



The Global Language of Business

Traceability – Challenges and Learnings

Panel Discussion

Chaired by Mr. Senthil Rajaratnam, Affiliate Relations Leader, Eli Lilly and Company, U.S.A.

6 November 2019

Introduction



Panelists:

- Chaired by Senthil Rajaratnam, Affiliate Relations Leader, Global Serialization Program, Eli Lilly and Company, USA
- Mr. Bhaskar Dey, Associate Director, Logistics & Exports at Abbott Healthcare, India
- Mr. Scott Mooney, Vice President Distribution Operations Supply Chain Assurance, McKesson Pharmaceuticals, USA
- Mr. Phill Marley, Product Security Advocacy Lead, AstraZeneca, UK

Setting the stage for the discussion



- Key drivers for traceability regulations
- Global Serialization and Traceability Landscape
- Traceability models
- Best practices

Key drivers for traceability regulations



Key Drivers for developing traceability regulation



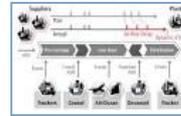
What issue is being addressed?



**Product
Protection &
Patient
Safety**



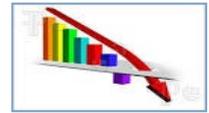
**Reimbursement:
Improve payment
monitoring and prevent
reimbursement fraud**



**Supply Chain
Visibility and
Efficiency**



**Recall
Improvement**



**Returns, Shipment
accuracy and
efficiency**

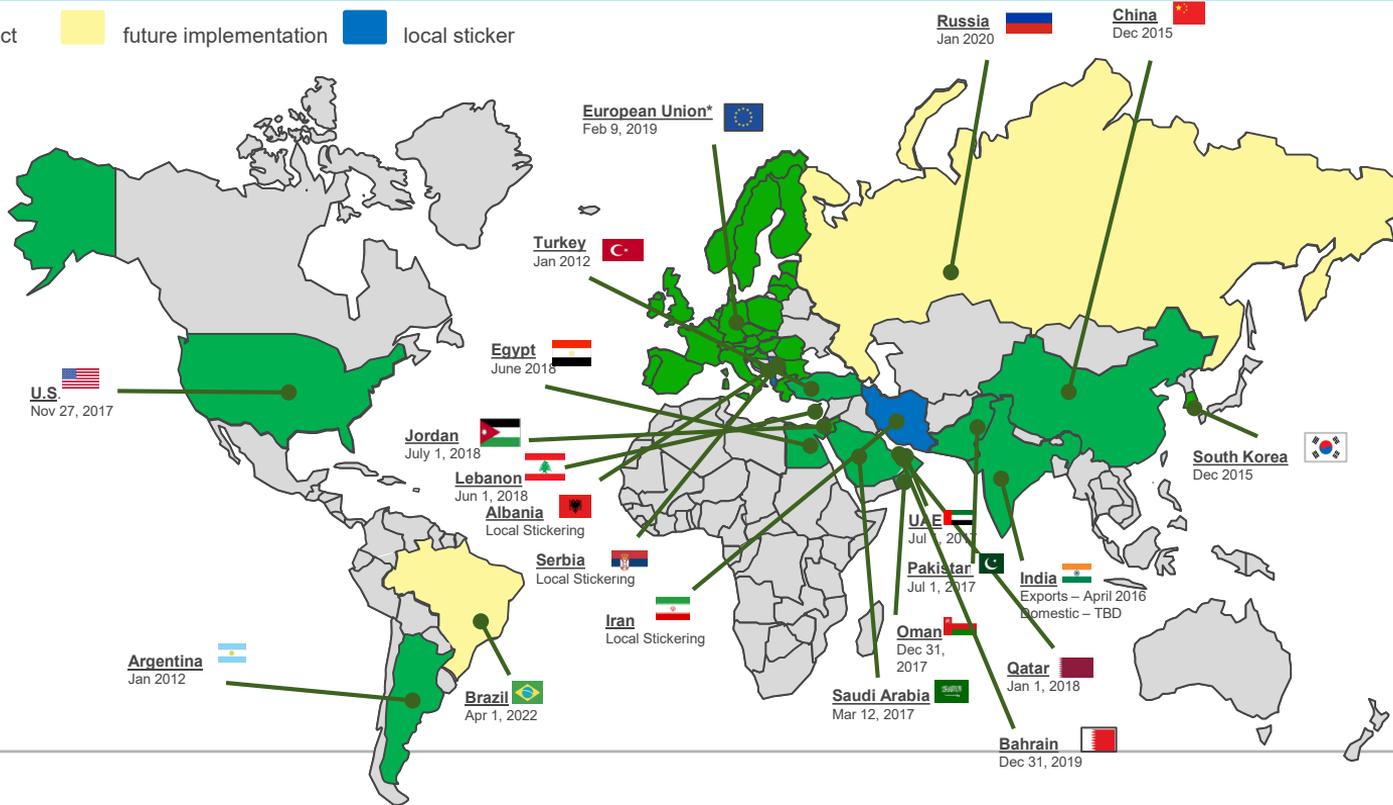
Global Serialization and Traceability Landscape



Global Serialization Implementation



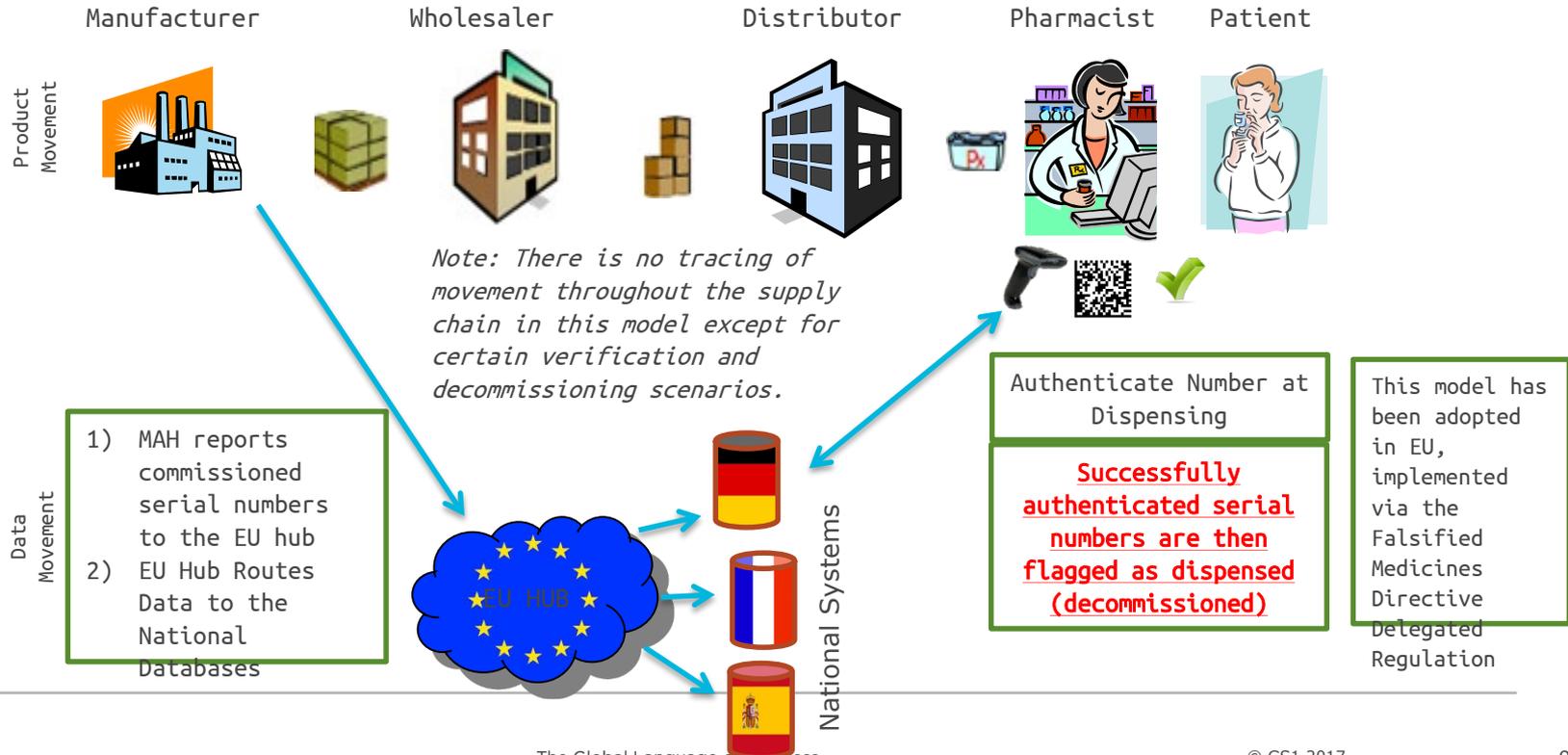
■ currently in effect ■ future implementation ■ local sticker



Traceability models

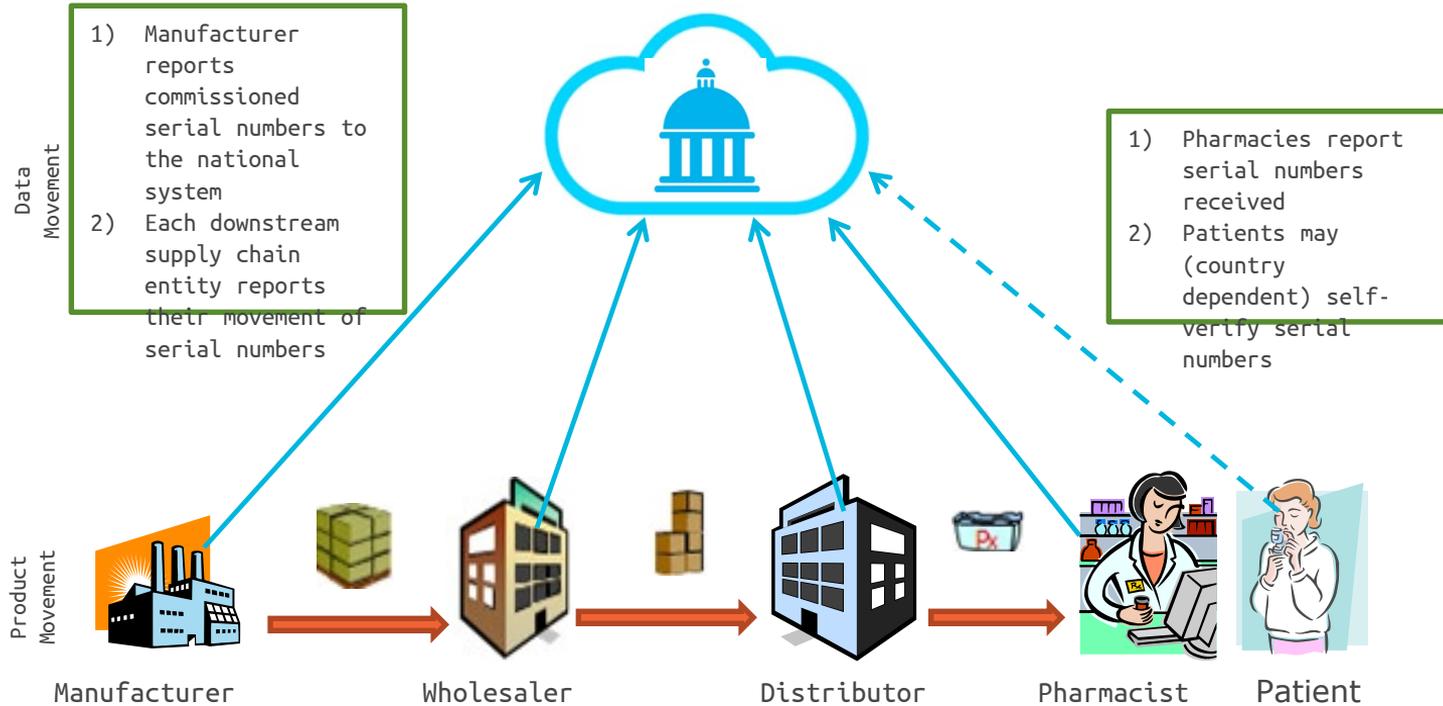


Point of Dispensing Verification





Full Track and Trace



This model has been adopted in Turkey, Argentina, South Korea, China, Saudi Arabia and Russia

Best Practices



Best Practices for Traceability Requirements



Identify:

The following are the most common data elements required to be included on the product package/label:

- GTIN – Global Trade Item Number
- Serial number
- Batch
- Expiry date

Capture:

- GS1 2D Datamatrix at the saleable unit
- GS1 128 linear barcode on the cases (shipper box)



(01)09504000059101
(21)19067811811
(10)563GS1
(17)200331

GS1 DataMatrix



GS1 128 barcode

Important: The order of printing and the order of encoding the above four data elements should not be mandated in the regulatory requirements. The GS1 standards provides flexibility to print and encode in any orders. The systems that are built on GS1 standard should be able to scan and read the data that is encoded in the barcode in any order.

Best Practices for Traceability Requirements



Packaging Level where serialization is applied

- Serialization starts at the “smallest saleable unit”. This is usually the carton that holds the primary package (or it could be the primary package if that is the smallest saleable unit). Smallest saleable unit is the lowest packaging unit that a manufacturer can sell to a pharmacy.



Serialization needs to be applied to primary package only if the primary package is sold as the smallest saleable unit.

Important: Primary package serialization is extremely complex and expensive to implement.

Panel Discussion