The Journey of Serialization and Traceability
Russia Market Deployment

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Agenda

Russian Pilot Deployment

• Timeline
• Regulatory Requirements
• Scope & What Has Been Done
• Next Steps

Challenges & Learnings (Globally)

Q&A
Russian Serialization and T&T

High-Level Timeline

- **2017:** Law published
- **2018:** 7 Nosologies, Essential Drug List (EDL), Russian Pilot
- **2019:** Full Implementation
- **2020:** Final deadline, all drugs serialized and tracked by all supply chain players
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High-Level Overview/Requirements

- GS1 standard license plate + commodity code (AI 240)
- Full track & trace (T&T), including pre-importation movements
- Bonded warehouse processes in scope
- Centralized T&T data repository – Labeling Information System (LIS)
- Push notifications to downstream players + database search using SSCC & SGTIN
- Comprehensive technical guidelines available, with business processes & messaging content
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Scope & What Has Been Done

- 40+ companies (~ 30 manufacturers, ~ 7-10 3PLs, couple hospitals and pharmacies)
- Millions of products commercialized and data available in LIS already
- GS1 database as data input to LIS: GTIN, manufacturer, product description, reg. date
- GRLS: MoH existing database, also used as data input to LIS
- Small batches, moving along in full throughout the supply chain
- Manual data upload (XML files) and search into LIS

“Supporting the regulator to mature LIS for a bigger scale implementation”
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Next Steps

• Final regulation confirming the technical guideline
• Definition of enforcement dates for 7 Nosologies and EDL
• Keep simulating business processes in LIS
• Keep influencing the LIS solution design and core functionalities
• Validate main LIS core functionalities E2E with supply chain players
• Be ready for the enforcement date with top priority on 7 Nosologies and EDL
Challenges & Learnings

• Lack of standardization with global standards for regulatory reporting solutions

• Buy *versus* develop internally the technical connectivity solution for pilots

• Collaboration among different supply chain players for horizontal integration

• Not aligned voice among supply chain players (multi-national x national manufacturers, manufacturers x distributors x retail expectations)

*Communication, collaboration and engagement are key factors for success!*