



Supply Chain Serialization for Business Applications and Competitive Advantage

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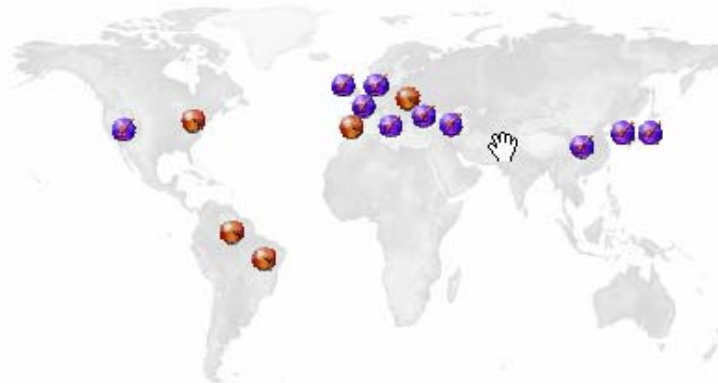
The Problem: Counterfeit Drugs

- Counterfeits in the legitimate supply chain are a real problem
 - Patient safety at risk
 - Creates drug-resistance
- Reimbursement fraud drives up cost of health care

To combat this problem and gain a better hold on the supply chain, drug serialization and “Track and Trace” / ePedigree is being implemented internationally



Global Serialization Landscape



2005 – 2015 mandates (thus far)

Italy	Japan – Codif.
Ireland - Pilot	USA – CA
Greece	USA – Federal
Belgium	Brazil
Turkey	Spain
China	Columbia
France – Codif.	Serbia
Korea – Codif.	Others ??

In place

In progress

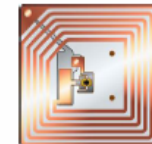
International Standards for Serialization



GS-1 2D Data Matrix



GS-1 128 Linear Barcode



EPCglobal RFID Tag Standard



Regulatory Driver

California Pedigree Law:

- Manufacturers:
 - 50% of SKU's uniquely serialized at the package by 01.01.2015 with accompanying ePedigrees
 - Remaining 50% serialized by 01.01.2016
- Wholesalers:
 - Serialized ePedigrees for all Rx purchases and sales by 07.01.2016
- Pharmacies
 - ePedigrees for all Rx purchases and sales by 07.01.2017



Authentication vs. Track & Trace

- Authentication Model (“Book End Approach”)
 - Manufacturer serializes products at the item level; aggregation typically not required
 - Manufacturer sends data to some centralized repository (owned by government, private agency, etc.)
 - Product sold throughout the supply chain; data does not follow the chain of custody
 - Upon dispensation, pharmacist scans the unique identifier (2D barcode), which is linked to the centralized database and confirms the authenticity of the drug product
- Track & Trace (T&T)
 - Manufacturer serializes products at the item level; aggregation typically required to reduce impact to logistics
 - As product is sold throughout the supply chain, the data follows the chain of custody, and supply chain partners are required to update the electronic records with transactional information. This concludes with the receipt at the pharmacy, unless a return is made.
 - All supply chain partners are required to retain serialization and transactional data for a set period of time.



Benefits to the Business

- Regulatory compliance
- Supports branding initiatives
- Solution that can be leveraged globally for local and international markets
- Aides in recall process, enabling Teva to know exactly which bottles were sent to whom
- Enhanced returns processing
- Future Track & Trace systems could be leveraged to obtain valuable marketing data downstream
- Supply chain security



Early Challenges

- Lack of previous use cases to from which to draw experience
- Technical Challenges
 - Integration with existing systems
 - WMS (Warehouse Management System)
 - ERP (Enterprise Resource Planning)
 - MES (Manufacturing Execution System)
 - Handling customer returns and product destructions
 - Error handling (Systems, Shipping etc.)
 - Rework of non-compliant product
 - Handling of serialized AND non-serialized product



What We Did

- Serial # tracking occurs *prior* to receiving in the distribution center
 - Serialization system in the packaging facility sends a notification to the WMS with the complete aggregation history of the serials
 - Details which items are on which cases, and which cases are on which pallets
- Upon receipt, cases are scanned for accuracy to ensure correct aggregation
 - If incorrect, rework required (for Teva-mfg'd product) or shipment rejected (for 3rd party supplied product)



What We Did

- Serial #'s are tracked at all operations in the DC
 - Replenishment
 - Picking
 - Audit
 - Packing
 - Inventory Control
 - Shipping
- Full aggregation history is sent along with shipment to customers in either EPCIS events or in pedigree document format



Overall Message...

- This IS possible....
 - Time consuming → requires long-term commitment
 - Constantly evolving process
 - Huge undertaking
 - Need dedicated resources
- Benefits the industry and patients
- Leverage to other industries
 - Food
 - Beverage
 - Med devices ...
- Continue refining data standards
 - Encourage collaboration in common forums
- Constant evolution
- ROI comes in time

