U.S. Drug Supply Chain Security Act (DSCSA) and Product Traceability

Peggy Staver
21 October, 2015
DSCSA

• Background

• High Level Requirements

• Product Tracing Requirements – 2015

• Lessons Learned
Background

- Counterfeit pharmaceuticals found in the legitimate supply chain
- Increase in cargo theft and diversion
- Patchwork of state pedigree requirements unworkable
- California law required item-level serialization and track-and-trace throughout the supply chain by 2017
- Industry stakeholders collaborated to propose a viable federal solution to legislators that would preempt existing state laws
Drug Quality and Security Act

November 27, 2013
H.R 3204
Public Law No: 113-54

“Drug Quality and Security Act”

Title II
“Drug Supply Chain Security Act”

Read the original article on the website (http://bigstory.ap.org/article/obama-signs-bill-more-scrutiny-drug-mixers)
Drug Supply Chain Security Act

- U.S. federal law – pertains to brand and generic prescription pharmaceuticals
- Human health finished goods (some exceptions) and the legitimate supply chain
- Product tracing, licensing, verification, notification, and serialization requirements
- Change of ownership emphasis
- Phased implementation – all sectors impacted
- State pedigree and licensing preemption
- Alignment with GS1 standards
Drug Supply Chain Security Act
Key Manufacturer’s Mandates

2015

Jan 1, 2015
• Product Tracing - (Lot Info)
  Provide for each Change of Ownership:
  • Transaction Info (TI)
  • Transaction History (TH)
  • Transaction Stmt(TS)
  • Single Document
  • Paper or Electronic
• Verification & Sys Requirements
  • Suspect Product
  • Illegitimate Product
• Requests for Information
  • TI, TH, TS < 48 hrs
• Notifications – Illegitimate <24 hrs
• Authorized Trading Partners

2017

Nov 2017
• Serialized Product Identifiers
  • Each Pkg. and Case
  • 2D DataMatrix on Pkg.
  • Linear or 2D on Case
  • NDC + Serial Number (SNI)
  • Lot and Exp Date
  • Human Readable and Machine Readable
• Provide TI, TH, TS in electronic format
• Verification Requirements
  • Product ID/SNI’s < 24 hrs
  • SNI for Saleable Returns
• Maintain Product Identifiers – 6 yrs

2023

Nov 2023
• Pkg (Item-level) traceability
• Interoperable electronic “Tracing”
• Exchange TI, TS in a secure, interoperable electronic manner
• TI to include product identifier
• Systems and Processes for “Verification” of Product at Pkg. level, including the SNI
• Systems and Processes to promptly respond with TI and TS and gather Transaction History
• Saleable Returns – TI and TS
• Requests for Information < 24 hrs

SELF-EXECUTING
### Product Tracing Requirements For 2015

- Acquire or provide on each change of ownership, a single document with:
  - Transaction History + Transaction Information + Transaction Statement

- Compliance documentation required for Sale, Purchase, Drop Shipment, Saleable Returns and retained for 6 years

<table>
<thead>
<tr>
<th>Transaction History (TH)</th>
<th>Transaction Information (TI)</th>
<th>Transaction Statement (TS)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Single</strong> document starting with manufacturer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Includes Transaction Information for each transaction going back to the manufacturer</td>
<td></td>
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</tbody>
</table>

Special versions of Transaction History possible for Direct Purchase wholesale distribution operations

Electronic or paper (initially)
- Electronic format required starting in 2017

- NDC
- Product Name
- Strength
- Dosage Form
- Container Size
- Number of Containers
- Lot Number (optional in certain scenarios)
- Transaction Date (business transaction)
- Shipment Date (if >24 hrs. from Trans Date)
- Transfer From Party (business name & address)
- Transfer To Party (business name & address)
- Wholesaler Contact Information (for Drop Shipment)

Statement attesting that party transferring ownership:
- Is authorized and registered
- Received product from authorized, registered party
- Received Transaction Information and a Transaction Statement from the prior owner
- Did not knowingly ship suspect or illegitimate product
- Had systems and processes in place to comply with verification requirements
- Did not knowingly provide false transaction info
- Did not knowingly alter the transaction history

Used with permission from TraceLink
Lessons Learned

• Collaboration with industry peers, trading partners, solution providers, standards bodies, regulators and legislators is key
• Connecting all the relevant stakeholders is no small task
• Electronic data exchange is preferred over paper-based solutions
• Implementation takes time even when leveraging existing technology
• Production environment (vs. testing) reveals new challenges
• Traceability has a significant impact on business processes, systems and operations
• A higher level of accuracy/precision is required in daily operations
• Exceptions must be resolved quickly
• Master data issues must be addressed early in the process
• Solution providers play a key role in the successful deployment
• Must implement early and test thoroughly before “go live”
• Start-up, technical issues should be expected
Thank You!

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The European Stakeholder Model (ESM)

Grant Courtney
Introduction

- Grant Courtney (GSK)
  - Previously a member of the EFPIA Serialisation & Coding Steering Team
  - Member of GS1 Healthcare Leadership Team
  - 20 Years experience in healthcare
A quick reminder

European Hub

Pharmaceutical Manufacturer

National System

Pharmacy

Wholesaler

National System

Pharmacy

Wholesaler

Parallel Distributor
Smart things about the ESM

- Accounts for national differences
- Governance
- Designed with cost in mind and who pays
- Data ownership and access
- Interoperability across countries
  - Parallel trade
  - Shared packs
  - Movement across boarders
- Standards Based
Supporting Parallel Trade

GTIN: 01234567890123
Batch: A12345PM
SN: 1, 2, 3

GTIN: 03211234567890
Batch: A12345PM A
SN: A, B, C
Shared Packs (Multi-country packs)
Movement across boarders
EPCIS ?
GS1 Standards

- Pharmacy
- Hospitals
- Supply Chain
- B2C
- Pharmacovigilence
- Customs
ensuring patients have access to safe medicines
Objective: Protection of patients from counterfeited medicines in the legal distribution chain

Content: Pan-European system to verify the authenticity of medicinal products

Non-compliance puts sales at risk
| **SAFETY FEATURES** | • Unique identifier with randomised serial number  
• Check of pack’s authenticity at point of dispense |
| **SYSTEM DESIGN** | • Flexible to implement national solutions within an EU technical framework (according to User Requirement Specifications)  
• Interoperable between different national systems through European Hub |
| **DATA** | • Transactional data belongs to stakeholder that generated it, e.g. pharmacists for dispensing data  
• No access to data of other stakeholders except for verification purposes |
| **GOVERNANCE** | • Systems governed by non-profit organisations, established and managed by relevant stakeholders  
• Systems supervised by EU and/or national authorities  
• Quality supervision by EDQM (tbd) |
Delegated Regulation will mandate rules for medicines verification

Serialization by manufacturer

+ Verification at point of dispense

Code (‘safety feature’) + Tamper evidence

System set up and governed by stakeholders under supervision of authorities

Product #: 09876543210982
Batch: A1C2E3G4I5
Expiry: 140531
S/N: 12345AZRQF1234567890

Verification of Medicinal Products in Europe

GS1
Budapest
21/10/2015
EMVO
European Medicines Verification Organisation

A Blueprint system is a lot more than standardised software

Main elements

• Implementation of national systems based on a common standard, i.e. compliance with URS
• Support for national stakeholders by EMVO during deployment process (to be paid for by national stakeholders)
• Management by EMVO on behalf of the respective national stakeholders (paid by them)
• Technical operation by a limited number of IT providers
Full operation phase: Who will have to pay?

MAHs selling products in a Member State pay for respective national system and a share of the European Hub.
Total cost of a national verification system includes three elements

- **System cost** (charged by service provider)
  - Estimate based on IT service providers’ “standard” offers, best and final offer to be negotiated country by country

- **NMVO cost** (*) (governance and administration)
  - Estimate by EMVO, to be reviewed country by country

- **Hub cost** (charged by EMVO)
  - Estimate based on EMVO business plan and proposed allocation scheme

* Part of NMVO cost to be covered by fees paid by all (full) NMVO members to achieve fair balance between rights and obligations
What are the actions/tasks at national level?

- Agreement between stakeholders
  - Principles for cooperation (MoU blueprint)
  - Establish stakeholder implementation project
  - Foundation of National Medicines Verification Organization (NMVO)
  - Definition of technical requirements
  - Select IT provider (if blueprint out of the EMVO selection)
  - Provide funding

- Cooperation with competent authority

- System implementation

⇒ System complete in 2018!
EPCIS In Healthcare

Scott Mooney, McKesson Corp.
October 21, 2015
#11 on Fortune 500 with Fiscal 2015 Revenues of $179B

- Distribution Solutions
  - Pharmaceutical
  - Medical/Surgical
  - Specialty
  - Plasma and Blood
- Technology Solutions
  - Pharmacy Systems & Automation
  - Electronic Health Records
  - Clinical Applications
    - Imaging Documentation
    - Practice Management
    - Revenue Cycle
  - Patient Relationship Solutions
  - Manufacturer Services
  - Adherence Programs
  - Austria
  - Belgium
  - Brazil
  - Canada
  - Denmark
  - France
  - Germany
  - Ireland
  - Italy
  - Mexico
  - Netherlands
  - Norway
  - Portugal
  - Slovenia
  - Sweden
  - United Kingdom
  - United States
EPCIS in Healthcare Application

- Objectives of EPCIS
- Session Objectives
- Basic Supply Chain Model
- Basic Data Architecture Models
- Models for EPCIS in Healthcare
  - Verification,
  - Traceability (custody & ownership)
  - Recalls
  - Aggregation
- Pilots
Objectives of EPCIS

• Enable disparate applications to share visibility event data, both within and across enterprises

• Enable trading partners to share information about the physical movement and status of products as they travel throughout the supply chain – from business to business and ultimately to consumers

• Answer the “what, where, when and why” questions to meet consumer and regulatory demands for accurate and detailed product information
Session Objectives

• Advance the dialogue around serialized data exchange utilizing the EPCIS Standard in Healthcare

• Establish a high level understanding of use scenarios

• Advance the adoption of EPCIS for additional pilots/proof of concept work
This is a simplified example of a basic supply chain with activities by different supply chain partners along the way that we will use for discussion purposes today. It represents a Manufacturer (M), Wholesale Distributor (W1) and a Dispenser (D).
Supplies Chains are More Complicated...

In reality, our supply chains are much more complicated and have many more participants at all points along the supply chain.
Centralized Repository Architecture

Data handling in a centralized model has supply chain partners posting EPCIS activity to a single point where relevant access exists for the supply chain.
Semi-Centralized Repository Architecture

Trading partners post EPCIS activity to multiple points organized by a geography, manufacturer, product type or other criteria again with relevant access to the supply chain partners.
In a de-centralized model, each supply chain partner receives, holds, and sends EPCIS data with upstream and downstream trading partners.
The data structure and the data rights of the various supply chain partners is something we will not cover today. While it is an important topic, we will assume that the following scenarios will work equally well under either of the three structures previously mentioned.

To aid in the discussion, we will represent any of those models as:
Authentication/Verification

Manufacturer posts EPCIS Commissioning Data with SGTIN

Supply chain partners may query on demand the data to authenticate

QUERY
Shipping EPCIS events are posted and are used by receiving party. Shipping events and receiving could occur multiple times through the supply chain.
Traceability-Ownership

The US DSCSA requires ownership changes as the activity to track for Rx drugs.

Ownership is evidenced by performance and financial responsibility to meet US needs.
Recalls

Notification of a recall by a manufacturer may be posted using EPCIS to the repository and pushed to the supply chain.

Trading partners could also query the repository on demand.
The Packing EPCIS event creating a Case SGTIN or SSCC for a mixed load identify inner contents and with the ship event post to the repository.

Aggregation could be used to ship and the contents inferred when received. Aggregation would happen again when shipping repacked totes to dispensers.
Beyond US DSCSA with EPCIS
The end point and transition period

US Industry Compliance Starts

Jan 2015
Share Lot Level Data

2017
Serialize Products

2023
Item Level Traceability

Lot level Management

Item Level Traceability

Serialized Product: DataMatrix

Lot level Data Sharing

Item Level Traceability Data Sharing
Global Traceability Co-Operation Forum (GTCF)

- Formed August 2015
- GS1 Global Office Healthcare providing secretariat services
- Members:
  - APEC Business Advisory Council (ABAC)
  - Healthcare Distribution Management Association (HDMA)
  - Open Serialisation Communication Standard (Open-SCS)
  - Pharmaceutical Distribution Security Alliance (PDSA)
  - Global Supply Chain Strategy Group (GSCSG)
  - RX360 Consortium
  - GS1 US RX Secure Supply Chain group (RXSSC)
  - GS1 Brazil Healthcare User Group
Global Traceability Co-Operation Forum (GTCF)

• Objectives:
  - To create synergy through multiple organisations working together:
    • Ensure there is common understanding of what the objectives are of each organisation, helping to ensure that those objectives are, to the extent possible, complementary,
    • Share progress and current status,
    • Identify gaps that one or more of the organisations may wish to address in their planned activities and
    • Document how the activities of the various organisation’s fit together, possibly arriving at a common objective and/or high level road map.
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Global Healthcare Conference

Cyndi Poetker, Senior Program Manager, Abbott
October 20–22, 2015
Cyndi Poetker

Cyndi Poetker is the Senior Program Manager for the global serialization program in the Global Standards and Serialization Office at Abbott. She has held various positions in IT, Manufacturing, and Quality IT Systems, at both the corporate and divisional level.

She holds a Bachelor of Science in industrial engineering, with an emphasis on manufacturing automation. She received her PMP certification in 2006. She provides strategic leadership, direction, implementation, and support for Abbott locations around the world.

Cyndi also tracks global regulatory regulations and commercial requirements related to bar coding and serialization through industry groups and regulatory agencies.
Lack of Standards in Daily Life Is Inefficient and Annoying

- Australia: Size 5.5
- Japan: Size 23
- Europe: Size 37.5
- USA: Size 7
- UK: Size 4.5
- China: Size 38

Plug Types:
- USA: Type A
- Europe: Type C
- UK: Type G
- China: Type L
- Japan: Type D
Objective:

Withdraw money at the local automated teller machine (ATM) in Hungarian forint, and have my checking account debited in converted U.S. dollars for that amount.
Consider This

Five steps to obtaining local currency

1. Find ATM

2. Put card into machine

3. Enter PIN code

4. Enter amount of money to receive, and press enter

5. Receive money
Data-Sharing Standards

• Master data
  - Card number
    • Cardholder name
    • Bank name
    • Bank account number
    • CVV – three-digit number
  - PIN code
  - Expiration date

• Transactional data
  - Verification
  - Deposits and credits
  - Withdrawals and purchases
  - Exchange fee

• Event data
  - Collection of transactional data with additional information, such as location, time, etc.
Master Data

The card number is constructed using an ISO standard and is used to identify the bank account and cardholder using a standard data format.
Master Data
The product is identified with a globally unique number (GTIN) that identifies the product and its description, strength, pack quantity, etc.

0800266 001692 8
GS1 Company Prefix Item Reference Number Check Digit
Verification

Master Data and Transactional Data
The PIN code is entered and used in conjunction with the card number to verify the authenticity of the card, using a standard protocol.
Correlation to Product Identification

Manufacturing Data and Transactional Data
The serial number is scanned and is used in conjunction with the product number to verify the authenticity of the package.
Banking Events

- Sept. 30: Deposit
  Location: Chicago, IL

- Oct. 2: Withdrawal
  Location: Frankfurt, Germany

- Oct. 5: Purchase
  Location: Frankfurt, Germany

- Oct. 9: Withdrawal
  Location: Munich, Germany

- Oct. 11: Purchase
  Location: Munich, Germany

- Oct. 12: Withdrawal
  Location: Munich, Germany

- Oct. 12: Purchase
  Location: San Diego, Ca. USA

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Correlation Summary

• Card master data
  - Card number
  • Cardholder name
  • Bank name
  • Bank account number
  • CVV – three-digit number
  - PIN code
  - Expiration date

• Product master data
  - Global product number
  • Product name
  • Company name
  • Product description
  • Packaging configuration, etc.
  - Covert/overt features, including serial number
  - Expiration date

• Transactional data
  - Verification
  - Deposits and credits
  - Withdrawals and purchases
  - Exchange fee

• Transactional data
  - Verification
  - Purchase orders, invoices, shipment notices
  - Credits, return authorizations
Correlation Summary

• Events
  - Deposit
  - Withdrawal
  - Purchase
  - Credits

• Events
  - Manufacturing
  - Shipping
  - Receiving
  - Dispensing
  - Inspecting

• Common data elements for events
  - What?
  - Where?
  - When?
  - Why?
  - Product
  - Location
  - Date/time
  - Business step/disposition
It’s Critical to Have Global Interoperable Standards for Data Exchange

Avoid this!
It’s Critical to Have Global Interoperable Standards for Data Exchange

Work toward global data-sharing standardization