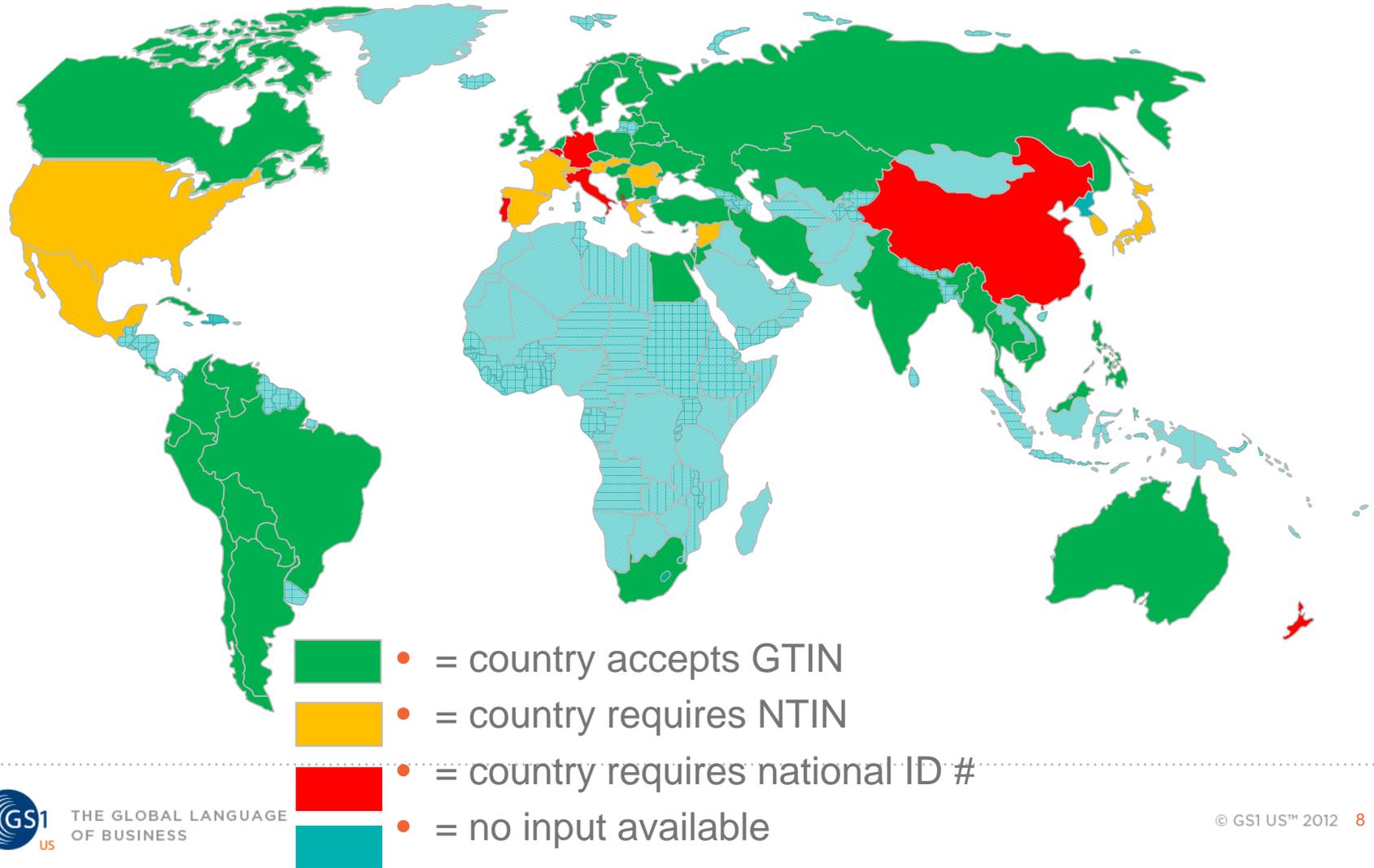
GLOBAL IMPLICATIONS

PHARMACEUTICALS

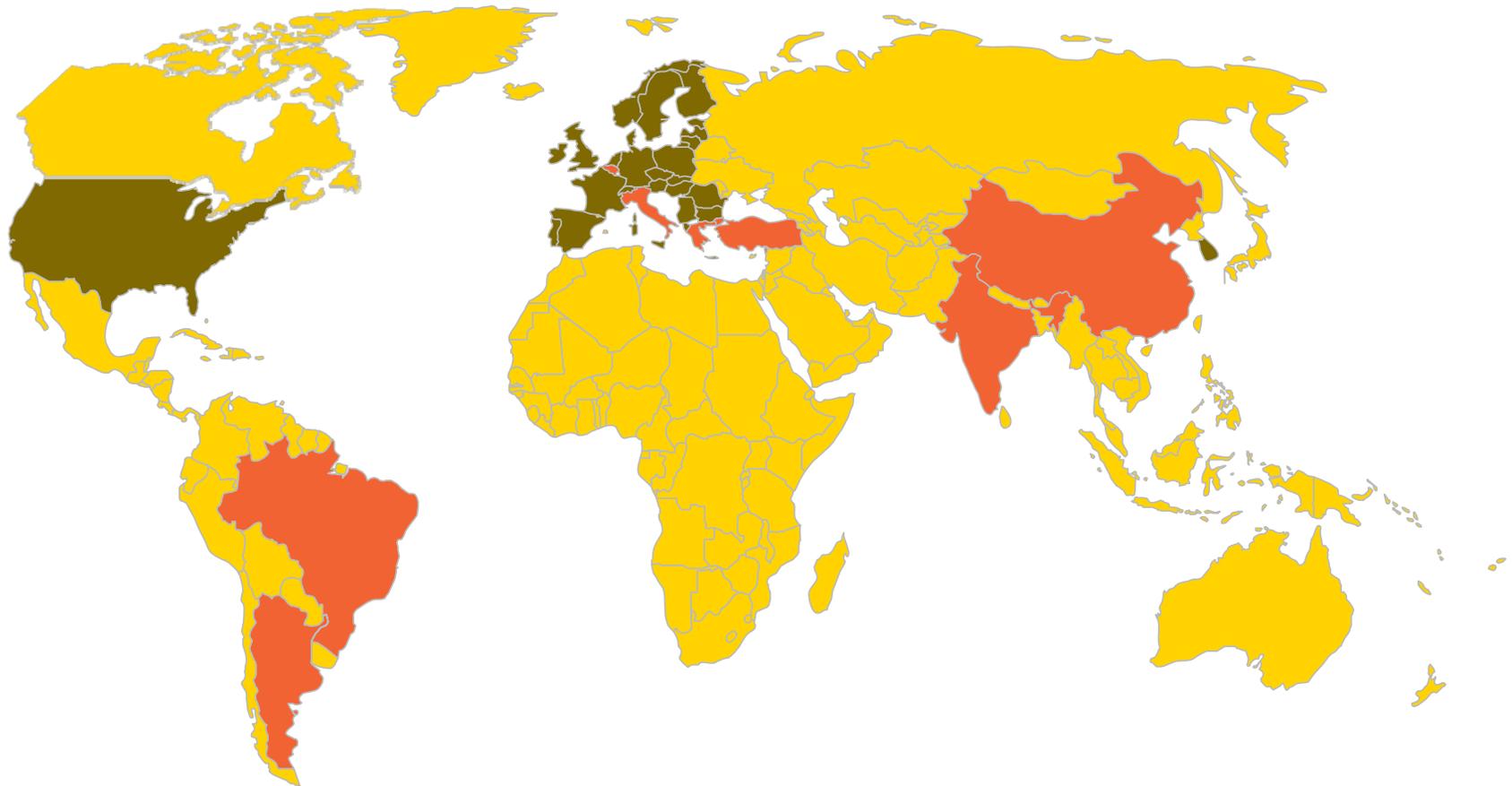
NEW CODING & SERIALISATION REQUIREMENTS



IDENTIFICATION OF PHARMACEUTICALS



SERIALISATION OF PHARMACEUTICALS



• = country requires serial number

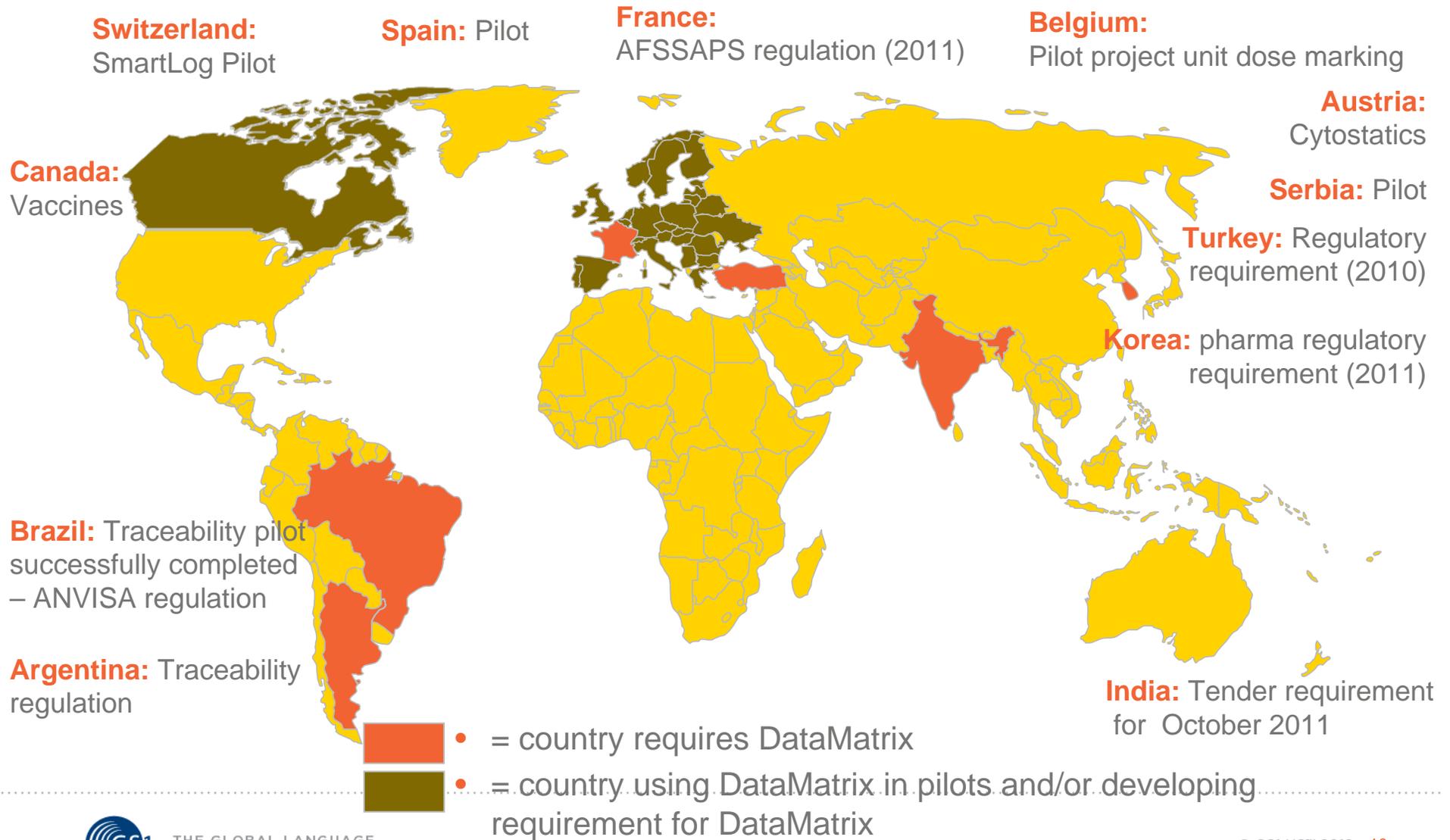


• = country developing requirement for serial number



THE GLOBAL
LANGUAGE
OF BUSINESS

DATAMATRIX ON PHARMACEUTICALS





PEDIGREE, TRACK & TRACE, VISIBILITY

VISIBILITY, TRACEABILITY, TRACK AND TRACE, PEDIGREE TERMS



Visibility:

All of Track & Trace / Traceability. Can also provide status or disposition of item. May include other attributes that provide insight as to whether the item is fit for use. Leverages separate Master Data management.

Traceability / Track and Trace:

Interchangeable terms. GS1 uses Traceability while others (FDA) use Track & Trace).

Provides ability to track forward to determine where the item currently is or trace back where it had been. Can leverage separate Master Data management.

Pedigree:

Usually defined by U.S. State or Federal law. Information to “trace” the distribution history of an item. May include Chain of Custody and/or Chain of ownership.



THE BALANCING ACT

THINGS TO CONSIDER, PERCEPTION ISSUES

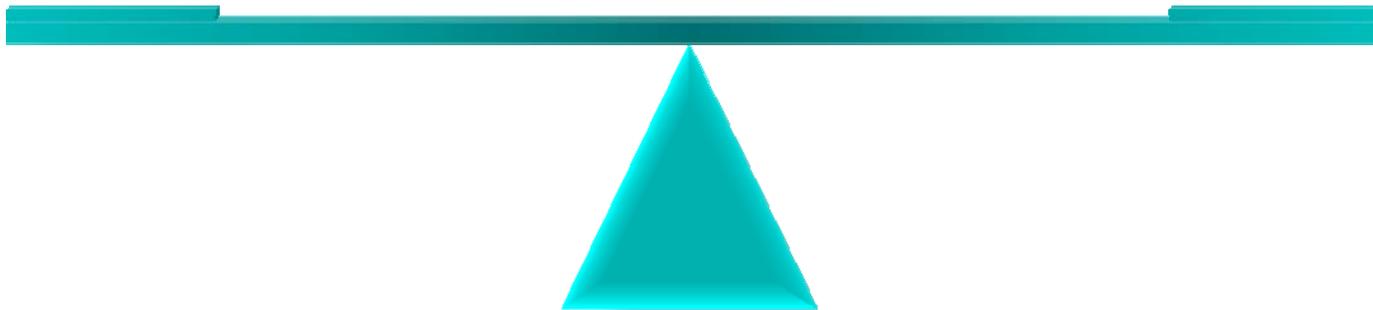
SERIALIZATION AND TRACK & TRACE

THE BALANCING ACT

Inference
1 Up, 1 Down
On Demand
Single Architecture Models

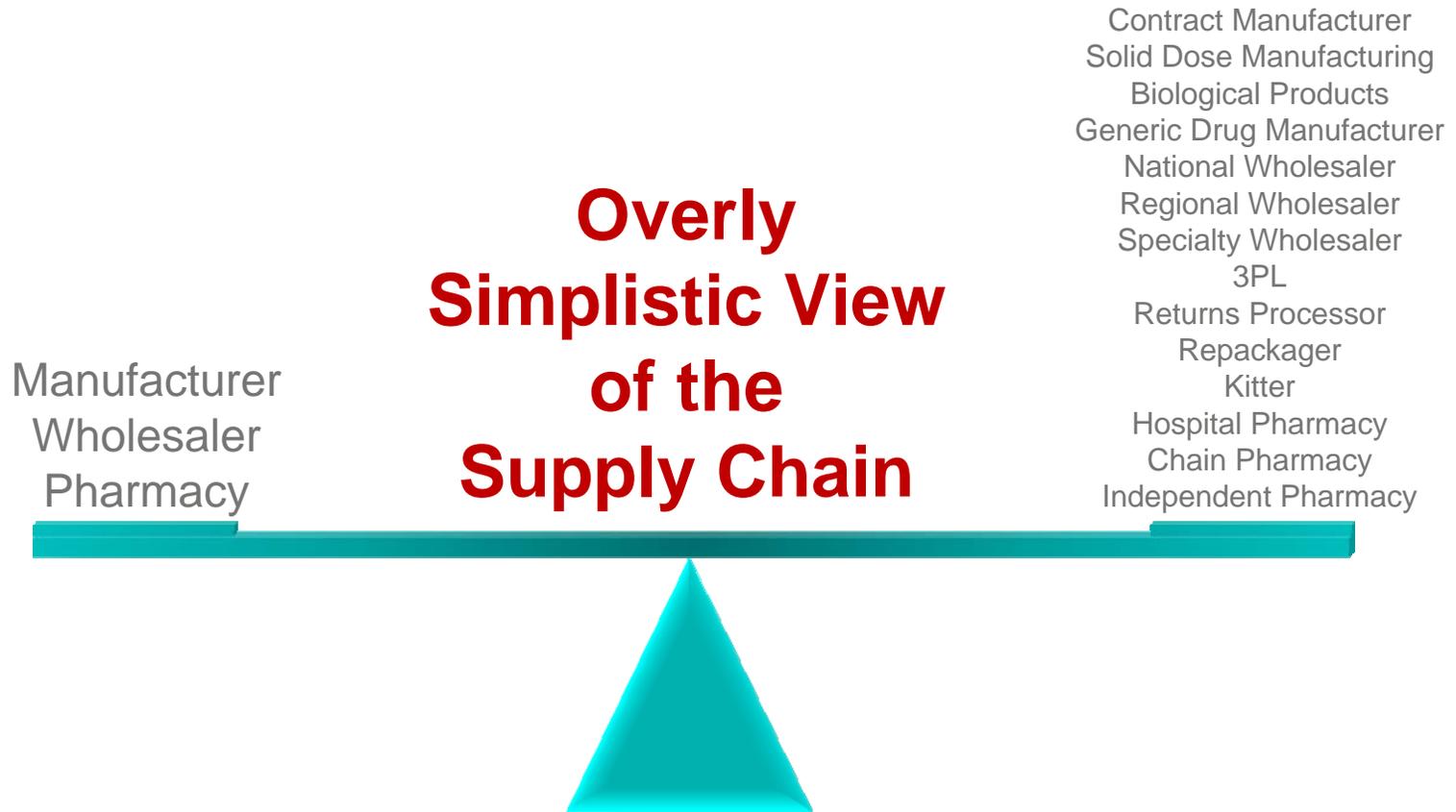
**Decisions,
Decisions,
Decisions**

Decommissioning
Track & Trace
On Arrival
Multi-Architectures



SERIALIZATION AND TRACK & TRACE

THE BALANCING ACT



SERIALIZATION AND TRACK & TRACE

THE BALANCING ACT

Normal Processes

Basic Forward Logistics
Drop Shipments
Kitting
Repackaging
Recalls
Returns
Withdrawals
Refusals

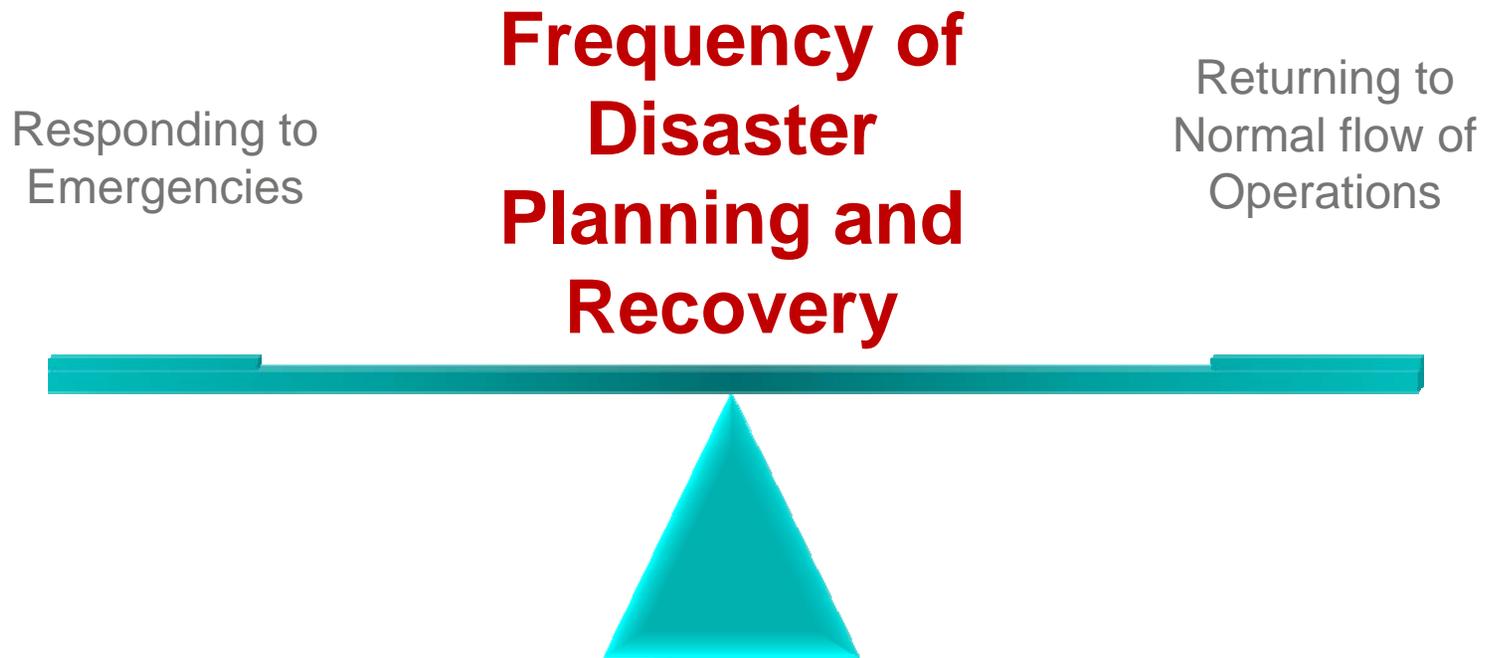
**Perception of
the amount
of Processes
Impacted or
Created**

Exception Processes

Visible Overage
Visible Shortage
Pedigree Serial # Discrepancy
Pedigree Lot Discrepancy
Product Inference Problem
Concealed Discrepancy
Physical Inventory - Visible Overage
Physical Inventory - Concealed Overage
Physical Inventory - Pure Shortage
Physical Inventory - Concealed Shortage
Pedigree Data Error
Pedigree Data Not Received
Undelivered Shipment
Lost Shipment
Unidentified Sender
Pedigree Security Error
Damaged Bar Code or RFID
Damaged Product
Damaged Shipment
Product Damaged after Receipt
Unauthorized Return

SERIALIZATION AND TRACK & TRACE

THE BALANCING ACT





STANDARDS ACTIVITIES IN THE U.S.

IMPLEMENTATION SUPPORT

SECURE SUPPLY CHAIN TASK FORCE

IMPLEMENTATION GUIDE UPDATE



GS1 Healthcare[®]
US Improving Patient Safety and Supply Chain Efficiency

Implementation Guide

**Applying GS1 Standards to
U.S. Pharmaceutical Supply Chain
Business Processes**

To Support Pedigree and Track & Trace

DRAFT
V0.13 (February 7, 2011)

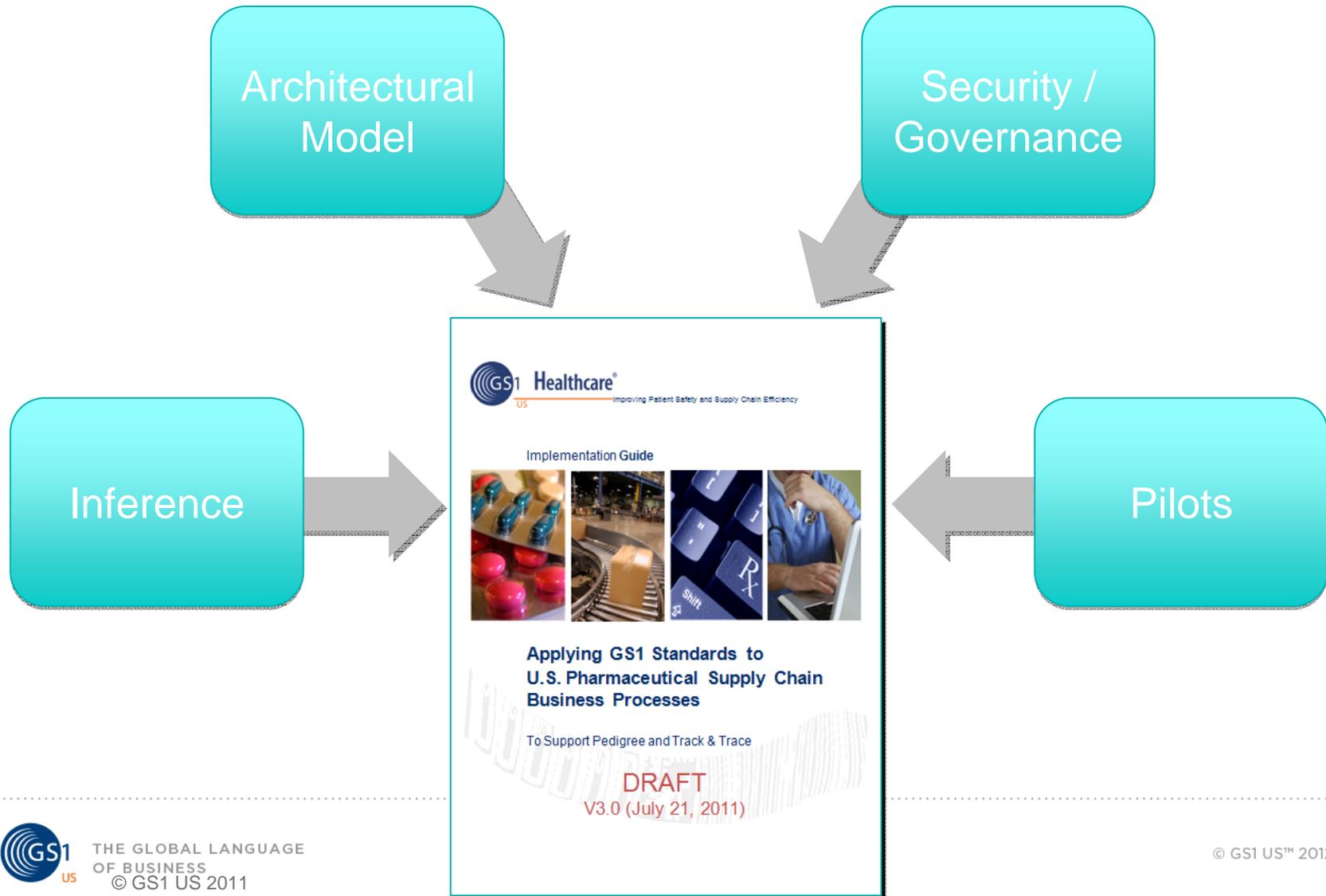
Contents of the guideline:

- Identifying Trade Units (Products, Cases, and Kits):
- Identifying Logistics Units (Cases, Pallets, and Totes)
- Identifying Parties & Locations
- Encoding GS1 Data Carriers
- Translating Captured Data
- Master Data Management (product and location data)
- Applying GS1 Standards for Event Data
- Supply Chain Events to be Captured for Pedigree
- Additional Supply Chain Events for Track & Trace
- Exceptions Processing
- Pilot learnings / best practices
- Forward Logistics Examples
- Reverse Logistics Examples
- Potential Architectural Models

Decisions that will affect final version:

- Track and Trace granularity (Lot, Item)
- Inference
- Architecture (Centralized, Decentralized, etc.)
- Data access governance

STANDARDS ACTIVITIES WITHIN THE U.S. IMPLEMENTATION SUPPORT



STANDARDS ACTIVITIES WITHIN THE U.S. IMPLEMENTATION SUPPORT - STATISTICAL SAMPLING MODEL



THE GLOBAL LANGUAGE
OF BUSINESS



| Statistical Sampling Plan | | | | | | | | | | Quality Characteristics of the Selected Plan | | | | | | | | | |
|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Input required by users: | | | | | | | | | | 1. Operating characteristic (OC) curve | | | | | | | | | |
| Size of shipment (in bottles): 1,000 bottles | | | | | | | | | | Shows the ability of the plan to distinguish between good and bad shipments. | | | | | | | | | |
| Acceptable quality level (%): 1.000% please select from the drop down list | | | | | | | | | | For any fraction nonconforming p , the OC curve shows the probability P_a that the shipment will be accepted. | | | | | | | | | |
| Output: | | | | | | | | | | Operating Characteristic (OC) Curve | | | | | | | | | |
| Code letter: J | | | | | | | | | | | | | | | | | | | |
| Normal Inspection: | | | | | | | | | | <p>Reduced Inspection (1): the probabilities of acceptance accompanied by continuation of reduced inspection.</p> <p>Reduced Inspection (2): the probabilities of not rejecting a shipment. The difference between the two curves equals to the probability that a shipment will be accepted but normal inspection will be reinstated.</p> | | | | | | | | | |
| Parameters of sampling plan: | | | | | | | | | | 2. Average Outgoing Quality (AOQ): | | | | | | | | | |
| sample size (n): 80 | | | | | | | | | | Calculates the average percentage of nonconforming items after inspection, <u>in the long run</u> . | | | | | | | | | |
| Acceptance number (c): 2 | | | | | | | | | | Please check in the "Model assumptions" tab for more information on how the AOQ is calculated. | | | | | | | | | |
| Sample plan instructions: | | | | | | | | | | | | | | | | | | | |
| 1. Randomly select 80 bottles out of all bottles in the shipment, and inspect them. | | | | | | | | | | | | | | | | | | | |
| 2. If the total number of nonconforming items found in the inspection is less than or equal to 2, accept shipment. | | | | | | | | | | | | | | | | | | | |
| Otherwise reject shipment. | | | | | | | | | | | | | | | | | | | |
| 3. Record inspection results in the results form. | | | | | | | | | | | | | | | | | | | |
| 4. If shipment was rejected, conduct 100% inspection of all bottles in the shipment. | | | | | | | | | | | | | | | | | | | |
| 5. Follow company policy to determine how to deal with any nonconforming items found during inspection. | | | | | | | | | | | | | | | | | | | |
| Switch to tightened inspection: | | | | | | | | | | | | | | | | | | | |
| 6. If 2 or more of the last 5 shipments from the same supplier have been rejected, switch to tightened inspection. | | | | | | | | | | | | | | | | | | | |
| Switch to reduced inspection: | | | | | | | | | | | | | | | | | | | |
| 7. Switch to reduced inspection if ALL of the following conditions have been met: | | | | | | | | | | | | | | | | | | | |
| - It seems likely that the product to be inspected under reduced inspection will be produced and delivered | | | | | | | | | | | | | | | | | | | |
| to the receiving party under the same conditions that gave rise to the recent good quality history; and | | | | | | | | | | | | | | | | | | | |
| - Reduced inspection is considered desirable by the responsible authority; and | | | | | | | | | | | | | | | | | | | |
| - The total number of nonconforming items found in the preceding 10 (or more) shipments is sufficiently low. To check | | | | | | | | | | | | | | | | | | | |

2015 READINESS PILOTS GET INVOLVED & LEARN FROM OTHERS



2015 READINESS PILOTS

SAMPLE PILOT TRACKER

| Pilots | Participants | Carrier Quality (Barcode, RFID) | | | Data Exchange | | | Operations | | | Functionality | | | | EPCIS Events/Steps | | | Exceptions | | | | | | | | | | | |
|---------------------------|----------------|---------------------------------|--|--|---------------------|------|-----------|---------------------------|------|----------------------|---------------|--|-------------------------|---------------|--------------------|---------|-------------|------------|--------------------|--------------------|-------------|----------|-----------|---------|----------|----------------------|-------------------|--------------------|----------------------|
| | | Barcode Verification | | | HDMA/EDI Guidelines | GDSN | Discovery | Shared Event Repositories | DPMS | Aggregation Accuracy | | | Basic Forward Logistics | Drop Shipment | Returns | Recalls | Withdrawals | Refusals | Item Commissioning | Case Commissioning | Aggregation | Shipping | Receiving | Overage | Underage | Serial # Discrepancy | Lot # Discrepancy | Concealed Shortage | Incorrect EPCIS data |
| Barcode Quality | Manufacturer X | X | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Pharmacy Z | X | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Extended Trading Partners | Manufacturer X | | | | X | | | | | | | | X | | | | | | | | | | | | | | | | |
| | Wholesaler Y | | | | X | | | | | | | | X | | | | | | | | | | | | | | | | |
| | Pharmacy Z | | | | X | | | | | | | | X | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

TRACEABILITY PILOTS TASK FORCE

PILOT PANEL CALLS

| Date | Agenda Topics |
|-----------|--|
| 2/29/2012 | Main Topic: Serialization on packaging lines (encoding,) |
| 3/14/2012 | Main Topic: Interoperability and exchange between partners |
| 3/28/2012 | Main Topic: Pilot Planning |
| 4/11/2012 | Main Topic: Managing traceability information and implementation across the enterprise (scaling, avoiding competing implementations inside your co) |
| 4/25/2012 | Main Topic: Labeling (AI (30), Item Count), labeling practices you might encounter |
| 5/9/2012 | Main Topic: Packaging level indicators |
| 5/16/2012 | Main Topic: Pharmacy/Clinic roundtable |
| 5/30/2012 | Main Topic: Master Data Management |

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Connect with the GS1 US community on

