

Serialization & Traceability

Challenges and Opportunities in the Brazilian Scenario

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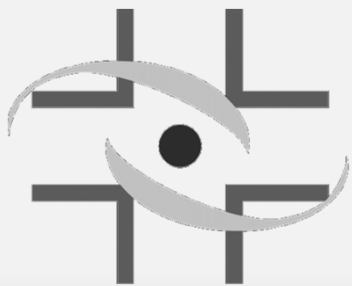
Agenda

- ✓ 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

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What is the RDC54 ?

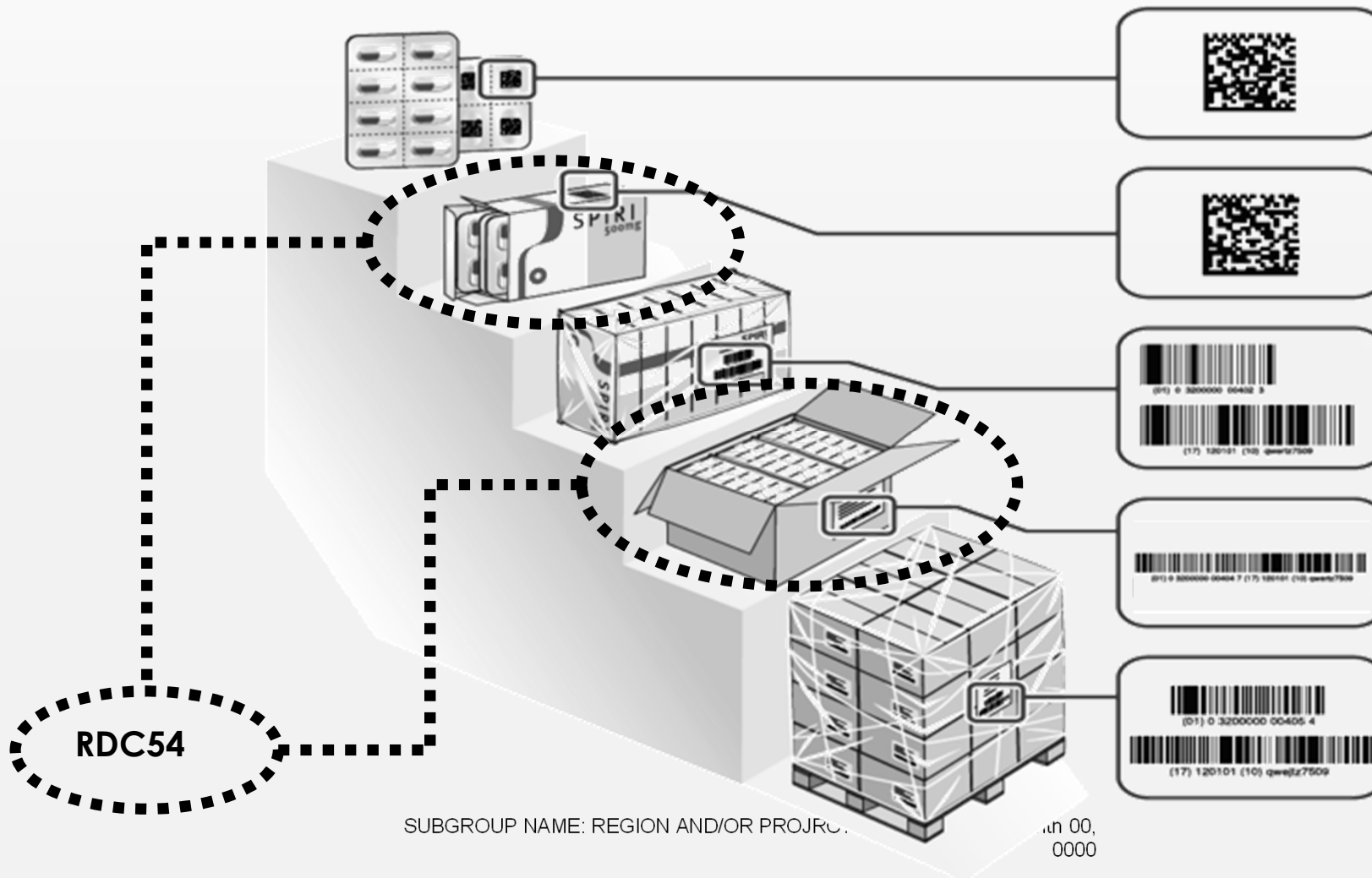
- **RDC54** = Anvisa Collegiate Board Resolution # 54
- Published December 10, 2013
- Final implementation date December 10, 2016
- Defines requirements for serialization and traceability
- Serialization and T&T for prescriptions and OTCs



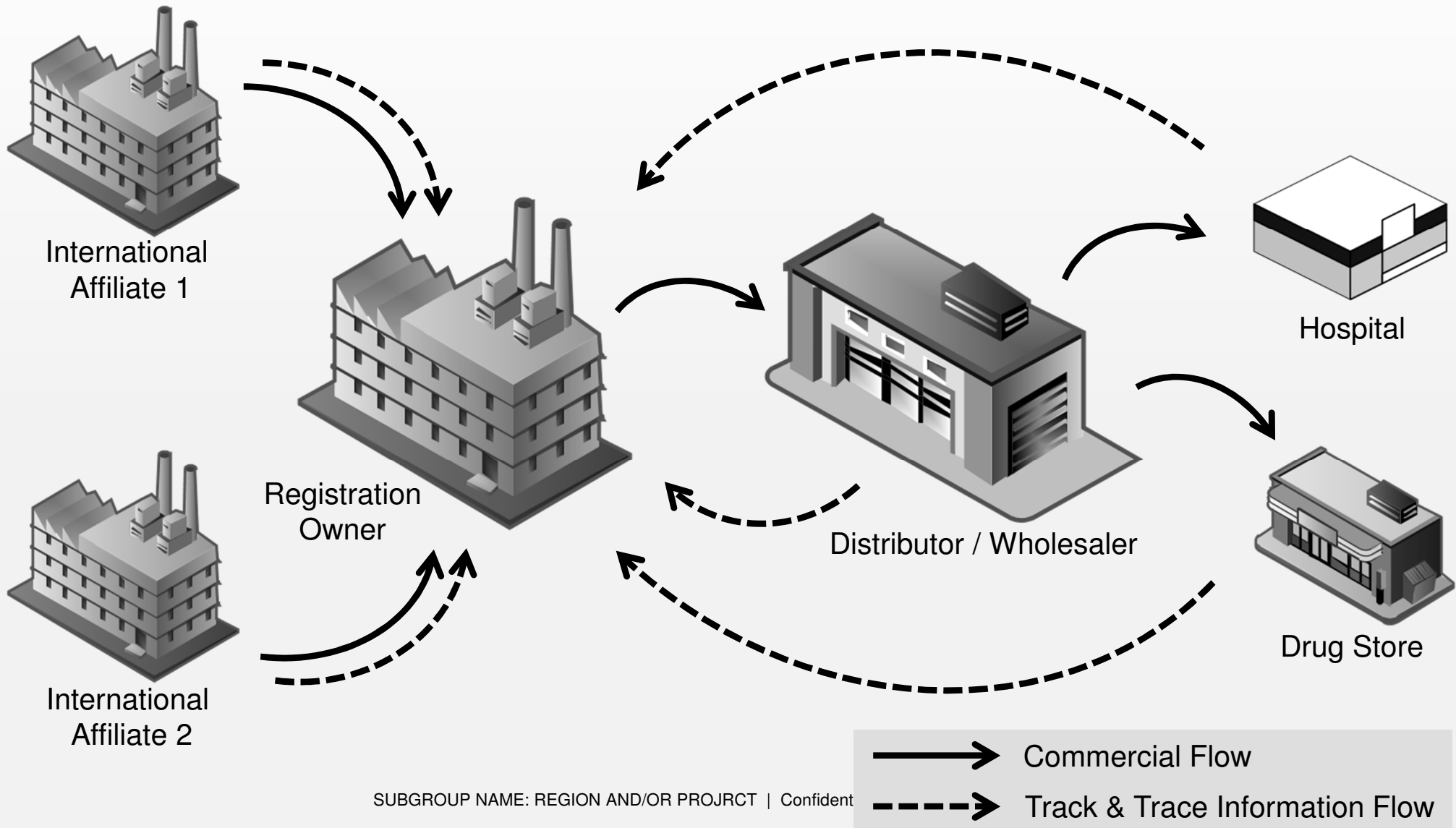
**Agência Nacional
de Vigilância Sanitária**

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RDC54 – Serialization & Aggregation



RDC54 – Track & Trace Requirements (Simplified)

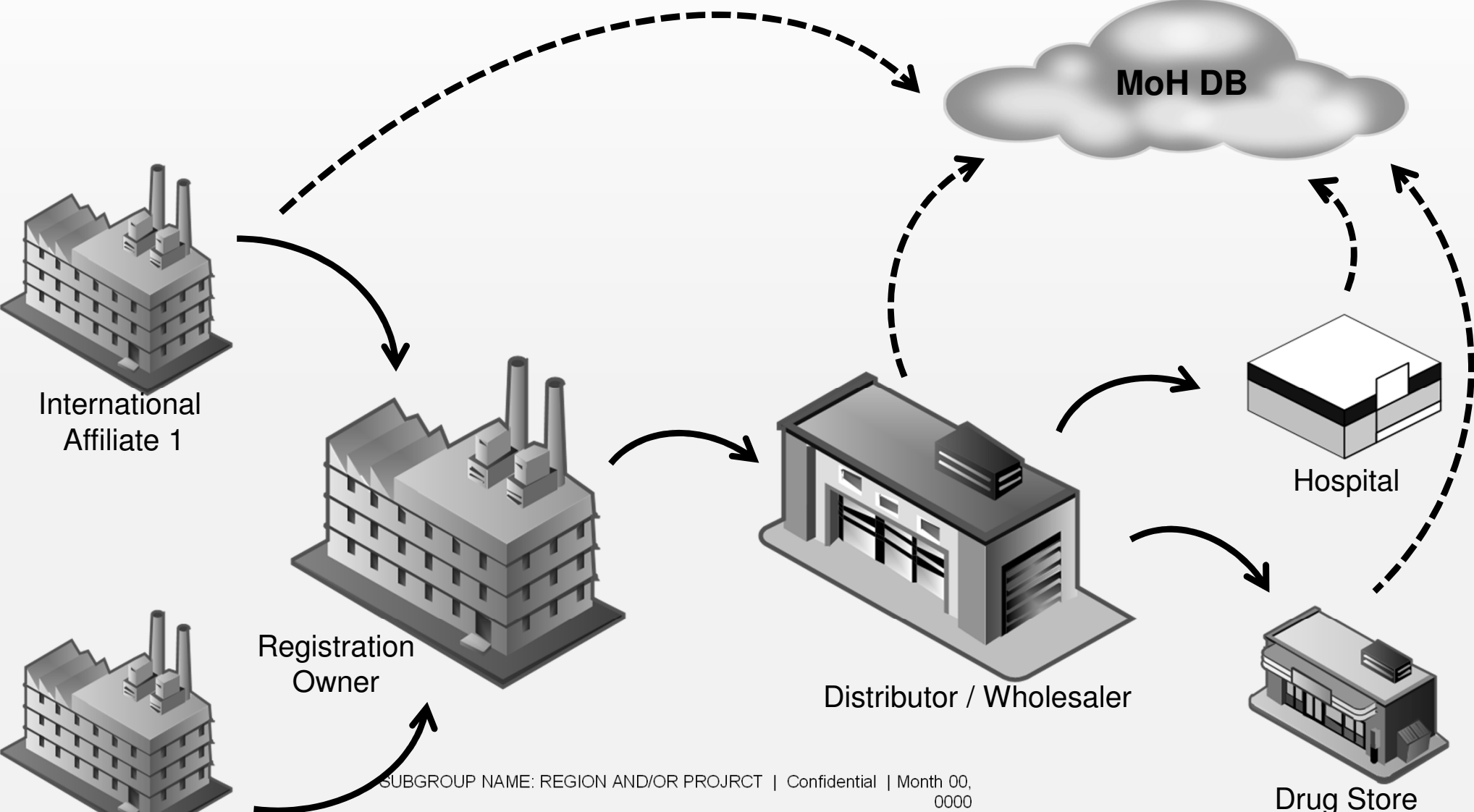


P.S. Track & Trace information flows back from Hospitals and Drug Stores to Distributors as a confirmation of goods receipt or reverse logistics, not detailed above.

How is it different from other regulations?

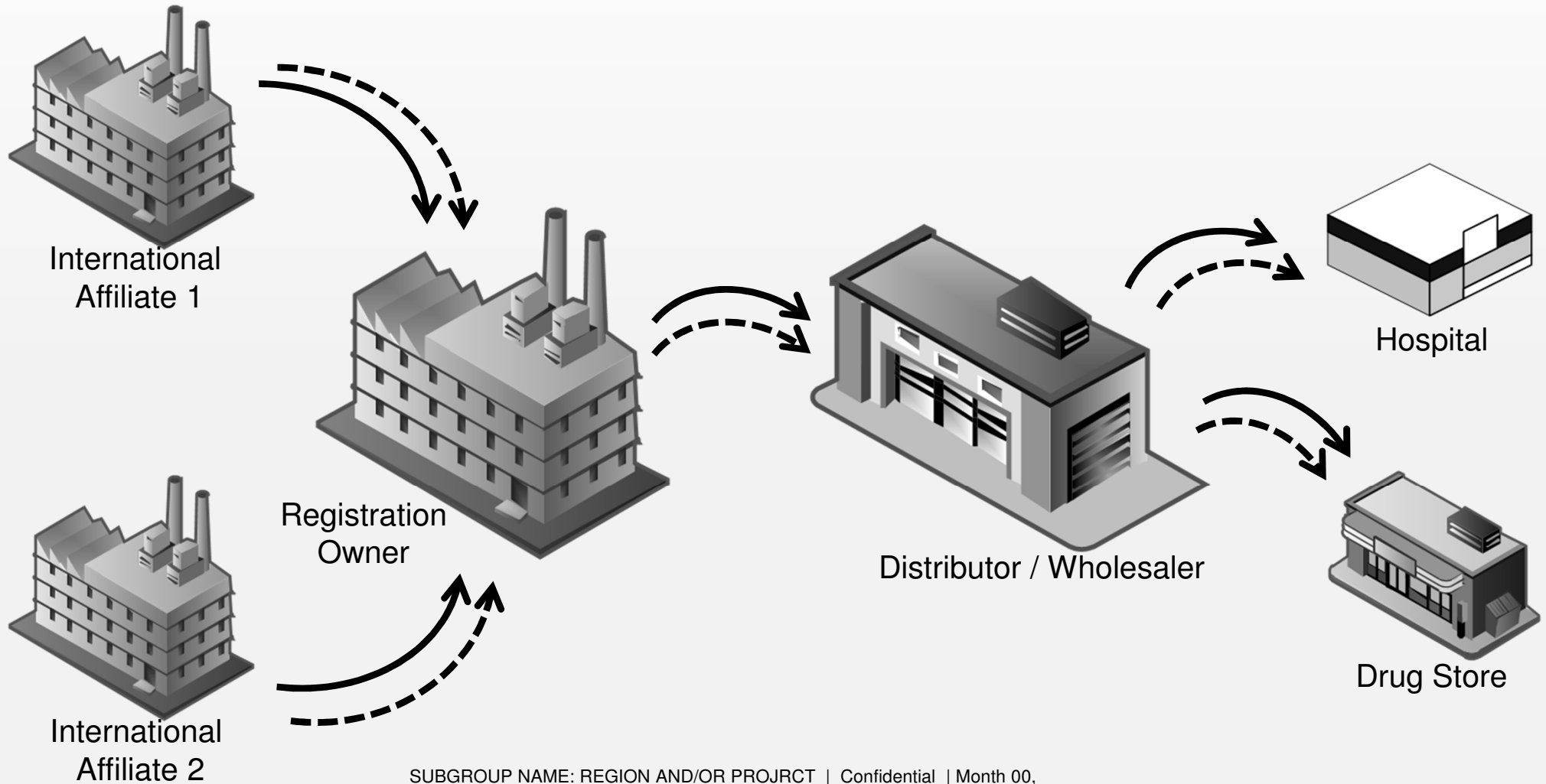
- 2 years for 3 batches and 3 years for full implementation
- Includes prescription drugs and OTCs
- Serial number with 13 digits totally randomized
- Serial number defined at the Registration Owner (local) and Manufacturer level (imported)
- Full T&T, from manufacturer until the point of dispense
- 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



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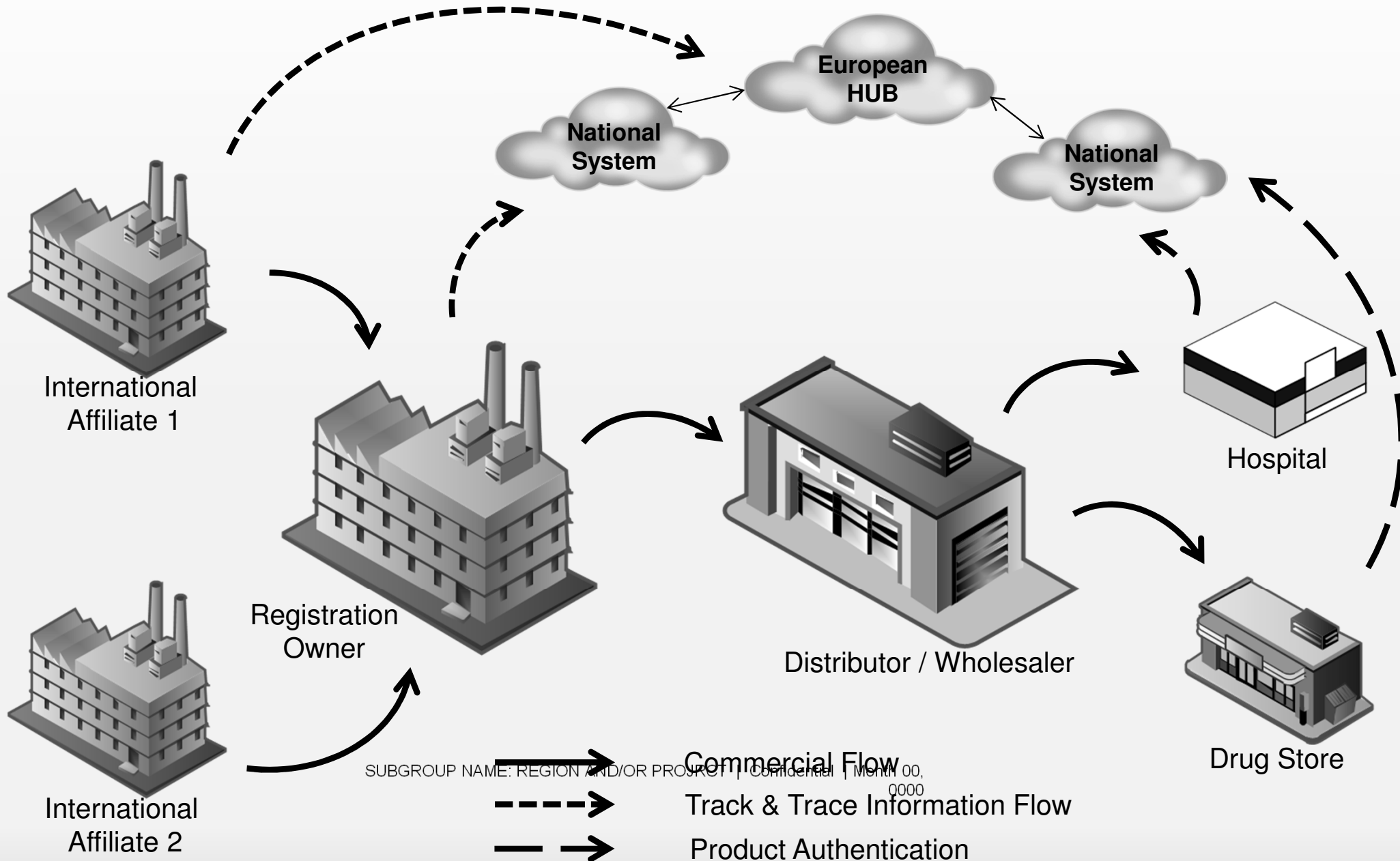
Traceability Models – United States



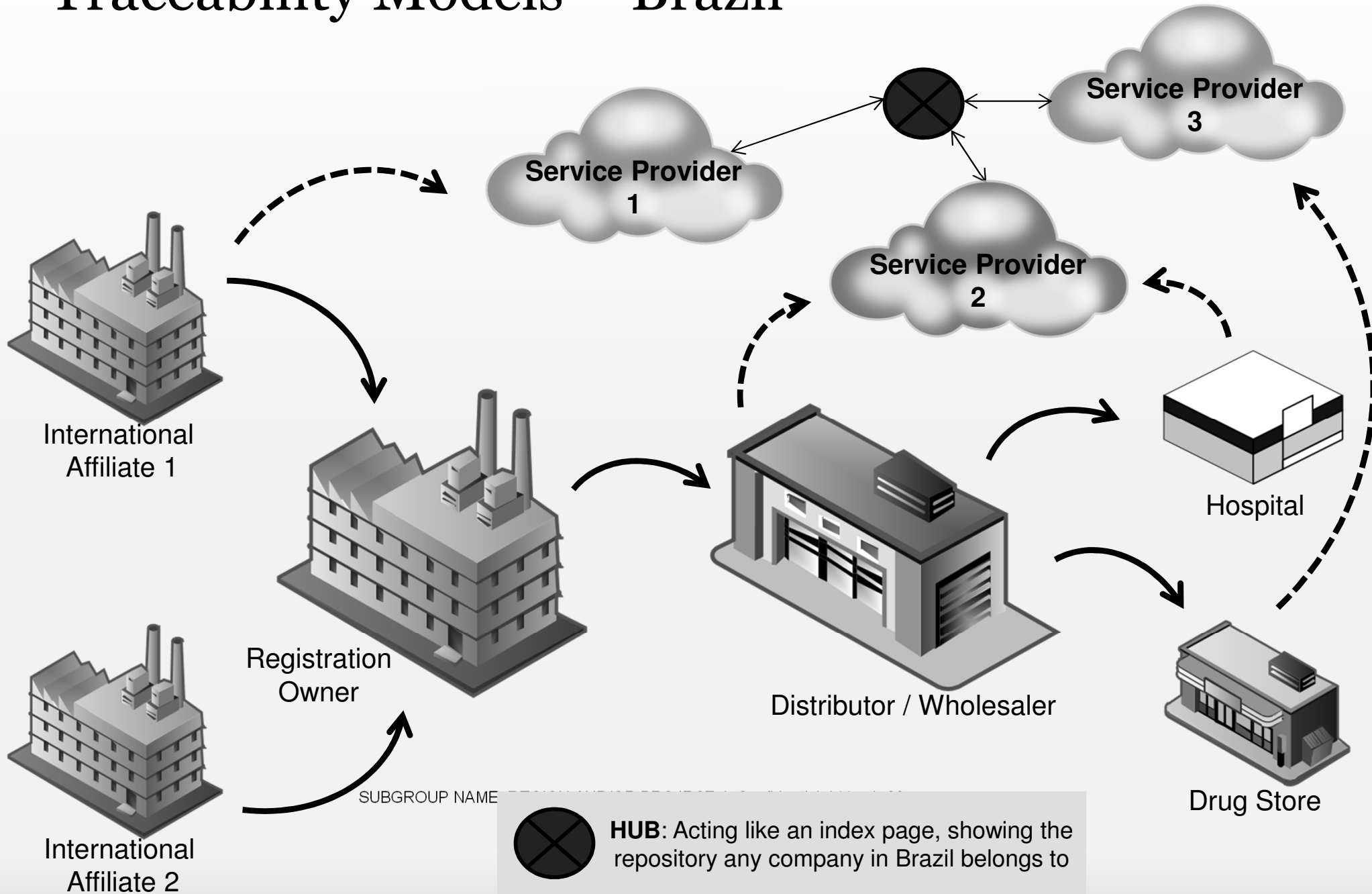
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Potential Approach: EPCIS

Traceability Models – European Union



Traceability Models – Brazil



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

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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 a 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

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Thank You

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