



Pharmaceutical Serialization

Senthil Rajaratnam

*Strategy and Implementation Lead
Global Serialization Program
Eli Lilly and Company*

Lilly

Topics

- Pharmaceutical counterfeiting – a global pandemic
- Serialization – another tool in the toolbox to fight fake medicines
- Regulatory environment – serialization and Track & Trace regulations around the world
- Other business values beyond compliance



PHARMACEUTICAL COUNTERFEITING
– A GLOBAL PANDEMIC



Counterfeiting – How bad is it?



- In some developing areas of Asia, Africa and Latin America up-to 30% of retail sales are counterfeit.
- 50% of sales on the internet are illegal.

Impact of counterfeit drugs



Geniune



Falsified

- According to Interpol more than 1 million people die each year from counterfeit drugs.
- Comparing with other causes of death:
 - The mortality of HIV/AIDS in 2016 was 1 million people (WHO, The Top 10 causes of death, Jan. 2017)
 - Road injuries killed 1.4 million people in 2016 and this is the 8th leading cause of death (WHO, The Top 10 causes of death, Jan. 2017)



SERIALIZATION – ANOTHER
TOOL IN THE TOOLBOX TO
FIGHT FAKE MEDICINES

What is serialization?

- Serialization adds a unique identifier (serial number) to the finished pack, typically the outer carton.
- In addition to the serial number, other key data elements such as the batch number and expiry date, and product identification number are printed on the packaging.
- This information is also included in a 2-dimensional barcode for more efficient use in processing.
- This information is used throughout the supply chain to track or verify authenticity.

Serialization – Building blocks

Identify:

This requirement specifies the information that need to be printed on the saleable unit, case and pallet and the standard that need to be followed. It includes information such as GTIN, serial number, batch, expiration date, etc. GS1 is the most widely adopted standard.

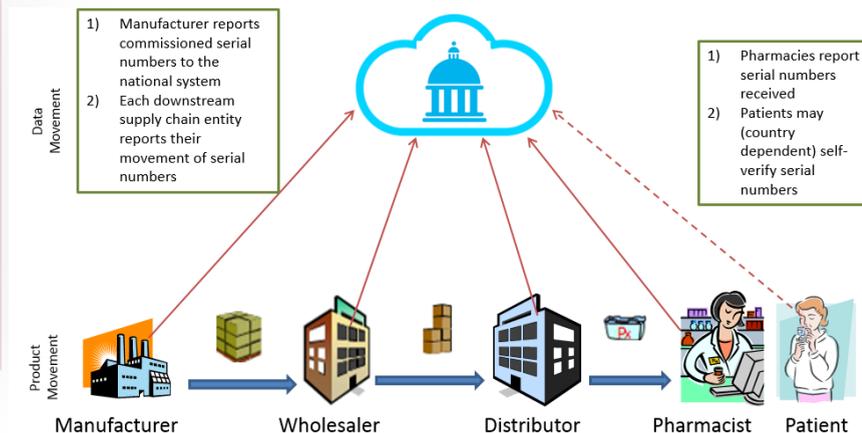
Capture:

This requirement defines how the data needs to be encoded. (i.e. barcodes) so that it can be captured by scanning technologies. This requirement includes the standard and symbology (2D GS1 Datamatrix, GS1-128 linear) for the barcodes.

Share:

The sharing requirements specifies how the serialization and relevant context data need to be shared externally. This requirement defines the file layout with data elements and business events that need to be shared. The sharing could be done by uploading the data to the Ministry of Health database or to the customer receiving the product and it differs for each market with no single global standard.

GTIN – Global Trade Item Number



Common Identify and Capture 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.



The following figure illustrates carton or bottle label variable information (highlighted in orange) printed on the packaging line.

GTIN: 12345678901231

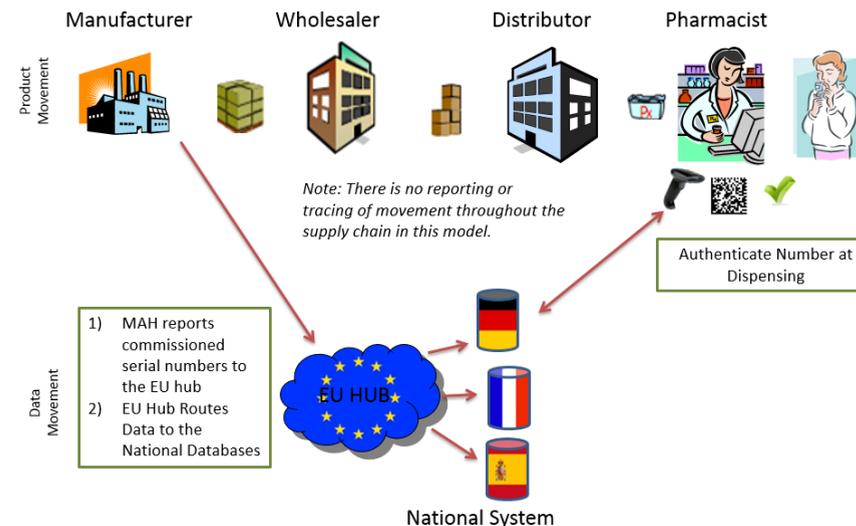
Exp. Date	12 2012	
Control No.	A123456A	
Serial No.	123456789012	

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

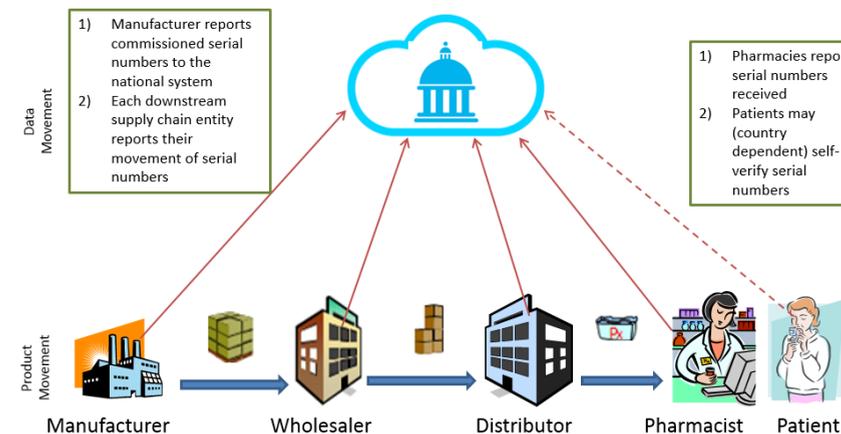
Common data sharing requirements - Traceability Models

Traceability of product packages are achieved by using the captured serial number and product identification information to track the movement of the product in the supply chain. The following are the two most popular traceability models:

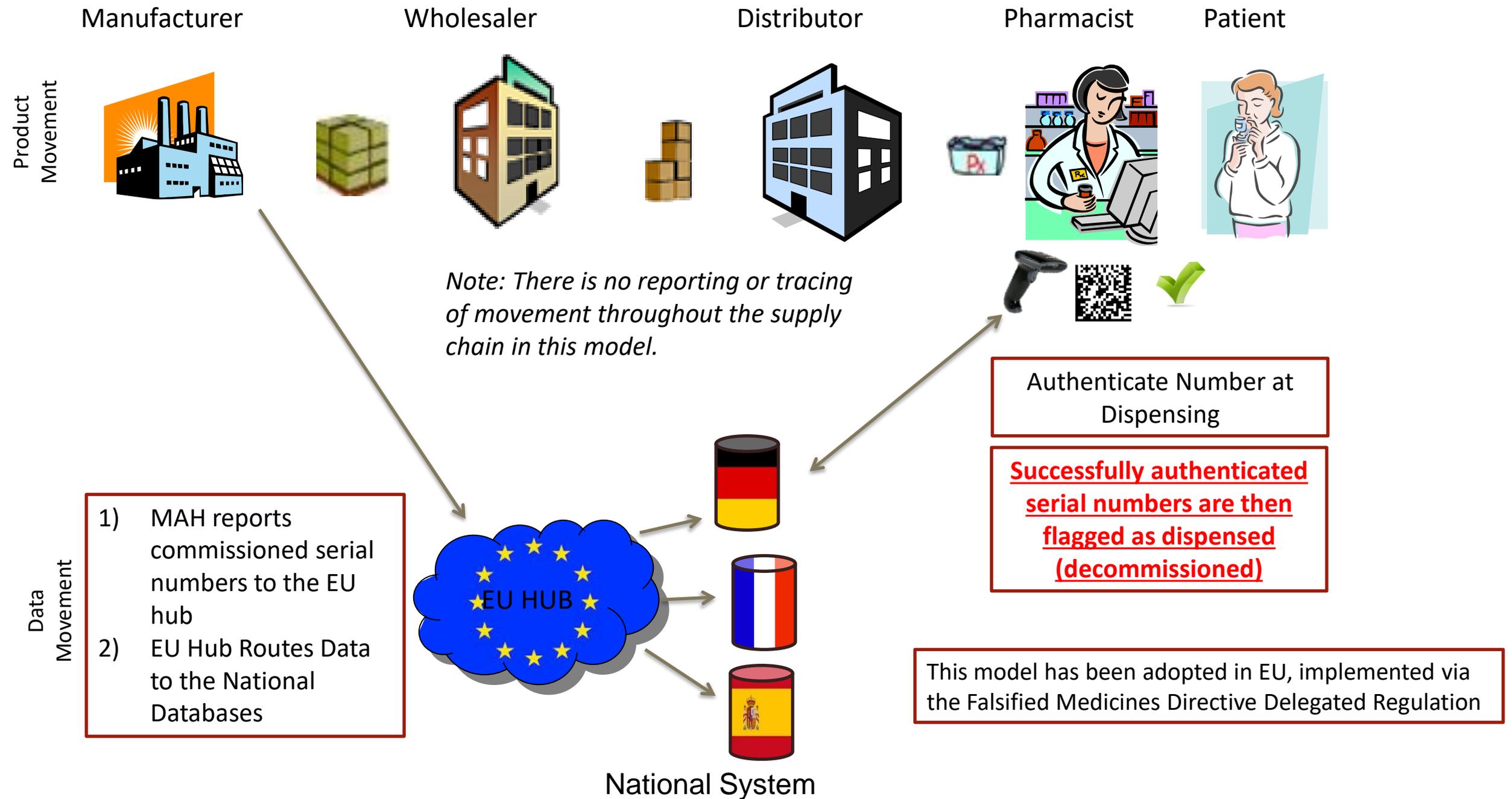
1. Point of Dispensing Verification



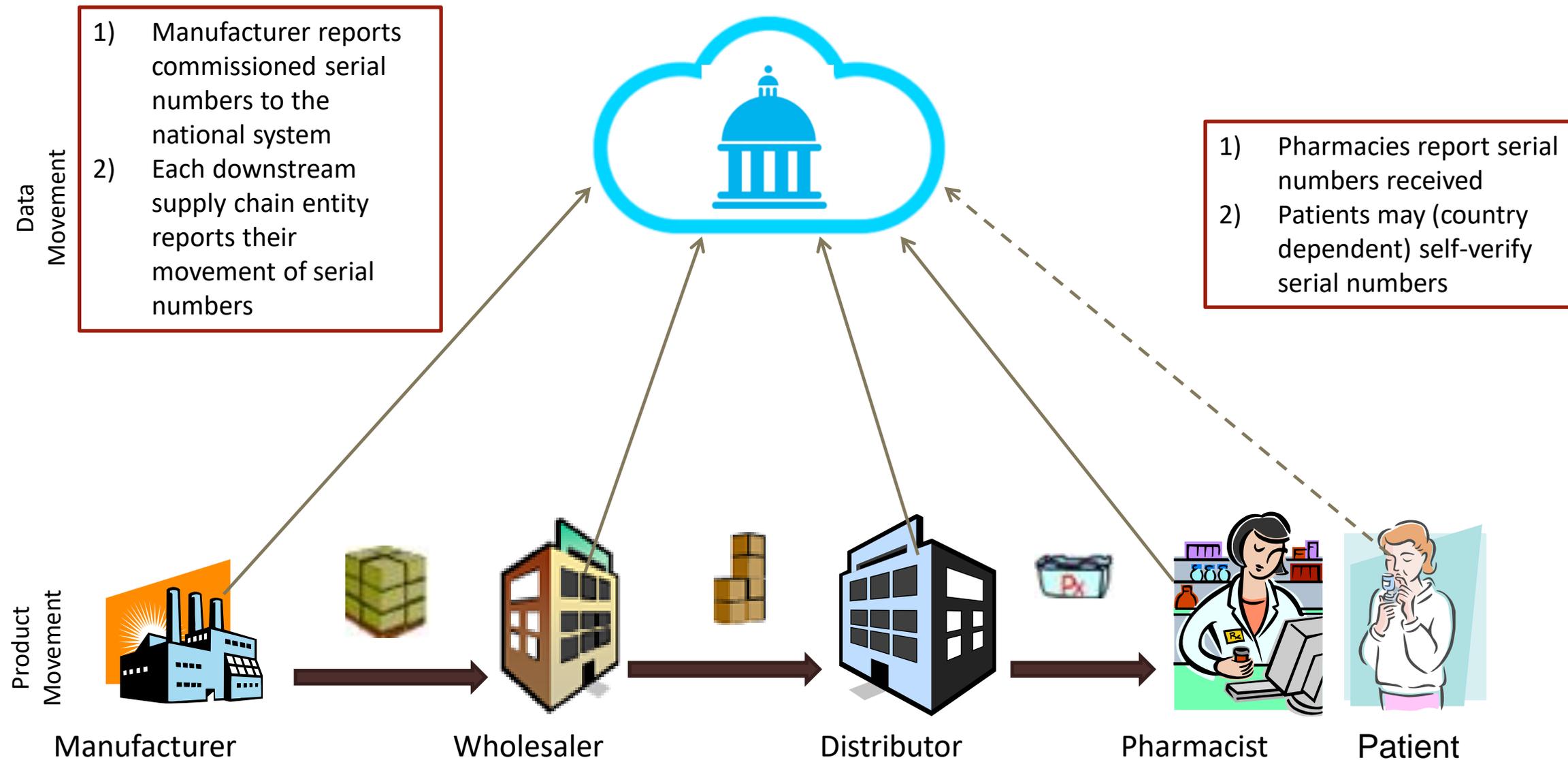
2. Full Track and Trace



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 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 and does not add much benefit to protect the product.



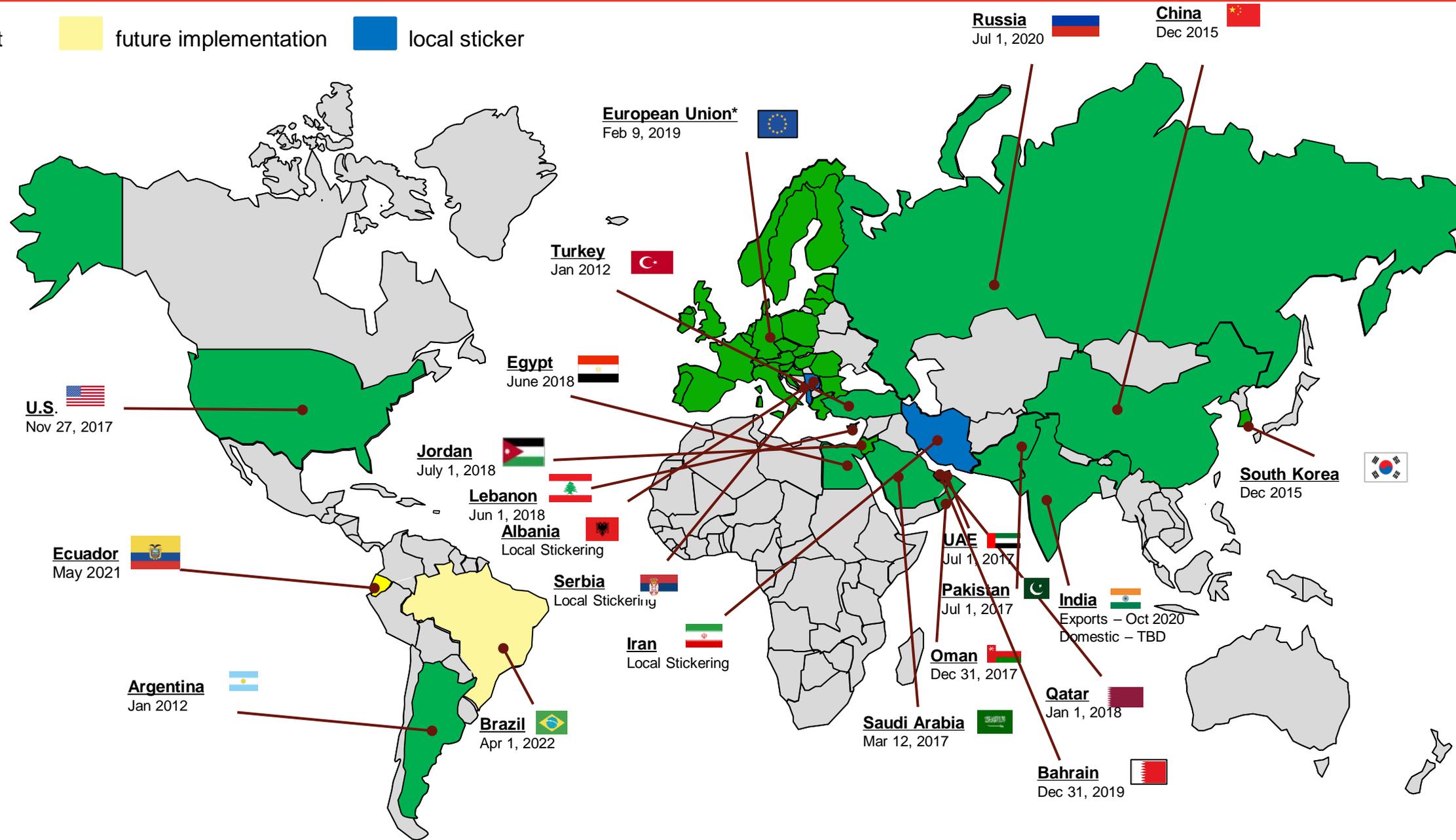
REGULATORY ENVIRONMENT –
SERIALIZATION AND TRACK &
TRACE REGULATIONS AROUND
THE WORLD



Global Serialization Landscape

Updated : Sep 1, 2020

 currently in effect  future implementation  local sticker





OTHER BUSINESS VALUES
BEYOND COMPLIANCE



Value of serialization beyond compliance

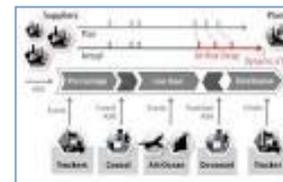
What some of the business drivers for serialization?



**Product
Protection &
Patient Safety**



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



**Supply Chain
Visibility and
Efficiency**



**Recall
Improvement**



**Returns, Shipment
accuracy and
efficiency**

The serialization coding and the data sharing infrastructure could be leverage to achieve business benefits beyond compliance. Some of these business use cases are at an early stage of discussion and will evolve in the coming years.

THANK YOU!