



The Global Language of Business

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Stronger together: How safety of patients benefits from close alignment of authorities and manufacturers

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Science For A Better Life



Stronger together: How Safety of Patients Benefits from Close Alignment of Authorities and Manufacturers

GS1 Global HealthCare Conference, Dubai, 19 April 2016

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Agenda

- Bayer – Committed to Anti-Counterfeiting
- Manufacturer's Experience with Global Requirements
- Manufacturer's Implementation Challenges
- Benefit of Alignment for Authorities & Manufactures



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Bayer – More than 150 Years of Innovation



Bayer develops **Aspirin**

1899



INNOVATION



Kovaltry® for Treatment of Hemophilia A

2016





Bayer - Our Business Areas



Pharmaceuticals

- Prescription drugs



Consumer Health

- Over-the-counter medicines, dietary supplements, dermatology products, foot care and sunscreen



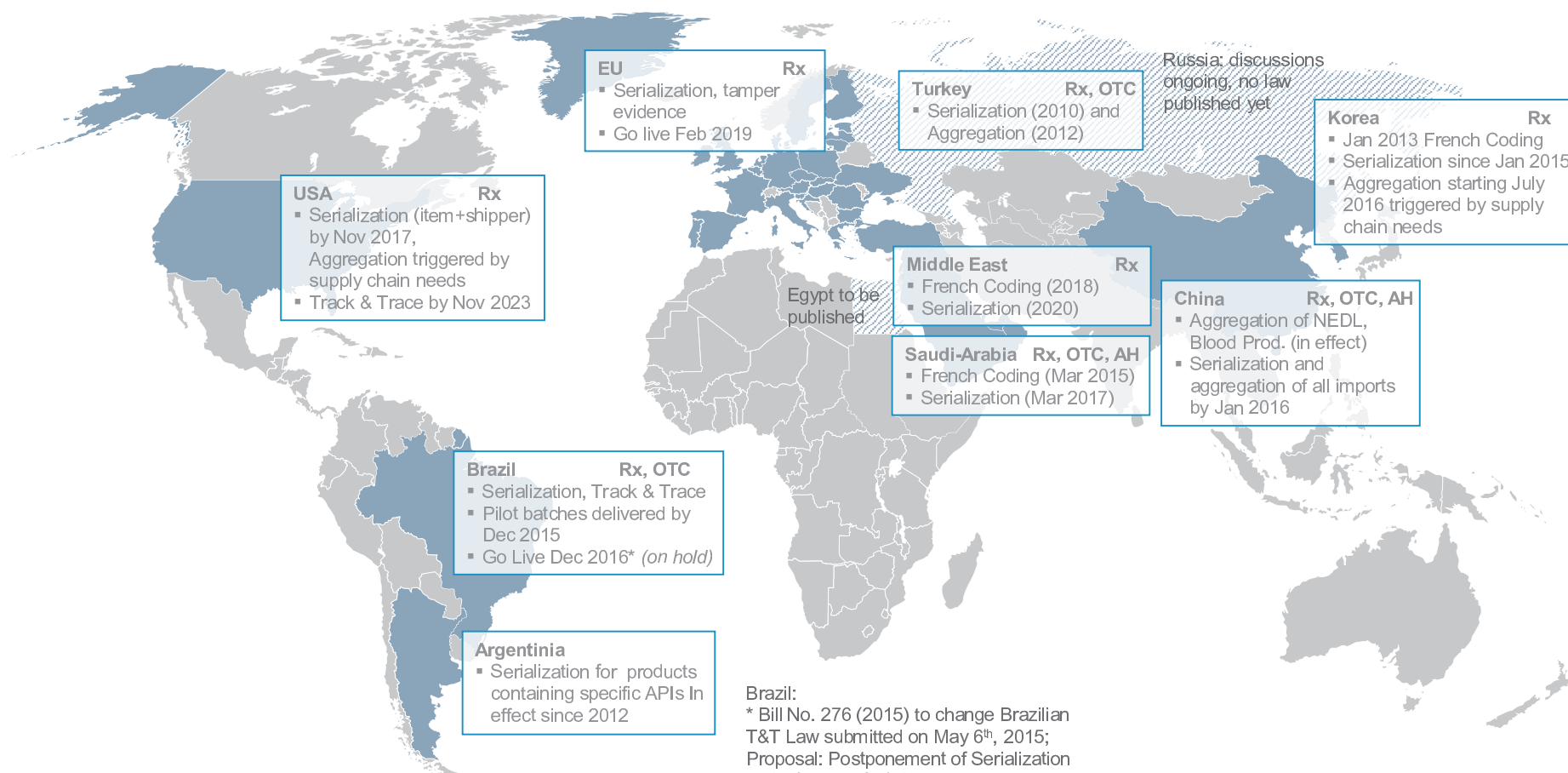
Crop Science

- Innovative crop protection and seeds



Bayer – Serialization & Coding Program

Regulatory Requirements in Scope of Bayer's Mass Serialization and Coding Program (MSC)





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Best Practice: Law Making Process

- Clear and timely legislation
- Ensure consistency across all regulatory documents (law, guidelines etc.)
- Involve stakeholders
 - Manufacturers
 - Wholesalers
 - Logistics service providers
 - Pharmacists
 - ...



Align with Requirements Globally: Scope of Products



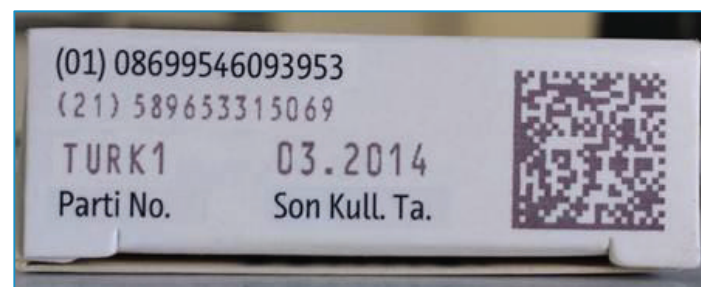
- Limit scope to Rx products
- Exclude
 - OTCs
 - Orphan drugs
 - Contrast media
 - Free samples
 - Radiopharmaceuticals
 - Cosmetics
 - Food supplements
 - Animal health products





Align with Global Standards

- Adhere to GS1 Global Standards for verification
 - GS1 system (numerology)
 - GS1 Data Matrix Code (symbolology)
 - Max. 5 data elements
 - GTIN (Global Trade Item Number)
 - S/N (Serial Number)
 - Batch
 - Expiry
 - NHRN (National Healthcare Reimbursement Number)
- QR code for information of patients (patient information / electronic leaflet) and healthcare professionals



Align with Global Approaches: Serialization



- Manufacturers generate the serial numbers themselves
- Apply serial numbers to the secondary package
- Use of mature coding technologies (e.g. GS1 Data Matrix Code)



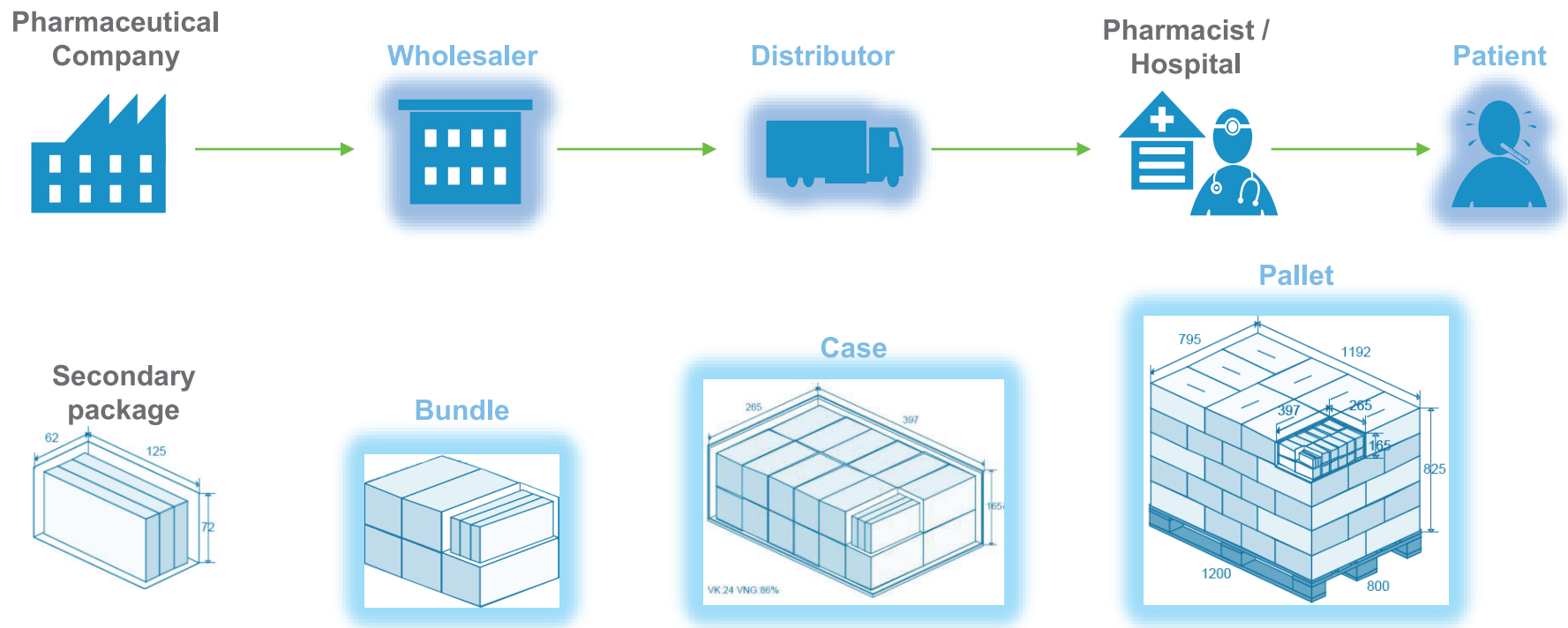
| | | |
|----------------|------|----------------|
| GTIN: | (01) | 09876543210982 |
| S/N: | (21) | 123456789012 |
| Batch: | (10) | A1C2E3G4I5 |
| Expiry: | (17) | 140531 |



Select between Global Approaches: Aggregation



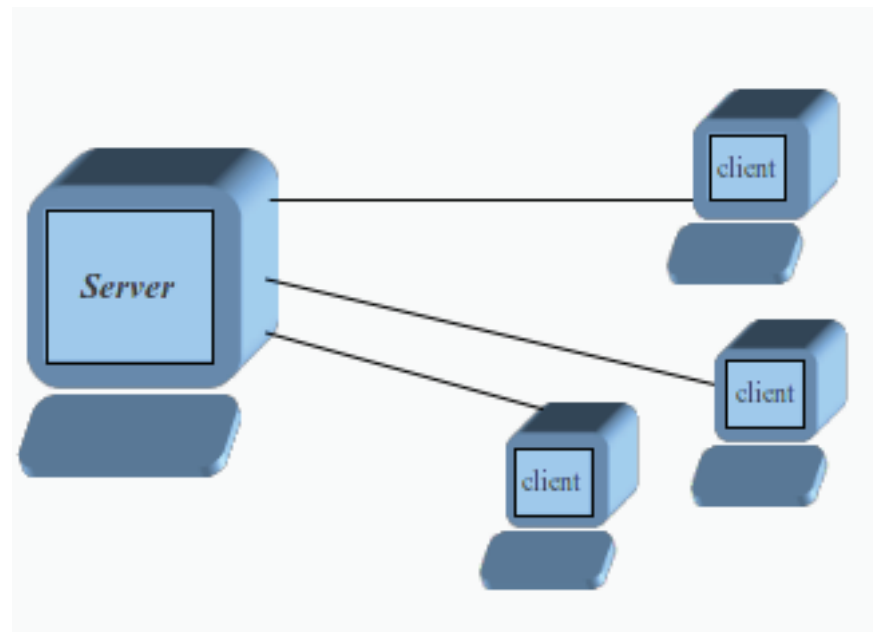
- What are the expected benefits of aggregation?
- Point-of-Dispense verification (EU model) vs. full Track&Trace (Turkey, Korea)
- Aggregation level: secondary packaging + shipper cases



Select between Global Approaches: Reporting



- Who operates the verification repository? – Governance Model
- Authorities- vs. stakeholder-driven
- Data control vs. responsibility for data security and availability



Best Practice: Timeline

- Realistic Implementation Timeline
- Staged Implementation (increasing complexity)
 - Non-serialized coding (French coding)
 - Serialization
 - Reporting / Point-of Dispense Verification
 - Aggregation
 - Reporting / Track&Trace





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Manufacturer's Implementation Challenges



- Project Execution Timeline
 - 1st line project incl. IT infrastructure approx. 24 months
 - Subsequent line projects 12-15 months
 - Artwork changes, regulatory change requests, re-registration
- CMOs
 - Technical and financial capabilities,
 - Sometimes only very few SKUs affected
 - Need for re-registration if current CMO is not capable





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Alignment of Authorities & Manufacturers ensures...



- Feasibility of Approach
- Reliable Implementation Timelines
- Cost-Effective Patient Safety
 - Minimize Cost Impact on Healthcare Systems
 - Affordable even for local small and medium-sized companies
- Patients' Access to Safe Medicines





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Thank you!