Serialization & Traceability
Challenges and Opportunities in the Brazilian Scenario

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Agenda

- What is the RDC54?
- RDC54 - Serialization, Aggregation and Track & Trace (T&T)
- How Is It Different From Other Regulations?
- Differences of Some Traceability Models
- Challenges and Opportunities
- Key Success Factors
What is the RDC54?

- **RDC54** = Anvisa Collegiate Board Resolution # 54
- Published December 10, 2013
- Final implementation date December 10, 2016
- Defines requirements for serialization and traceability
- Serialization and T&T for prescriptions and OTCs
RDC54 – Serialization & Aggregation
RDC54 – Track & Trace Requirements (Simplified)

International Affiliate 1 → Registration Owner → International Affiliate 2

Hospital → Distributor / Wholesaler

Drug Store

Commercial Flow

Track & Trace Information Flow

P.S. Track & Trace information flows back from Hospitals and Drug Stores to Distributors as a confirmation of goods receipt or reverse logistics, not detailed above.
How is it different from other regulations?

- 2 years for 3 batches and 3 years for full implementation
- Includes prescription drugs and OTCs
- Serial number with 13 digits totally randomized
- Serial number defined at the Registration Owner (local) and Manufacturer level (imported)
- Full T&T, from manufacturer until the point of dispense
- Free samples and clinical trials (stage IV) also in scope
- Focus on changes of custody, including internal movements
- Information always returning to the manufacturer
- Pro-active anomalies reporting by the industry itself, not Anvisa
Traceability Models – Argentina, Turkey & China

International Affiliate 1

Registration Owner

International Affiliate 2

Distributor / Wholesaler

Hospital

Drug Store

MoH DB
Traceability Models – United States

International Affiliate 1

Registration Owner

International Affiliate 2

Distributor / Wholesaler

Hospital

Drug Store

Potential Approach: EPCIS
Traceability Models – European Union

International Affiliate 1

Registration Owner

International Affiliate 2

European HUB

National System

Drug Store

Hospital

Distributor / Wholesaler

Commercial Flow

Track & Trace Information Flow

Product Authentication
Traceability Models – Brazil

- International Affiliate 1
- International Affiliate 2
- Registration Owner
- Service Provider 1
- Service Provider 2
- Service Provider 3
- HUB
  - Acting like an index page, showing the repository any company in Brazil belongs to

Diagrams:
- International Affiliate 1
- International Affiliate 2
- Registration Owner
- Service Provider 1
- Service Provider 2
- Service Provider 3
- HUB
- Hospital
- Drug Store
- HUB: Acting like an index page, showing the repository any company in Brazil belongs to
Challenges and Opportunities

- Not possible to ensure all supply chain partners have a GLN, workaround may be necessary to ensure implementation

- Proprietary traceability model defined in the guideline created by the major Brazilian pharmaceutical associations

- Reasonable synergy among pharmaceutical associations in Brazil (Strategic), but lack of collaboration and initiatives on the tactical and technical levels, among supply chain players

- Single governance model around the overall traceability solution for the sector to be established, to support the challenges above

- Challenge that will be faced by hospitals to adapt the current process based on unitization at the goods receipt, to the secondary packaging model/control
Key Success Factors

- Follow GS1 global standards for product identification and product traceability as an overall solution foundation.

- Put all necessary effort to make sure the overall sector is moving towards an unique serialization and traceability solution.

- Centralized governance with creation of focused working groups.

- Alignment of technical teams from different supply chain players: industry, distribution, retail, GS1, MoH, service providers, other important stakeholders.

- Use experience and lessons learned of other markets to drive discussions with MoH authorities and among companies and associations in the sectors.

- Promote collaboration and robust communication plans.
Thank You

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