Pharmaceutical Traceability for manufacturers and wholesalers

GS1 Healthcare Conference
25 October 2016 in Beijing
# Batch/Lot vs. Serialized Visibility

<table>
<thead>
<tr>
<th>Feature</th>
<th>GTIN</th>
<th>GTIN + Lot</th>
<th>GTIN + Serial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Precision Identification</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Medium Precision Identification</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>High Precision Identification</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional data needs to be physically marked</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Serialization required</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Traceable item exist in multiple locations at the same time</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Traceable item exist only at one location at the same time</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Product Recall</td>
<td></td>
<td>All units of a given GTIN</td>
<td>All units of a given GTIN + Lot</td>
</tr>
<tr>
<td>Enables anti counterfeit measures</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enables to monitor products with finite shelf life</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>
EPCIS enables supply chain visibility

• **Tracking**
  *Where are the pharmaceuticals I shipped?*

• **Tracing**
  *Where did this batch of pharmaceuticals come from?*

• **Chain of Custody (CoC)**
  *Which parties had custody of these pharmaceuticals?*

• **Recall**
  *Where are products produced at site XYZ on 2016-10-20?*
For more information on EPCIS . . .

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Serialization Implementation and Traceability

Peggy Staver
Director, Product Integrity

October 2016
Our Purpose:
Innovate to bring therapies to patients that significantly improve their lives

Our Mission:
To be the premier, innovative biopharmaceutical company

Our Four Imperatives:

<p>| | |</p>
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Fix the innovative core and generate medicines that profoundly impact health</td>
</tr>
<tr>
<td>2</td>
<td>Make the right capital allocation decisions to maximize value and enhance shareholder return</td>
</tr>
<tr>
<td>3</td>
<td>Earn greater respect from society</td>
</tr>
<tr>
<td>4</td>
<td>Create an ownership culture</td>
</tr>
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</table>

Our Values:
- Customer focus
- Community
- Respect for people
- Performance
- Leadership
- Collaboration
- Integrity
- Quality
- Innovation
<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue in 2015</td>
<td>$49 billion</td>
<td>in revenue in 2015</td>
</tr>
<tr>
<td>Manufacturing sites</td>
<td>63</td>
<td>worldwide</td>
</tr>
<tr>
<td>Markets</td>
<td>175</td>
<td>in which Pfizer sells products</td>
</tr>
<tr>
<td>Products</td>
<td>7</td>
<td>with sales greater than $1 billion in 2015</td>
</tr>
<tr>
<td>New R&amp;D Collaborations</td>
<td>200</td>
<td>in 2015</td>
</tr>
<tr>
<td>Colleagues</td>
<td>97,000</td>
<td>around the world</td>
</tr>
</tbody>
</table>

*As of April 1, 2016*
SERIALIZATION IMPLEMENTATION
Communicating event data to governments and/or trading partners in support of compliance.

Packaging Sites (Pfizer sites, Contract Manufacturers, etc)

Configuration of Pfizer and Contract Manufacturers packaging lines based on unique mandate requirements.

All data management occurs with the Serialization Control Tower (SCT) system

Packaging Line

Encoding of key data elements into a GS1 2D Data Matrix barcode.

- GTIN
- Serial Number
- Expiry Date
- Lot Number

Pfizer / CMO Plant Warehouse

Capture of key events from Operations for each Serial Number as it moves through the Supply Chain.

Wholesale Distributor

Hospital / Pharmacy

Communicating event data to governments and/or trading partners in support of compliance.

Patient
The average timeline for enabling a packaging line for Serialization is 18 months start to finish, and requires integrating with numerous other site priorities.

**Typical Enablement Project Timeline**

### Packaging Line Readiness
- **Project Planning**
- **Procurement (RFP, URS)**
- **Equipment Design, Test, Build**
- **Install, Qualify, Test**

### BT Design & Verification
- **BA Modeling & Design**
- **Analyze, Config & Test**
- **Cut Over**

### Milestone Tracker
- **Notify**
- **Planning Start**
- **Planning End**
- **Funding**
- **Design**
- **Procurement**
- **Build, Test, Qualify**
- **Go Live**
Serialization Enterprise Solution Overview

**Supply Network**
- **US**
  - XX PGS sites; XX ES sites
  - XX SKUs
  - XX packs
- **EU**
  - XX PGS sites; XX ES sites
  - XX SKUs
  - XX packs
- **EM**
  - XX PGS sites; XX ES sites
  - XX SKUs
  - XX packs
- **Total**
  - XX PGS sites; XX ES sites
  - XX SKUs
  - XX packs

**Logistics**
- **US**
  - XX DCs
- **EU**
  - XX DCs
- **EM**
  - XX DCs
- **IC**
  - XX LCs

**Internal Pfizer**
- Internal Control Tower (SCT)
- Typically 1 integrated government report per mandate
- B2B integration with Trading Partners for traceability
- Some markets / other manufacturer’s provision SNs

**External Pfizer**
- US
- EFPIA (Europe)
- Local Markets
- EU Member Markets
- Local Solution
- Brazil, China (Import), India Export, Korea, SA Phase II
- Argentina, China (Domestic), Nigeria, Turkey

**Role of Manufacturing, Logistics, CMOs**
- Provision, apply and aggregate SNs
- Commission and notify SNs
- Manage inventory and SN data in parallel

**Role of Downstream Supply Chain**
- Wholesalers, distributors, pharmacies, etc.
- Fulfill authentication, track & trace, pedigree, and other requirements
- Capture events and report as required
- Manage inventory and SN data in parallel

**Key**
- Serial Number Management
- Event Capture
- Reporting Data
- Transport/Product Flows
- Serialized Product Data
- Out of Scope
TRACEABILITY
• Electronic Product Code Information Services (EPCIS)
  – Standard for supply chain “events” recording handling of products in the supply chain
  – What, when, where, why
  – Useful for many different business purposes

*Used with permission from Ken Traub Consulting*
Each step is recorded by an EPCIS Event

Used with Permission from Ken Traub Consulting
PFIZER’S PROGRAM OPERATING MODEL AND GOVERNANCE
Pfizer has developed a “Program Operating Model” to guide each new mandate from initial requirements through to Business as Usual.

**Program Operations**

**Monitoring**
- Actively monitor mandates / regulations not in scope of program
- Monitor in program local solution requirement changes
- Determine impacts of Pfizer wide initiatives based on mandate requirements
- Monitor and bring back learnings from pilots

**Evaluation**
- Coordinate alignment of all workstreams to ensure successful mandate compliance
- Management of Enterprise schedule
- Report Program and mandate status

**Engagement**
- Form in country team and meeting cadence
- Finalize approach and design for scope
- Update Enterprise master schedule to include enablement schedules from all workstreams impacted
- Enhance Enterprise solution
- Secure site / source funding

**Enablement**
- Coordination of schedule and resources
- Enable impacted Pfizer supply chain
- Enable data management across Pfizer supply chain
- Lead change management and training across Pfizer Supply Chain
- Transition to Enterprise support

**Compliance Management**
- Manage Issue and risks
- Monitor and track progress across all in scope mandates
- Manage program communications
- Manage program scope and financials

**Business as Usual**
- Transition supply chain and enabling functions to standard operational activity
- Ongoing monitoring

*Phases may occur in parallel or cyclical nature*
Monitor Regulations: Mandates are monitored for emerging regulations, and ongoing changes to existing requirements.

- Local Regulatory
- In-Country Teams
- GS1 and other groups
2 Evaluate Impact to Pfizer: Program works with source locations to identify impacts and technical configuration requirements.
Engage Cross-Functional Teams and Plan for Enablement: Collaborate across stakeholder groups (country, center, site) to begin enabling network for serialization.

- Local project managers identified
- Center led project managers appointed to ensure standard processes are utilized
Enable Supply Chain: Standard implementation methodology is utilized to accelerate timelines and ensure compliance with Enterprise Solution.

- Standard Core Solutions
- Repeatable Implementation Process
- Modular
Monitor Compliance: Stakeholders monitor compliance and ensure supply continuity.

- **2015**
  - China Phase III
    - ~50 SKUs & Traceability Reporting
  - Korea Phase III
    - ~140 SKUs & Traceability Reporting
  - Saudi Arabia Phase II (unit serialization)
    - ~281 SKUs
  - US – Phase II (unit and case serialization)
    - ~1000 SKUs
  - Brazil Phase II
    - ~350 SKUs – on hold pending legislation

- **2016**
  - EU – February 9, 2019 (unit serialization)
    - ~6000 SKUs (by F-Code)
  - Russia Pilot Prep
    - Jan – Dec 2018
  - Russia Pilot
    - Jan – Dec 2017

- **2017**
  - Wholesaler Aggregation Reqt (2019)
  - Russia Phase I
    - 7 Nosologies

- **2018+**
  - US – Phase III
    - (2023) Traceability Reporting
  - Russia Phase II
    - Essential Drug List
  - Russia Phase III
    - TBD

Note: Slide depicts overlapping work efforts and is not reflective of compliance deadlines.
Transition to BAU: Process standards created for long-term transition to Business as Usual strategy.

- Sustainable execution of operations by the appropriate and state owner with serialization processes and tools incorporated.
- Owners of BAU processes vary by function.
Program Governance

Executive Sponsor

- Pfizer’s Corporate spokesperson
- Communicate business impact
- Elevate issues to Pfizer ELT

Program Governance Committee

- Endorse Program Deployment/Compliance Plan
- Endorse cost avoidance strategies (sourcing changes)
- Endorse investment deferrals and associated risks
- Participate in quarterly updates and elevate issues

PMO Steering

- Oversight and guidance of PMO workstream activities
- Establish core solution strategies and scope
- Obtain funding for workstream resources
- Monitor Program Deployment/Compliance Plan
- Stakeholder communication and awareness

Pfizer PMO Program Leads

- Day to day management of PMO
- Coordination of workstream activities
- Development of program metrics

Supply Chain Security

Program Operations

Supply Network Enablement
External Supply Enablement
Supply Chain Planning
BT Solution Enablement
Market Enablement & BU Engagement
Program Financial Management

Capital Controls
Logistics Enablement
Quality Operations
Industry Alignment/Customer Engagement
Embed and Optimize
Program Operations
KEY CHALLENGES
Key Challenges

Serialization is a broad and complex area of impact for an organization. We will spend some time explaining key challenges across the program.

- 10+ Mandates (current focus)
- 18+ Mandates (monitoring)
- 100+ Sites
- 350+ packaging lines
- ~10,000 SKUs
- 30+ Plant Warehouses
- Thousands of data transmissions

Key Challenges for Discussion:
1. Timelines
2. Project Complexity
3. Stakeholders
4. Operational Impact
5. Journey to BAU
Timelines for serialization compliance are often extremely challenging, especially with changing requirements and multiple mandates occurring simultaneously.

**TAKEAWAYS**

- Leverage industry trade associations and regulatory groups to drive for reasonable implementation timelines and clear requirements.
- Phased implementations are desirable.
- Reporting requirements are needed early in the process.
- Encourage the adoption of GS1 standards.
- Start the implementation process early!
Implementing Serialization is highly complex, and much more than adding packaging line equipment.

- Standardization of a global technology solution for Serialization data configuration and reporting
- Create interoperability with multiple types of site/line solutions
- Rationalize master data
- Leverage centralized project management capability to ensure compliance to global standards
Serialization impacts a large number of internal and external stakeholders throughout the supply chain.

- Campaign for broad organizational awareness of impacts of Serialization
- Leverage a strong governance structure to gain support of senior leaders
- Collaboration with trading partners and regulators is key to a successful deployment
Operational Impact

Serialization comes at a large cost (financial and operational) to the organization that must be minimized. Deviations from global standards further increases cost and complexity and reduces efficiency.

- Operational Efficiency impacts can be significant in beginning phases, and eventually return to normal.
- Implementation costs can be high, especially if utilizing a non-standard solution.

**Baseline, Relative Production Output (%)**

- **Line down/Set up**
- **Recovery Phase**
- **Return to stable**

**Relative Duration (Weeks)**

- **High Impact**
- **Medium Impact**
- **Low Impact**

**TAKEAWAYS**

- Align with business and investment plans (network optimization, sourcing strategies, etc.)
- Create harmonized standards, modular builds and consistent timing
- Leverage global solution architecture to improve speed and flexibility
- Focus on sharing learnings and working for continuous improvement
Achieving initial compliance is the first of many steps towards sustainably embedding serialization in BAU operations.

**Business As Usual**
- Sustainable execution of operations by the appropriate end state owner with serialization processes and tools incorporated as required
- Owners of BAU processes vary by function

**TAKEAWAYS**
- Drive for broad awareness from the onset
- Leverage existing business processes, systems, and stakeholders wherever possible
- Develop solutions with a mindset for future operationalization in the business
- Embed and Optimize
Questions?

Thank You!

Contact Information
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GS1 – China Conference
AmerisourceBergen Overview

DSCSA Activity Update

October 2016
Who Are Our Customers?

**Pharma Manufacturers**

Purchase services that increase product awareness and market share, including:
- Strategic Consulting
- Patient Support Services
- Global Logistics
- Customer Contracting

**Healthcare Providers**

Purchase pharmaceuticals and healthcare products and provide them to their patients:
- Retail Pharmacies
- Specialty Pharmacies
- Health Systems
- Physicians Offices
- Veterinary Practices
Leading Global Healthcare Solutions Company

LEADING PROVIDER OF

- Pharmacy Services Administration Organization (PSAO) services
- Retail pharmacy business consulting
- Patient access services
- Hub programs
- Commercialization services for manufacturers of all sizes
- Sterile compounding solutions
- Unit dose packaging

LARGEST

- **DISTRIBUTOR** of blood plasma, nephrology, vaccine & biological injectable products
- **DISTRIBUTOR** of specialty oncology products to private practice settings
- (Part of largest) Global generics purchasing **ORGANIZATION**

GLOBAL PROVIDER of clinical trial logistics
AmerisourceBergen: By the Numbers

$136 Billion in annual revenue

Daily delivery to 50,000+ North American healthcare facilities

1.5M product lines delivered from 30+ North American distribution centers

18,000+ associates

170+ offices

50+ countries

100%

Percentage of major U.S. pharmaceutical manufacturers served

95%

U.S. hospitals served with specialty medications

49%

Market share of specialty distribution to U.S. physician practices
Expanding global market opportunities
Bridging human and animal health

Across Canada
100+ specialty clinics
Commercial 3PL facility
Full commercialization services

US
$1 billion invested over 10 years
Full commercialization services

Across Brazil
Specialty distribution to 3,500 clients
Full commercialization services

Globally
Crucial role in 15,900+ clinical trials

EU
Market access services

Across Australia
Commercial 3PL facility

KEY GLOBAL OFFICE LOCATIONS (11)
OFFICE LOCATIONS (170+)
NORTH AMERICAN DISTRIBUTION CENTERS (30+)
DRUG STORAGE DEPOTS (14)
SPECIALTY CLINICS (100+)
SPECIALTY PHARMACIES (20)
COMPOUNDING CENTERS (4)
CALL CENTERS (8)
ANIMAL HEALTH DISTRIBUTION CENTERS (30+)
Sourcing and distribution
At the core of our business and your success

- Single point of access for providers
- Serving 60,000+ facilities daily in human health and animal health
- Largest distributor of specialty products in the United States

We drive access to products
US DSCSA Requirements
What industry is currently focused on:

November 27, 2017:
- Manufacturers are required to place a serialized barcode on the smallest salable unit, no mandate to incorporate the serialized barcode data into the required transactional data exchange.
  - The serialized barcode contains the following data elements: a product identifier, serial number, lot number and the expiration date.
    - Global Trade Identification Number (GTIN)
    - Serial Number (SNI)
    - Lot (Batch) Number
    - Expiration Date

November 27, 2018:
- Repackagers are required to place a serialized barcode on the smallest salable unit, no mandate to incorporate the serialized barcode data into the required transactional data exchange.

*data from June 2014 to June 2015
US DSCSA Requirements
What industry must plan to deliver:

November 27, 2019:
- Wholesalers may only engage in transactions that have the serialized barcode placed on the package.
- Upon the receipt of a saleable return, verify the serialized barcode is accurate before being able to resell that return, and also associate the transactional information to the returned product.

November 27, 2020:
- Dispensers may only engage in transactions that have the serialized barcode placed on the package.

November 27, 2023
- Manufacturers, wholesalers and dispensers shall exchange the required serialized transactional information in a secure, interoperable, electronic system. Serialized data exchange is required between all trading partners upon a change of ownership.

*Data from June 2014 to June 2015*
### Business Units Impacted by DSCSA

And associated timeline

<table>
<thead>
<tr>
<th>DQSA Expectations</th>
<th>Effective Date</th>
<th>AHP</th>
<th>Blue-point</th>
<th>ICS 3PL</th>
<th>ICS Title</th>
<th>ABSG</th>
<th>Onc. Supp</th>
<th>Drug</th>
<th>Thera Com Dist.</th>
<th>Thera Com Pharm.</th>
<th>US Bio</th>
<th>Central Fill</th>
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</thead>
<tbody>
<tr>
<td>Transactional Information Provided by Manufacturer, Wholesaler and Re-packager</td>
<td>1.1.2015</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
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<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Suspect &amp; Illegitimate products - SOP</td>
<td>1.1.2015</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
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<tr>
<td>Authorized Trading Partner</td>
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<tr>
<td>Transactional Information Accepted by Dispensers</td>
<td>7.1.2015</td>
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</tr>
<tr>
<td>Federal Licensure Standards Wholesale/3PL</td>
<td>2015</td>
<td>✔</td>
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<td>✔</td>
<td>✔</td>
<td>✔</td>
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<td>✔</td>
<td>✔</td>
<td>✔</td>
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<tr>
<td>Manufacturers Serialize</td>
<td>11.27.2017</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
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<td>✔</td>
<td>✔</td>
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<tr>
<td>Re-packagcers Serialize</td>
<td>11.27.2018</td>
<td>✔</td>
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<td>✔</td>
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<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Wholesalers Accept/Sell Serialized Product &amp; Validate Serialize Number on Saleable Returns</td>
<td>11.27.2019</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
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<td>✔</td>
<td>✔</td>
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</tr>
<tr>
<td>Dispensers cannot accept product that is not serialized</td>
<td>11.27.2020</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
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<tr>
<td>Complete Traceability</td>
<td>11.27.2023</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
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<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
</tbody>
</table>
ABC DSCSA Program Objectives:

• One ABC Enterprise System – Add Value to the Business
  • Single point of data exchange environment
  • One source of truth to customers, suppliers and regulators

• Managed as an Enterprise Program – Leverage Existing Synergies
  • Various teams engaged representing all company sectors and IT
  • Budget managed at the Enterprise Level

• Deliverables will exceed all regulatory mandated timelines

• Leverage Existing Customer Solutions

• Leverage Existing Investments
  • Object Event Repository (OER) – Processing Rules and Data Storage
  • Process Integrator (PI) – Data Transfer and Translation
  • New – HUB / Cloud Service (Pharma Hub Network)

*Data from June 2014 to June 2015
2019 Saleable Returns

What is the impact to AmerisourceBergen

- Annual revenue dollar: $2.1B per year.
- 15,259,042 saleable returns per year.
  - Representing 2% of our annual business revenue and 1.7% of all units.
- Daily number of saleable returns across network: 62,000 → 115,000.
- ABDC peak number of saleable returns for a Greenfield: ~10,000 units per day.
- ABSG average number of salable returns ~200 units per day.

No established industry solution to manage serialized returns

*data from June 2014 to June 2015*
HDA Returns Pilot Objectives

- Gain key learnings on various processes to address salable return
- Illustrate to members of the supply chain the relative practicality of possible solutions
- Identify where standards can be applied for simplification in the communications and providing access to information via interoperable systems.
- Provide data to the FDA to illustrate the realities faced by manufacturers and wholesalers in processing DSCSA compliant saleable returns.
- Begin the process of building consensus on likely approaches that will work without adding significant burden to the supply chain.
## Scenario List of Saleable Returns Options

<table>
<thead>
<tr>
<th>Number</th>
<th>Scenario Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Live Pilots</strong></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Manufacturer sends purchased unit product identifiers to respective wholesale distributor</td>
</tr>
<tr>
<td>3</td>
<td>Central repository – manufacturers send all data to central database which the distributors accesses for verification</td>
</tr>
<tr>
<td>7</td>
<td>Distributors scans product on outbound</td>
</tr>
<tr>
<td>9</td>
<td>Verification Discovery Router Service – distributor query is routed to appropriate manufacturer database</td>
</tr>
<tr>
<td><strong>Desktop Pilots</strong></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Distributor accesses each manufacturer’s database through portal</td>
</tr>
<tr>
<td>8</td>
<td>Distributor manually confirms with manufacturers at time of return via phone or email</td>
</tr>
<tr>
<td><strong>White Papers</strong></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Manufacturer sends product identifiers for all units shipped within the U.S. to all direct purchase distributors</td>
</tr>
<tr>
<td>4</td>
<td>Verification services – Distributor builds point-to-point interfaces to each manufacturer’s verification service, which automatically returns a verification response</td>
</tr>
<tr>
<td>6</td>
<td>Distributor scans all purchased product identifiers on inbound receipt</td>
</tr>
</tbody>
</table>
Internal and HDA Sponsored Pilots: ABC Key Learnings

- **AmerisourceBergen:**
  - **What worked well?**
    > Executed end to end process flow.
    > Coordination and execution with our partners.
    > Captured 90,000 inbound GS1 EPCIS SNI’s for Commissioning Events, ~700 Scans within our DC’s
  - **Where were there bumps?**
    > GS1 EPCIS Data Exchange.
    > Some scanning challenges.
  - **What did we learn?**
    > Not all labeling is equal.
    > Operational impacts were significant.
    > Exceptions WILL be a challenge in both data and processes.
    > Data exchange… Test. Test. Test.

- **SAP:**
  - ATTP performed better than expected and allowed for the flexibility necessary to process transactional files
  - Pharma Network performed as expected directing electronic traffic as needed
Packaging “Shipper/Case” Current State
Huge variations in conformance to guidelines and standards
DGFT… impact on US Supply Chain Management

Tertiary and Secondary GTIN on Same Homogenous Case

Per SNI & GS1 Standards you can have only ONE GTIN per Current Trade Item & SSCC Contained on case that was NOT a logistic unit

Two Different GTINs

Shouldn’t have SSCC
DGFT… impact on US Supply Chain Management

Tertiary and Secondary GTIN on Same Homogenous Case, Tertiary GTIN ALSO on Inner pack

You can not have the same GTIN on different levels of packaging
SSCC Contained on case that was NOT a logistic unit
DGFT… impact on US Supply Chain Management

Duplicate GTIN on Case

SAME GTIN Twice?

Same GTIN Printed Twice??? And
SSCC Contained on case that was NOT a logistic unit
How do you function with “standards”? ✓ Flexibility while keeping end state in focus!

- Master Data (Product only*)
- Deliveries - as Transactions
- Standard Text and custom Data
- Downloads, Reporting and exporting

Legends:
- ATTP Release 2
- Standard ATTP with additional enhancements
- Custom ABC
IT: Service Model – GS1 Standards Based Approach

GS1 EPCIS Standards: Including GTIN and GLN
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Where knowledge, reach and partnership shape healthcare delivery.
Johnson & Johnson Supply Chain’s Experience:
Pharmaceutical Traceability – what does it mean for a pharmaceutical manufacturer

Mike Rose
Vice President, Supply Chain Visibility
October 25, 2016
Johnson & Johnson

Global Presence

• Global leader in Health Care
• More than 275 operating companies in 60 countries
• Selling products in more than 175 countries
• Approximately 128,000 employees worldwide
Johnson & Johnson Aspiration

Caring for the world, one person at a time, inspires and unites the people of Johnson & Johnson.

We embrace research and science - bringing innovative ideas, products and services to advance the health and well-being of people.
Johnson & Johnson Credo

COMMON SET OF VALUES UNIFYING DIVERSE BUSINESS

• Created in 1943
• Drives deep commitment to ethical principles
• The Four Tenets
  – Customers
  – Employees
  – Communities
  – Stockholders
Serialization

Item level serialization using GS1 standards

A unique identification number is assigned to each item identifying it with a product number and associated serial number. It’s applied at every package level (bottle, case, and pallet).
**Track & trace**

**Traceability using GS1 and EPCIS standards**

12 serialized & aggregated Prezista bottles in a case

261 cases to a pallet. Each case has the parent serial number

Pallet is shipped (truck, boat, or airplane) to DC

Wholesaler ships product to pharmacies, hospitals, etc. They scan bar code with serial number

Wholesaler Customer receive products, scans every case and ships to pharmacies, hospitals, etc.

DC where individual cases get pulled from the pallet, scanned and shipped to Customer

Regulatory mandates are demanding visibility of products from point of packaging to point of dispense.

- These mandates demand improved supply chain visibility
- Products are identified, serialized, authenticated, tracked & traced
- What product? Where has it been? Where is it going? How long has it been there?
- Using data captured as product moves through the supply chain, answers questions as to the disposition of inventory
The importance of standards

- Ability to make and deliver anywhere
- More efficient and cost effective infrastructure
- More efficient product handling
- Consistent look for our products
- Enable quick searches to track serialized product status
Practical lessons learned
Manufacturing benefits realized through standards, process improvements and information

- Reduction of manual work, increase in productivity
- More precise data aids investigations of deviations
- Increased efficiency in product issue resolution
- Improvements in label print quality
- Reduction in amount of disposable materials and waste
Practical lessons learned
Distribution center operations

• **NO** additional headcount was necessary

• Savings from better accuracy and standardized labelling for error correction

• Higher fidelity inventory accuracy and visibility
  – Reduced need for checks and counts
  – Reduction in claims and credits
Practical lessons learned
Customer track & trace pilots

• Collaboration pilots is critical
• Enabled through GS1 standards
• Clear interpretation of standards
  – E.g., expiry date, unit of measure
• Process alignment
  – E.g., data must arrive before physical product
• Opportunities for value creation
Brazil pharmacy pilot
Regional pilot to test feasibility of scanning

- Internal and external collaboration
- Identify suspect or illegitimate product
- Scanned and verified serial number
EU Falsified Medicines Directive

Product safety features
- Authenticity Pack Identity
- Tamper evidence
- Medicines Verification System
- Feb 9, 2019

Good distribution
- Wholesalers & Brokers
- GDP
- 2013-Q1

Active substances
- GMPs for excipients
- Jan 2, 2013
- Registration API activities
- July 2, 2013

Internet sales
- Community logo
- 2015
Point of dispense verification

1. **Pharmaceutical Manufacturer**
   - Unique Serialization with Random Numbers
   - Upload Number

2. **Wholesaler**
   - Product Flow

3. **Wholesaler**
   - Product Flow

4. **Pharmacist**
   - Product Flow

5. **Patient**
   - Verification upon Dispense to Patient

6. **Medicines Verification System**
   - Risk Based Verification
   - Authenticate Number
Pan-European System
National verification Systems (NMVS) connected by the European Hub
European Stakeholder Model
Aligned to a Common vision to protect patients

- Protect patients
- Secure the legitimate supply chain
- Be proactive as market partners
- Formed a stakeholder-governed model that is
  - Functioning
  - Harmonised
  - Cost-effective
  - Inter-operable
- Established the European Medicines Verification Organization (EMVO)
German securPharm pilot
Pharmacy point of dispense verification

- Approximately 400 pharmacies
- Partnership between pharmacies and manufacturers
- Receive scan confirmation
Traceability challenges encountered

- Serialization adds extra layer of complexity
- Aggregation adds ~50% cost and implementation time
- Protecting impact to overall equipment effectiveness (OEE)
- Alignment with external manufacturers
Solutions implemented
Critical components to manage risk and drive consistency

- Utilize GS1 standards
- End-to-end view
- Multi-tiered governance structure
- Vendor management program
- Serialization training centers
- Change management program
- Customer collaboration pilots
7 Billion Reasons to Care

Serialization and track & trace will benefit patients and consumers around the globe
EU – 2011, 2016
Falsified Medicine Directive (FMD)

Status: Directive 2011/62/EU on prevention of the entry into the legal supply chain of falsified medicinal products

Scope: Pharmaceuticals – prescription drugs

Purpose: Counterfeiting

Requirements: composition, format & carrier of the unique identifier fully harmonised

- Packaging level: secondary level packaging
- Data elements: Unique identification number, Batch/Lot number, Expiry date, Serial number, national reimbursement number (if applicable)
- Data carrier: DataMatrix for unique identification (possible QR for marketing purposes)
- Deadlines:
  - 2011: Adoption of a new Directive on falsified medicines (FMD)
  - 2019 (+ 6 years if preexisting measures : EL, IT, BE): requirements implementation

Data Submission Portal: Stakeholder model – EMVO

Traceability Model: Authentication model

Open point(s)/upcoming dev.: Delegated Acts adopted on 2 Oct. 2015 and published on 9 Feb. 2016 (date of publication is to be taken into account for the calculation of the implementation deadlines). FAQs released by EC (not mandatory) and Implementation plan released by EMA on 9 Feb. 2016.
USA – 2015, 2017, 2023
Drug Supply Chain Security Act (DSCSA)

**Status:** Legislation

**Scope:** Pharmaceuticals (prescription drugs)

**Purpose:** Traceability, combat counterfeit

**Requirements as applicable:**
- Packaging level: saleable units and homogeneous cases
- Data elements: NTIN, Expiry date, lot/batch number, serial number
- Data carrier: 2D DataMatrix
- Deadlines:
  - First phase lot based (2015) – delayed to 1 March 2016 for dispensers
  - Serialisation (SNI) after four years (2017)
  - Full track & trace after 10 years (2023)

**Data Submission Portal:** Not determined, under discussion

**Traceability Model:** First lot based traceability, full track & trace in 10 years

**Open point(s)/upcoming dev:** US FDA points to EPCIS as one of possible way for exchange of traceability data in their draft guidance

GS1 US Rx Guideline for DSCSA([www.GS1US.org/RxGuideline](http://www.GS1US.org/RxGuideline)): includes application of EPCIS for serialized item-level traceability

**PP Database Dossier #: 738USAPH140430**

**Status:** Regulation on traceability system for the control of pharmaceutical products from the manufacturer to the patient

**Scope:** Pharmaceuticals

**Purpose:** Supply chain efficiency

**Requirements as applicable:**

- **AIDC:**
  - Packaging level: Secondary packaging
  - Data elements: GTIN, Serial Number - AI (21)
  - Data carrier: GS1-128, DataMatrix, RFID tag

- **Data Submission Portal:** Central database hosted by ANMAT

- **Traceability Model:** Track & Trace

- **Open point(s)/upcoming dev.:**
  Disposición 963/2015 expends the ANMAT drug traceability system to 33 more drugs by 2 March 2015.

  Circular 0002-15 provides 3 deadlines for implementation for products already regulated by previous ANMAT requirements: 30th April 2015, 30th June 2015 and 30th August 2015.


  This Regulation is not amending the current traceability system but its scope.
Wholesaler Perspective on Traceability

October 25, 2016

Scott Mooney
Vice President Distribution Operations
McKesson Distribution Solutions

- U.S. Pharmaceutical
- McKesson Canada
- Celesio (Europe and South America)
- McKesson Medical-Surgical
- McKesson Specialty Health
- McKesson Pharmacy Systems and Automation
* McKesson Packaging Solutions

McKesson Technology Solutions

- McKesson Health Solutions
- Imaging and Workflow Solutions
- Connected Care and Analytics
- Business Performance Solutions
- Enterprise Information Solutions

#5 on Fortune 500
McKesson is an industry leader in:

- Pharmaceutical distribution in the U.S., Canada and Europe
- Medical-surgical distribution to alternate care sites
- Generics pharmaceutical distribution
- Medical-management software and services to payers
- Business and clinical services for providers
- Connectivity services

More than 200,000 physicians use our technology and services

1/3 of all pharmaceuticals used each day in North America are delivered by McKesson

4th largest pharmacy chain
3,000+ retail pharmacies are members of our Health Mart® franchise

76% of hospitals with >200 beds are McKesson customers

100% of the top 25 health plans are McKesson customers
Network Statistics

- 33,000 Customers Delivered Daily
- 23,000 Products Stocked (Rx and OTC)
- Order cut offs as late as 9pm local
- 90% Deliveries before 11am local
- 4800 Purchase Orders received daily
- 1.8 Million cases per month transferred
  - 840 Thousand cases delivered to customers per month
Product Encoding

Product Identification (Serialization)

- No later than 4 years (11/27/2017), manufacturers, followed by repackers (11/27/2018) shall place a unique product identifier on certain prescription drug packages
  - 2D bar code
- Product identifier
  - National Drug Code
  - Serial number
  - Lot number
  - Expiration date

The UI – Properties

- The UI is carried by a 2D barcode (Data Matrix ECC200);
- Minimum printing quality;
- Human-readable format.

Encoding is nearly the same in the US and EU
US requires NDC embedded in GTIN
EU FMD Model

“Point of Dispense Verification” is effective and efficient

- Upload Data
  - Product #
  - Batch
  - Expiry
  - S/N

- Product Flow
  - Pharmaceutical Manufacturer and Parallel Distributor
  - Wholesaler
  - Wholesaler
  - Pharmacist
  - Patient

- European Hub
- National System 1-n
- Verification upon Dispense to Patient
- risk-based verification by Wholesale distributors

Verification:
- ✔️
- ❌
US DSCSA Model

Product Verification

Risk Based

Returns Nov. 2019

Risk Based

Traceability Data Flow Nov. 2023

Traceability Data Flow Nov. 2023

MANUFACTURER

DISTRIBUTOR

DISPENSER
Model Requirements

- Manufacturers identify who serial products are sold to and send DSCSA data
- Distributor to receive/send DSCSA data for every transaction with a trading partner
- Distributor must verify returned goods before restocking
- Dispenser may verify on a risk based approach but is not required

- Manufacturers post commissioned serial products to European Hub
- Distributors to verify on a risk based system
- Dispenser must verify before dispensing to patient
Distributor Implications

- Distributors will transact twice as much data as manufacturers and dispensers
- Distributors fulfill both full case and each unit sales with dispensers
  - The knowledge of the relationship between inner and outer packaging will be critical to capture serial numbers
  - Customer often purchase full cases and return an each
  - Aggregation would answer this for US

- Case, bundle and each serials may be posted to European Hub
- Aggregation unnecessary to post serials for verification
Readiness

- 2D Barcodes beginning to appear on packaging
  - Estimate no more than 15% of selling units currently have 2D bar code on them
  - Lots of issues with data formats at this time
    - Incorrect GTIN for intended country
    - Origin country and intended country standards differ
    - Date formats not following GS1 standards

- Scanning technology requires upgrading to imagers
  - White on Black vs. Black on White
  - 2D vs. Linear capability

- Not all 2D bar codes are serialized
Resources

- “A European Medicines Verification System” presentation by Grant Courtney at Global GS1 Healthcare Conference, Copenhagen, Denmark, April 2014


- “Drug Supply Chain Security Act (Title II of the Drug Quality and Security Act) Taking a Step To Further Protect Public Health” presented by Connie Jung, RPh, PhD, U.S. Food and Drug Administration, Silver Spring, MD June 4, 2014
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• Mr. Michael Rose, Johnson & Johnson Supply Chain
  *Vice President, Supply Chain Visibility*

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