Global Traceability Regulations

A Snapshot
Agenda

• Plethora of global Pharma traceability regulations

• Common models

• Brazil example

• Implications
Pharma - Europe coding & serialisation requirements

- Cyprus 2010 Product Code
- Denmark 2011 Product Code
- France 2011 Batch Variable
- Slovenia 2015 Product code & Batch/Expiry date
- Europe Q4 2014 Delegated acts finalised
- Europe 2018 Compliance to Falsified Medicines Directive (FMD)
- Turkey 2010 Track & Trace
- Europe 2011 European Legislation
- England/NHS 2014 GTIN, GLN and product data
- Denmark 2014 AMGROS: DataMatrix or bar code on injection & infusion
- Serbia 2010 Traceability regulation
- Ukraine 2017 Serialisation
- Regulated requirement
- Tender requirement
- Important development
- Emerging Regulatory requirements

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EU – 2011, 2014, 2018
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 (incl. vaccines)
Purpose: Counterfeiting

Requirements as applicable:
– AIDC
– 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
– Deadlines:
  – 2011: Adoption of a new Directive on falsified medicines (FMD)
  – 2014: Delegated Acts to provide more detailed requirements on this capability
  – 2018: requirements implementation in all EU Member States
– Data Submission Portal: Stakeholder model
– Traceability Model: Authentication model

Open point(s)/upcoming dev.: EU Delegated Acts on safety features should be adopted end 2014/early 2015.

PP Database Dossier #: 200EUPH053011
Medical devices
coding and database requirements

2009
- Turkey 2009
  Product code & database

2010
- Cyprus 2010
  Product code tender Guidance

2011
- GHTF 2011
  UDI Guidance
  - Spain - 2009
    SAS product code
  - Japan Q1 2010
    Product code & variable - Rest

2012
- EU Q3 2012
  EC proposal MD Regulation
  - USA Q2 2012
    Draft FDA UDI Regulation
  - USA Q3 2012
    Final FDA UDI Regulation
  - England/NHS 2012
    GTIN, GLN and product data

2013
- Belgium 2013
  Law on MD Traceability
  - USA Q3 2013
    FDA UDI Implementation
    Life supporting/sustaining devices

2014
- Netherlands/NVZ 2012
  Product code
  - Germany 2013
    UDI Recommandation
  - England/NHS 2014
    UDI Roadmap
  - IMDRF 2013
    UDI Roadmap

2015
- Argentina 2014
  Traceability System of Medical Devices – first product
  - USA 2015
    FDA UDI Implementation
    Life supporting/sustaining devices

2016
- Spain - 2009
  SAS product code

2018
- USA 2018
  FDA UDI Implementation
  Class 1

Canada, China, Spain, Korea, India, Japan, Brazil, etc.: UDI regulatory requirements under dev.
**DSCSA Timelines**

Manufacturers, repackagers, wholesalers must exchange lot-level TI, TH, TS for 100% of shipments

1/1/2015

Dispensers must receive lot-level TI, TH, TS

6/1/2015

Manufacturers required to send electronically

11/27/2017

Unit-level traceability for entire US supply-chain

11/27/2023

**2014**

Supply-chain must have systems and processes in place to verify transaction data at lot-level

1/1/2015

**2015**

**2016**

**2017**

**2018**

**2019**

**2020**

**2021**

**2023**

11/27/2017

Manufacturers:
- Serialize 100% of units + homogeneous cases
- Verify transaction data at unit level

11/27/2018

Repackagers:
- Buy/sell only serialized products
- Verify transaction data at unit level

11/27/2019

Wholesalers:
- Buy/sell only serialized products
- Verify transaction data at unit level

11/27/2020

Dispensers:
- Buy only serialized products
- Verify transaction data at unit level

11/27/2017

Lot Traceability

Serialization
## 4 Core Areas of DSCSA

<table>
<thead>
<tr>
<th>Product Tracing</th>
<th>Serialization</th>
<th>Verification</th>
<th>Request for Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Single document which includes transaction information, transaction statement, and transaction history</td>
<td>• Apply a Standardized Numeric Identifier (SNI) to uniquely identify a package or sealed homogeneous case.</td>
<td>• Determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date</td>
<td>• Must respond within 1-2 business days to a request for TI, TH, TS in the event of suspect or illegitimate product</td>
</tr>
<tr>
<td>• Provisions for both lot and unit level tracing</td>
<td>• Must not buy or sell unless product is serialized</td>
<td>• Systems and processes to validate TI, TH, TS for product in possession.</td>
<td>• Must respond within 24 hours to a request for information at a unit level – coincides with serialization timelines</td>
</tr>
<tr>
<td></td>
<td>• Rolling timelines starting November 27th, 2017</td>
<td>• Lot verification starts January 1st, 2015</td>
<td></td>
</tr>
</tbody>
</table>
## TI/TH/TS Definitions

### Transaction Information
- The proprietary or established name or names of the product
- The strength and dosage form of the product
- The National Drug Code number of the product
- The container size
- The number of containers
- The lot number of the product
- The date of the transaction
- The date of the shipment, if more than 24 hours after the date of the transaction
- The business name and address of the person from whom ownership is being transferred;
  - The business name and address of the person to whom ownership is being transferred.

### Transaction History
A statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

### Transaction Statement
A statement, in paper or electronic form, that the entity transferring ownership in a transaction—
- Is authorized as required under the DQSA
- Received the product from a person that is authorized as required under the DQSA
- Received transaction information and a transaction statement from the prior owner of the product
- Did not knowingly ship a suspect or illegitimate product
- Had systems and processes in place to comply with verification requirements
- Did not knowingly provide false transaction information
- Did not knowingly alter the transaction history
# 5 Key Strategies for Interoperability

**1. Paper / Portal**
- Minimal impact to existing systems and processes
- Likely occur by modifying packing slip or providing a customer portal

**2. Document Pedigree Messaging Standard (DPMS)**
- Purpose built EPCGlobal standard to meet existing state pedigree laws
- Mature supply-chain use-cases
- A number of supply-chain participants have invested in DPMS compatible systems

**3. HDMA ASN**
- Released Q2 2014 on HDMA website
- Modified version of ANSI X12 ASN 856
- Transaction histories and master data replication hurdles
- Expect revision to be released any day

**4. EPCIS 1.1/CBV**
- Released Q2 2014
- Axway is involved in GS1 working groups
- Outlines lot-level traceability using EPCIS transactions
- GS1 US Healthcare Guidance will align standard with DSCSA.

**5. FDA Interoperability Guidance**
- Released no later than November 27th, 2014
- May 8th, 9th FDA Public Workshops
- Current RFI docket open for public comment until June 9th, 2014
- Not expected to endorse a single interoperability format

### Key Considerations:

- **Trading partner’s infrastructure capabilities**
  - Paper will exist in supply-chain on January 1st, 2015

- **Will your trading partners accept DPMS?**
  - Maturity of supply-chain use-cases

- **Role in supply-chain**
  - Migration path from lot traceability to item level serialization
  - Data storage

- **Migration path from lot traceability to item level serialization**
  - Global compliance strategy
  - Aggregation / Inference
  - On-going maintenance of standard

- **Companies can not wait for guidance to start implementation**
  - Be involved.
Compliance Models
Typical Labeling Requirements

- Automated Identification / Data Capture Technology (AIDC)
- Packaging level:
  - Tertiary (Pallet; Case/Carton);
  - Secondary (common marketing pack),
  - Primary (dispensing item – e.g. one blister in a box of 4)
- Data elements:
  - Product Code / GTIN
  - National Healthcare Reimbursement Number (NHRN)
  - Expiration Date
  - Batch/Lot Number
  - Serial Number - by Regulatory Body or Manufacturer
- Data carrier: EAN/UPC, GS1-128, DataMatrix; RFID
Traceability Models
Central Government Repository e.g. China

Contract Manufacturer

Manufacturer

3PL

Wholesaler

Pharmacy / Dispenser

Serial Numbers

Government Regulatory Body

Transaction History

Government mandated

Commercial/Logistics
Traceability Model
Regulated Supply Chain (Stakeholder Model) – e.g. USA
# Serialized Traceability Snapshot - Evolving

<table>
<thead>
<tr>
<th>Country</th>
<th>Package Level</th>
<th>Serial Numbers By...</th>
<th>Transaction Recording / Reporting</th>
<th>Year in Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>1st</td>
<td>Manufacturer</td>
<td>To define</td>
<td>2014 (?)</td>
</tr>
<tr>
<td>China</td>
<td>2nd</td>
<td>Government</td>
<td>Report to Govt</td>
<td>2012-2015</td>
</tr>
<tr>
<td>USA</td>
<td>2nd</td>
<td>Manufacturer</td>
<td>Pass to Buyer; Store</td>
<td>2015-2023</td>
</tr>
<tr>
<td>Brazil</td>
<td>2nd / 3rd</td>
<td>Manufacturer</td>
<td>Accessible to Govt</td>
<td>2015-2016</td>
</tr>
<tr>
<td>EU</td>
<td>2nd</td>
<td>Manufacturer</td>
<td>Serial Numbers to Central Database</td>
<td>2018</td>
</tr>
<tr>
<td>Turkey</td>
<td>2nd</td>
<td>Manufacturer</td>
<td>Report to Govt</td>
<td>2010</td>
</tr>
<tr>
<td>Argentina</td>
<td>2nd</td>
<td>Manufacturer</td>
<td>Report to Govt</td>
<td>2013</td>
</tr>
<tr>
<td>South Korea</td>
<td>2nd</td>
<td>Manufacturer</td>
<td>Under discussion</td>
<td>2015</td>
</tr>
<tr>
<td>Ukraine</td>
<td>2nd</td>
<td>Manufacturer</td>
<td>Report to Govt</td>
<td>2017</td>
</tr>
<tr>
<td>Jordan</td>
<td>2nd</td>
<td>To define</td>
<td>To define</td>
<td>2017</td>
</tr>
<tr>
<td>Saudia Arabia</td>
<td>2nd</td>
<td>To define</td>
<td>Stakeholder</td>
<td>2017</td>
</tr>
</tbody>
</table>
Brazil
ANVISA Update

- December 10th, 2013
  - Passed RESOLUTION RDC N.º 54 outlining new requirements for unit-level traceability.
  - Defined timelines for implementation
  - Defined high-level initial architecture

- February 17th, 2014
  - ANVISA establishes Steering Committee on Drug Control System
  - Representatives from government, professional health care advice, industry representatives and organizations of different areas of the medical sciences

- Next Steps
  - ANVISA to define interoperability standards for remote access interface to government
## Definitions (1/2)

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug Product Tracking</strong></td>
<td>Set of procedures that allow background information tracing, application or localization of drugs, by means of previously recorded information, through an exclusive product identification system, to be applied for the control of all and every drug product unit produced, dispensed or sold in national territory.</td>
</tr>
<tr>
<td><strong>Drug Product Chain (Business Step)</strong></td>
<td>Pharmaceutical product flowchart from the source to the consumption, comprising the following stages: <em>production, importation, distribution, transportation, storage and dispensing</em>, as well as other types of movement foreseen by the sanitary controls.</td>
</tr>
<tr>
<td><strong>Movement</strong></td>
<td>All transactions regarding the displacement of drug product units between establishments throughout the pharmaceutical production chain, the dispensing, as well as returns and recalls of already dispensed products.</td>
</tr>
<tr>
<td><strong>Movement Nature (Business Step)</strong></td>
<td>Purpose of the movement, such as sales, donation, transferences, returns, recalls, disposals, losses, among others.</td>
</tr>
<tr>
<td><strong>Exclusive Product Identification (Serialization)</strong></td>
<td>Attribution of the Drug Product Single Identification (IUM) code, corresponding to the smallest commercializing unit, according to the established herein.</td>
</tr>
<tr>
<td><strong>Outsourcers</strong></td>
<td>Producing companies/manufacturers, wholesalers, retailers, importers; transporters, buyers, dispensing units and drug product prescribers.</td>
</tr>
</tbody>
</table>

*Source: Interfarma English translation of RESOLUTION RDC N.º 54, DECEMBER 10th, 2013*
### Definitions (2/2)

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Product Single Identification (IUM) code</td>
<td>A series of numeric, alphanumeric or special characters created through identification and codification standards, which allow the exclusive and unmistakable identification of each specific unit of drug product commercialized in the market, according to the disposed herein.</td>
</tr>
<tr>
<td></td>
<td>IUM Data Elements:</td>
</tr>
</tbody>
</table>
|                                                                      | • Drug product Anvisa registration number, containing 13 (thirteen) digits  
• Serial Number  
• Expiry date, format: MM/YY and  
• Batch number                                                                                     |
| Serial Number                                                       | Individual non-repetitive 13-digit number in the IUM, corresponding to each drug unit to be commercialized in the Brazilian territory, establishing the two-dimensional barcode and written in a way that is readable to the human eye on the commercial package, according to the disposed herein. |
| Transportation package                                              | Package used for the transportation of drug products placed in its primary or secondary packages.                                                                                                           |
| Drug Product Control National System (SNCM)                         | Corporate repository to store product traceability data                                                                                                                                                   |
| Controlled Product National System (SNGPC)                         | An interface allowing Brazilian Sanitary Surveillance Agency to retrieve data from corporate repository.                                                                                                    |
## Brazil Requirements

<table>
<thead>
<tr>
<th>Regulatory Requirement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Traceability Model</strong></td>
<td>Unit-level traceability of physical movement of product. Government and trading partner external reporting.</td>
</tr>
<tr>
<td><strong>Supply-Chain Participants Effected</strong></td>
<td>Producing companies/manufacturers, wholesalers, retailers, importers, transporters, buyers, dispensing units and drug product prescribers.</td>
</tr>
<tr>
<td><strong>Item level serialization</strong></td>
<td>Unique identifier across all products; Drug Product Single Identification (IUM).</td>
</tr>
<tr>
<td><strong>Physical Data Carrier</strong></td>
<td>2D DataMatrix</td>
</tr>
<tr>
<td><strong>Tertiary Packaging Serialization</strong></td>
<td>Yes, aggregation and inference required</td>
</tr>
<tr>
<td><strong>Randomization Required</strong></td>
<td>Yes</td>
</tr>
</tbody>
</table>
| **External Reporting** | External reporting is required by all members of the supply-chain:  
  - Supply-chain participants required to report back to the manufacturer  
  - Manufacturer / brand owner is required to provide Brazilian Sanitary Surveillance Agency remote access to data. |
| **Interoperability Format** | ANVISA to establish interoperability standards for remote access interface |
| **Record Retention** | Must retain item-level tracking data for 2 years after product expiration date |
| **Implementation Dates** | **December 10th, 2015** - Three (3) batch/lots traced through supply-chain and made available to the Brazilian Sanitary Surveillance Agency  
  **December 10th, 2016** - 100% of products serialized and tracked |
ANVISA Proposed Architecture

Drug Product Chain

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What does it mean for a Global Pharma Organization?
Some Implications of Global Compliance

• Evolving regulations
  – Agile Architecture

• Support multiple models and multiple legal roles
  – Serial number management
  – Central / distributed repositories
  – Different obligations depending on the role

• Supply Chain and Government - Interoperability
  – Diverse technology and level of sophistication
  – Multiple standards
Phased Approach

Now - Assessment
• Assess current serialization project
• Develop strategy with end-state in mind
• Harmonize on GS1 standards
• Evaluate current infrastructure
• Evaluate partner capabilities
• Identify strategic business opps

Phase 1 - Lot Level Tracing
• Implement enterprise platform which supports serialized and nonserialized tracking
• Locate required attributes in backend and partner systems
• Build-out required interfaces to ERP, WMS, and partner systems
• End-to-end testing with trading partners

Phase 2 - Serialization
• Learn from early pilots with trading partners
• Develop enterprise serial number management strategy
• Rollout and testing of manufacturing lines / CMO’s
• Rollout and testing of distribution center edge systems / 3PL’s

Phase 3 - Unit-Level Tracing
• Learn from early pilots with trading partners
• Enable support for aggregation and inference
• Enable traceability for returns
• Advanced exception handling
Thank you