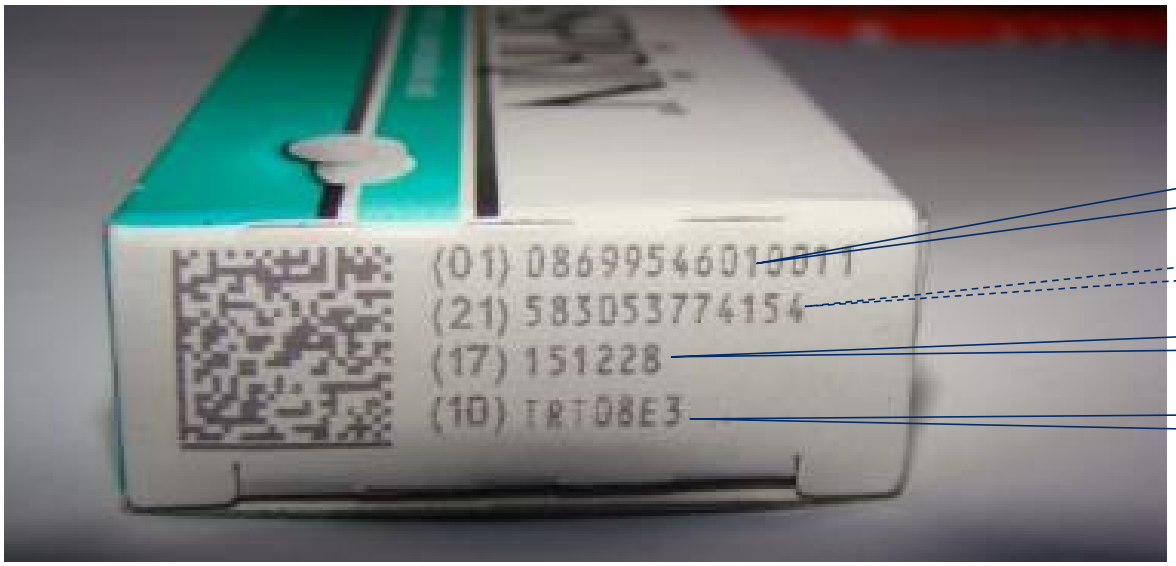
Regulatory environment

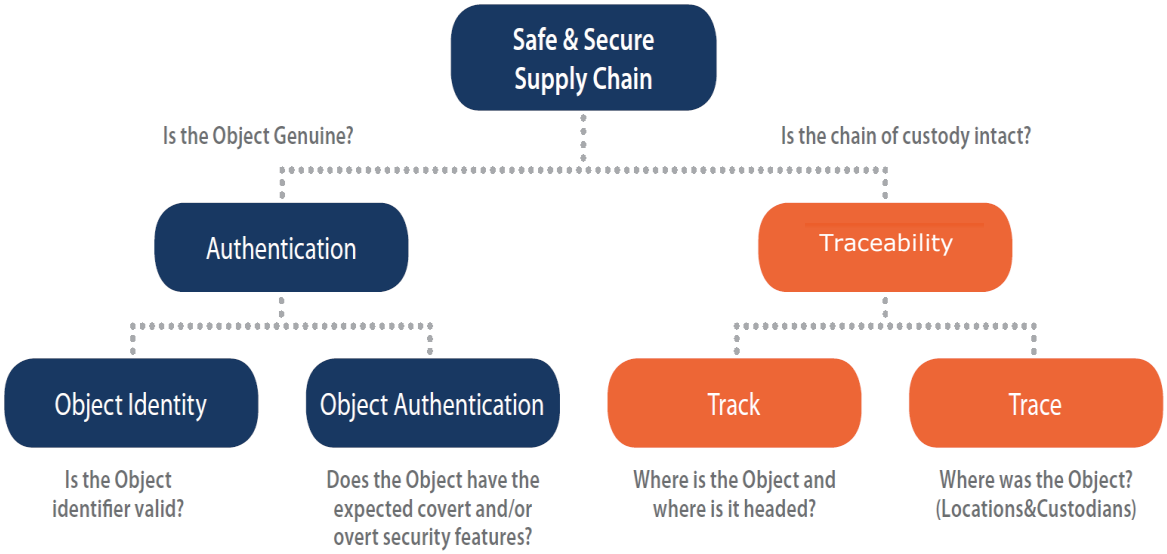
Copyright Notice

The big trend: a serialised secondary pack…

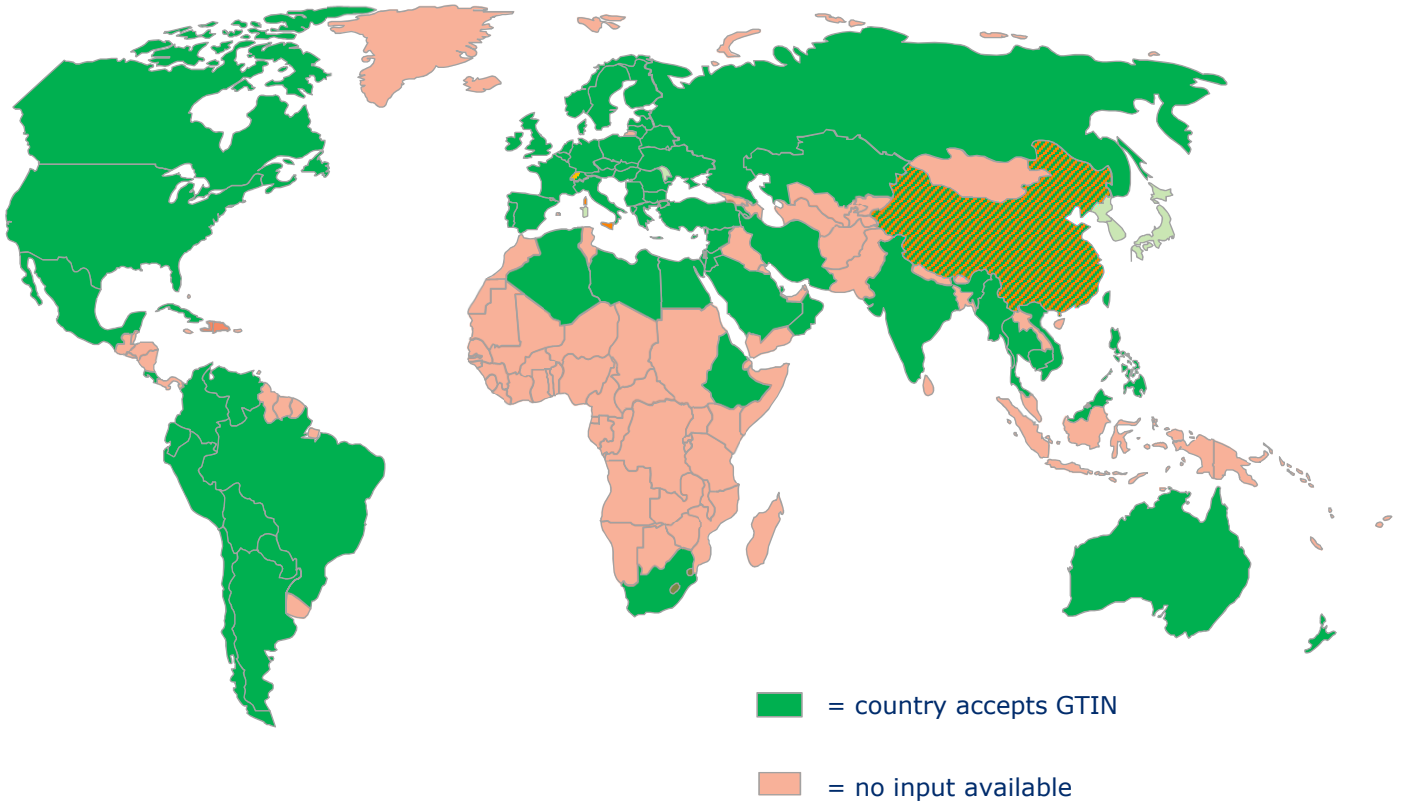


Different approaches

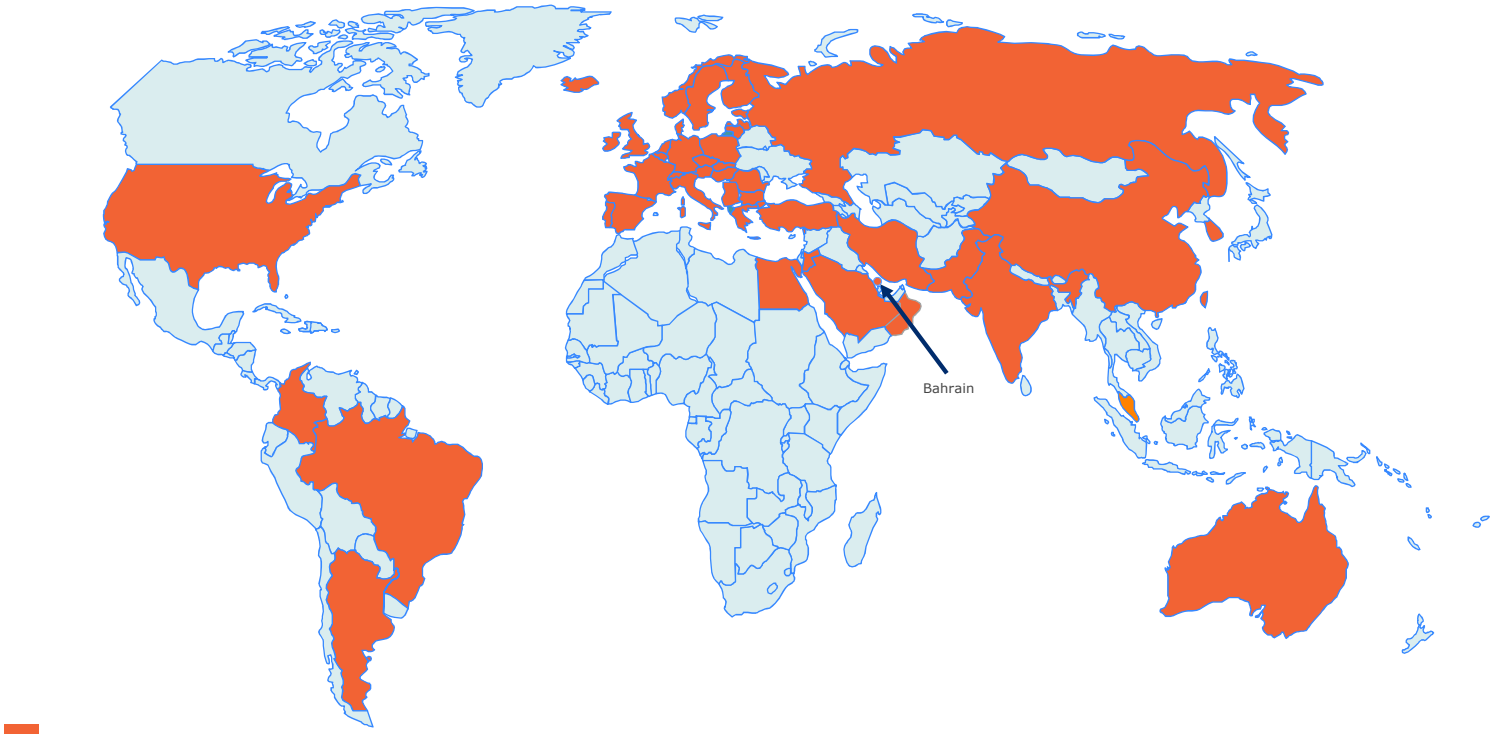
- Can the product identification features be verified?
- Can the product be tracked to where it is – or traced from where it has been?



Harmonisation around the identification of pharmaceuticals

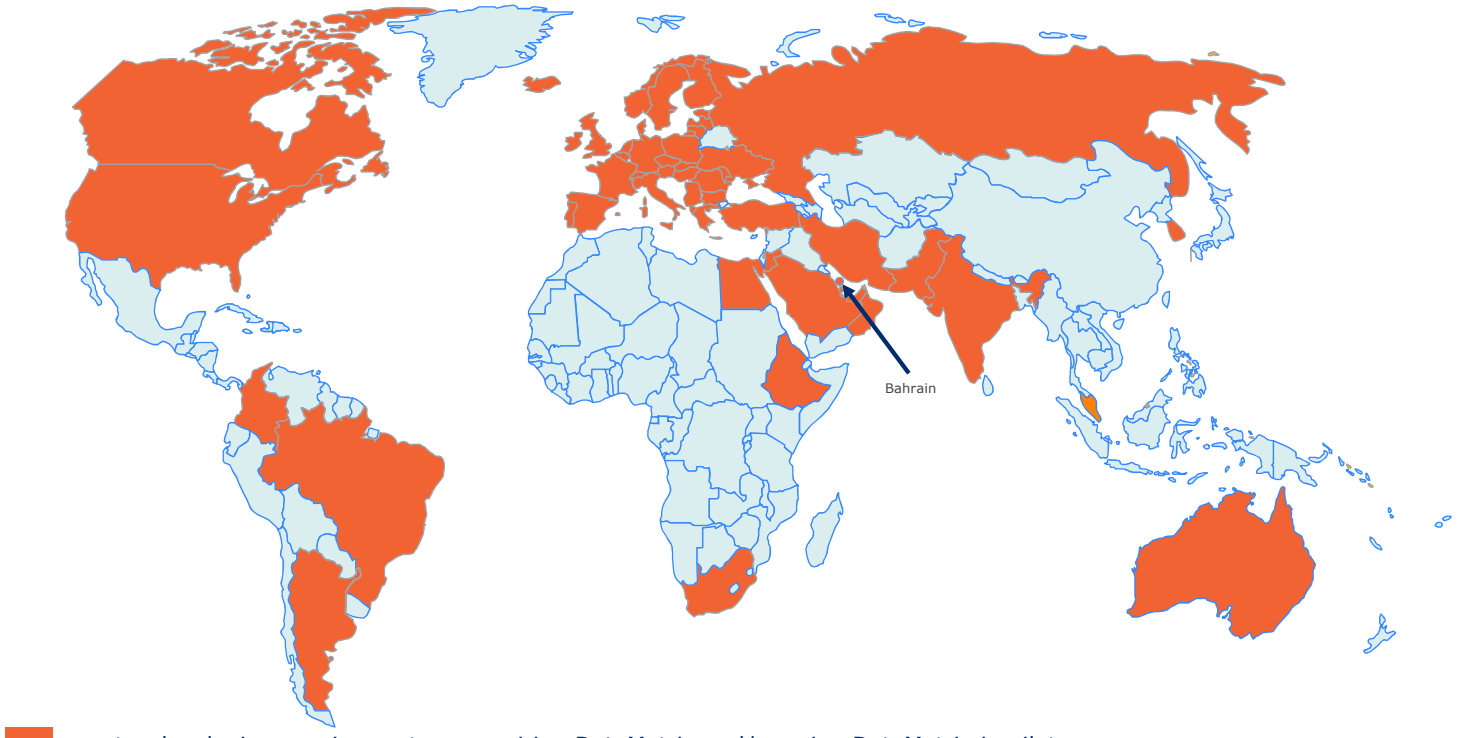


Serialisation of pharmaceuticals



= country developing requirement or requiring serial number

GS1 DataMatrix on pharmaceuticals



country developing requirements or requiring DataMatrix and/or using DataMatrix in pilots

In the EU - the Falsified Medicine Directive

EU Falsified Medicine Directive 2011/62/EU (FMD)

http://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf

EU Commission Delegated Regulation 2016/161

https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2016_161/reg_2016_161_en.pdf

Prevent the entry into the legal supply of falsified medicinal products by requiring the placing of safety features consisting of a **unique identifier and an anti-tampering device** on the packaging of certain medicinal products for human use for the purposes of allowing their **identification and authentication**.

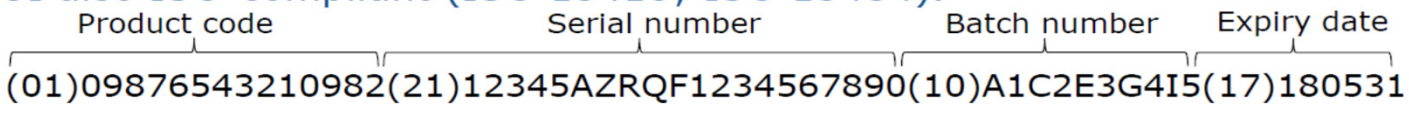
The Unique Identifier in the Delegated Regulation (EU) 2016/161

Source: EU Commission Stakeholder Meeting, February 2016

European Commission

The UI - Composition

- The UI will contain:
  - **Product code:** ISO-compliant (ISO 15459); < 50 characters; globally unique; issued by ISO-compliant coding agencies;
  - **Serial number** (max 20 characters; randomised)
  - A **national reimbursement or identification number** (optional)
  - **Batch number**
  - **Expiry date**
- UI also ISO-compliant (ISO 15418; ISO 15434).



Illustrative example – not binding

European Federation of Pharmaceutical Industries and Associations (EFPIA)

Recommendation for Coding of Pharmaceuticals in Europe

Data Matrix – Coding proposal derived from GS1 standards
(EAN 128 syntax with Application Identifiers; DataMatrix ECC200)

Manufacturer Product Code (GTIN): 14 digits
Unique Serial Number (randomized): up to 20 alpha-numeric characters
Expiry Date: 6 digits (YYMMDD)
Batch Number: up to 20 alpha-numeric characters

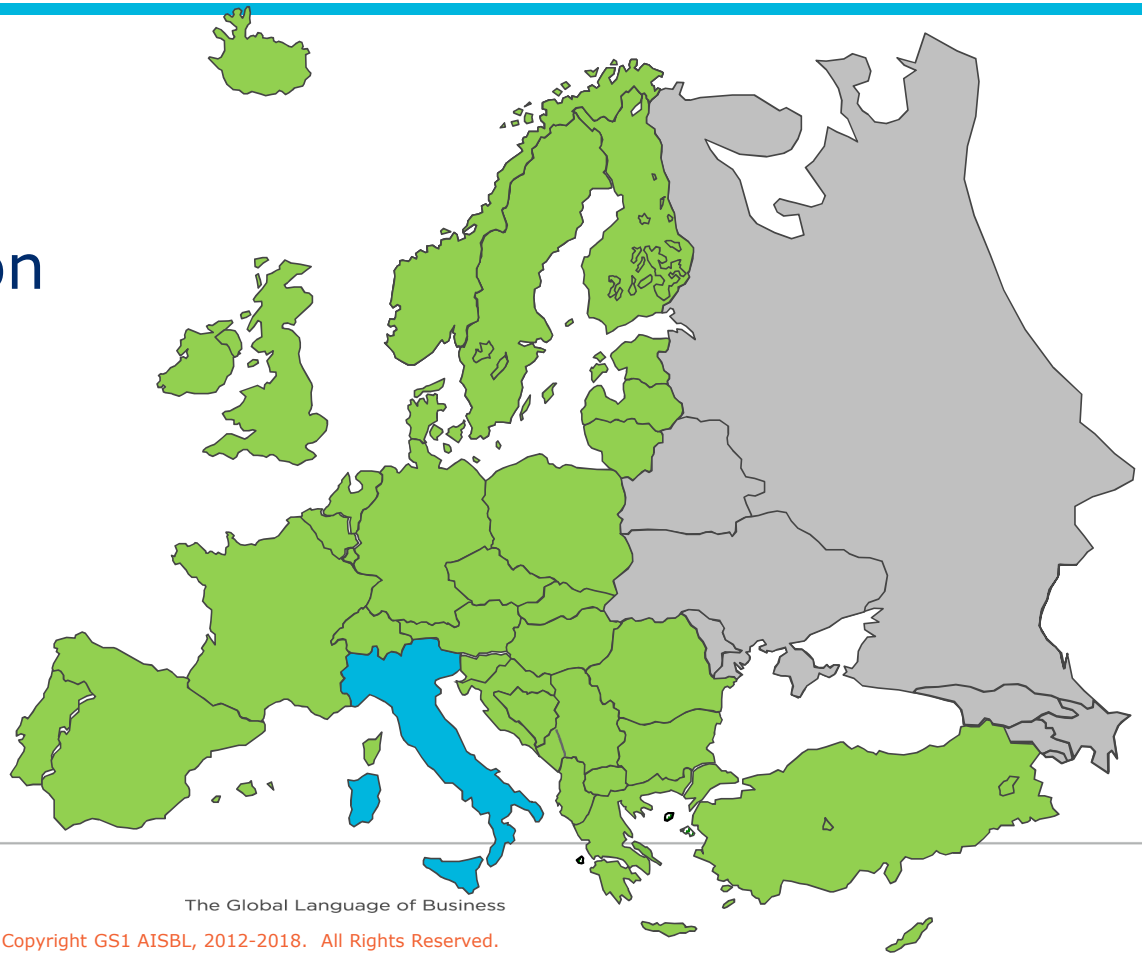
+ minimum requirements on quality of randomisation

Example:

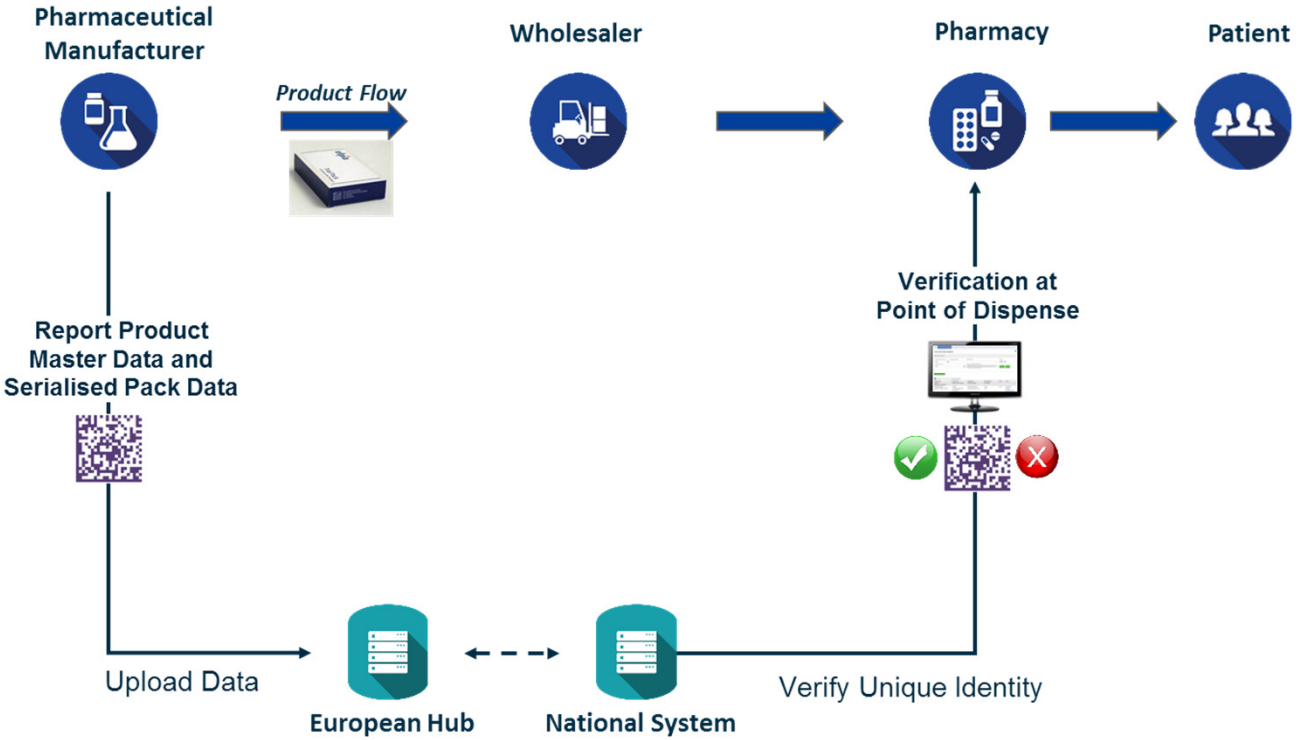
GTIN:	(01) 07046261398572
Batch:	(10) TEST5632
Expiry:	(17) 130331
S/N:	(21) 19067811811

Specifications provided in EFPIA's:
"European Pack Coding Guidelines"

The move towards harmonisation and GS1 standards in Europe



EU FMD representation - Authentication



England – NHS

Objectives:

- Deliver efficiency and productivity gains
- Improve data, information and transparency
- Re-think clinical engagement in procurement
- Improve trust capabilities in procurement

Actions:

- **Mandate through contracts GS1 standards GTIN, GLN and GDSN – inclusion in tenders**
- **Six large NHS trusts as "demonstrator sites"**
- Standards for eProcurement
- Standards for datasets/classification
- Strong implementation support

In the rest of the world - traceability

"Traceability is the ability to **track forward** the movement through specified stage(s) of the extended supply chain and **trace backward** the history, application or location of that which is under consideration".

USA – 2015, 2017, 2023
Drug Supply Chain Security Act (DSCSA)

Scope: Pharmaceuticals (prescription drugs)

Purpose: Traceability, combat counterfeit

Requirements :

- Packaging level: saleable units and homogeneous cases
- Data elements: NTIN, Expiry date, lot/batch number, serial number
- Data carrier: 2D DataMatrix
- Deadlines - Full track & trace after 10 years (2023)
  - First phase lot based (2015) – delayed to 1 March 2016 for dispensers
  - **Serialisation (SNI) after four years (Nov. 2017)**

Traceability Model:

First lot based traceability, full track & trace in 10 years, different guidance documents published

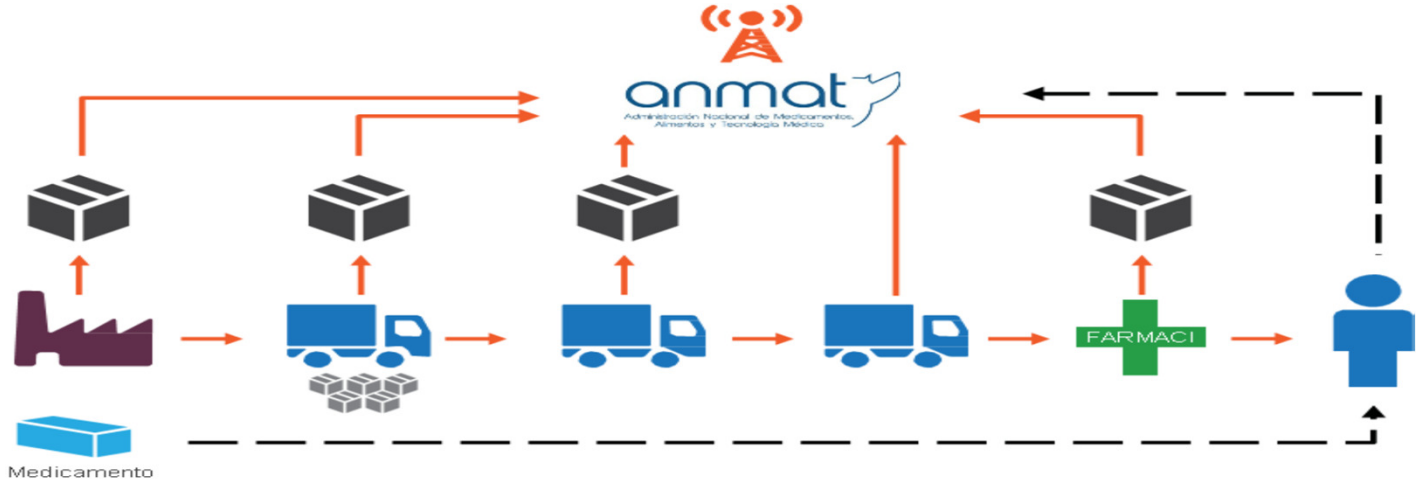
US FDA points to EPCIS as one of possible way for exchange of traceability data in their draft guidance, industry alignment around that, several guidance documents published

GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability (R1.2)

http://www.gs1us.org/industries/healthcare/gs1-healthcare-us-initiative/dscsa/implementation-guide

Argentina - ANMAT

- Individual and unambiguous identification of each pharmaceutical product to allow its traceability all along the distribution chain. Each time the product moves to a different location, the shipping event data is reported real-time to the ANMAT central repository.
- Products are identified using a GTIN and location using a GLN.
- Phased implementation (2011-2016) by product category based on risk and value.



http://www.gs1.org/docs/healthcare/13_GS1_HC_RefBook2013_All.pdf

Other LA countries also working on drug traceability

Brazil
Pilot on-going
Full implementation after 3 years
Guideline published

Peru
under dev.

Columbia
Pilot done
Draft resolution released

Mexico
Draft regulation

Chile
under dev.

Turkey – 2010
Track & Trace

Status: Regulation
Scope: Pharmaceuticals
Requirements as applicable:

- Packaging level: Secondary packaging
- Data elements: GTIN, Expiration Date - AI (17), Serial Number - AI (21), Batch/Lot Number - AI (10)
- Data carrier: DataMatrix
- Deadlines: June / 2010

Data Submission Portal: Maintained by regulatory authorities
Traceability Model: Traceability (Track & Trace)

Turkey – ensuring a safe and reliable supply chain

- The main challenge in Turkey was to ensure and guarantee the reliable supply of drugs to patients
- The solution is traceability, which is defined as full, end to end, actionable visibility of finished pharmaceuticals in healthcare globally, from point of production to point of use.
- Results of Turkey's efforts have been tremendous, and the nation is seeing savings of 1 billion US dollars annually.
- For more information: http://www.gs1.org/sites/default/files/docs/healthcare/gs1_healthcare_reference_book_2015-2016.pdf

High level of activities in the MENA region

Egypt
serialisation
reporting: guideline to be published, uses EPCIS

Jordan
Change from1D to 2D Barcoding and serialisation

Oman
serialisation
purchasing requirements

Qatar
purchasing requirements
barcoding

Saudi-Arabia
Barcoding and serialization, reporting: pilot took place

UAE - DHA
purchasing requirements
Barcoding and master data

Bahrain
uploading of master data
barcoding and serialization

Lebanon
Regulation in Dec. 2017
Pilot in 2018
Implementation from 2019

GCC – Drug barcoding specifications

Status: Drug barcoding specifications version 0.1 (Sept 2018)
Scope: Pharmaceuticals

Requirements as applicable:

- Packaging level: secondary packaging
- Data elements: GTIN, Batch/Lot Number, Expiration Date, Serial Number
- Data carrier: DataMatrix
- Aggregation: recommended for packaging stages of the supply chain

Timeframe: Recommendation to the GCC countries

Developments in Africa

South Africa
Draft barcoding regulation with serialisation

Rwanda
Discussions on traceability

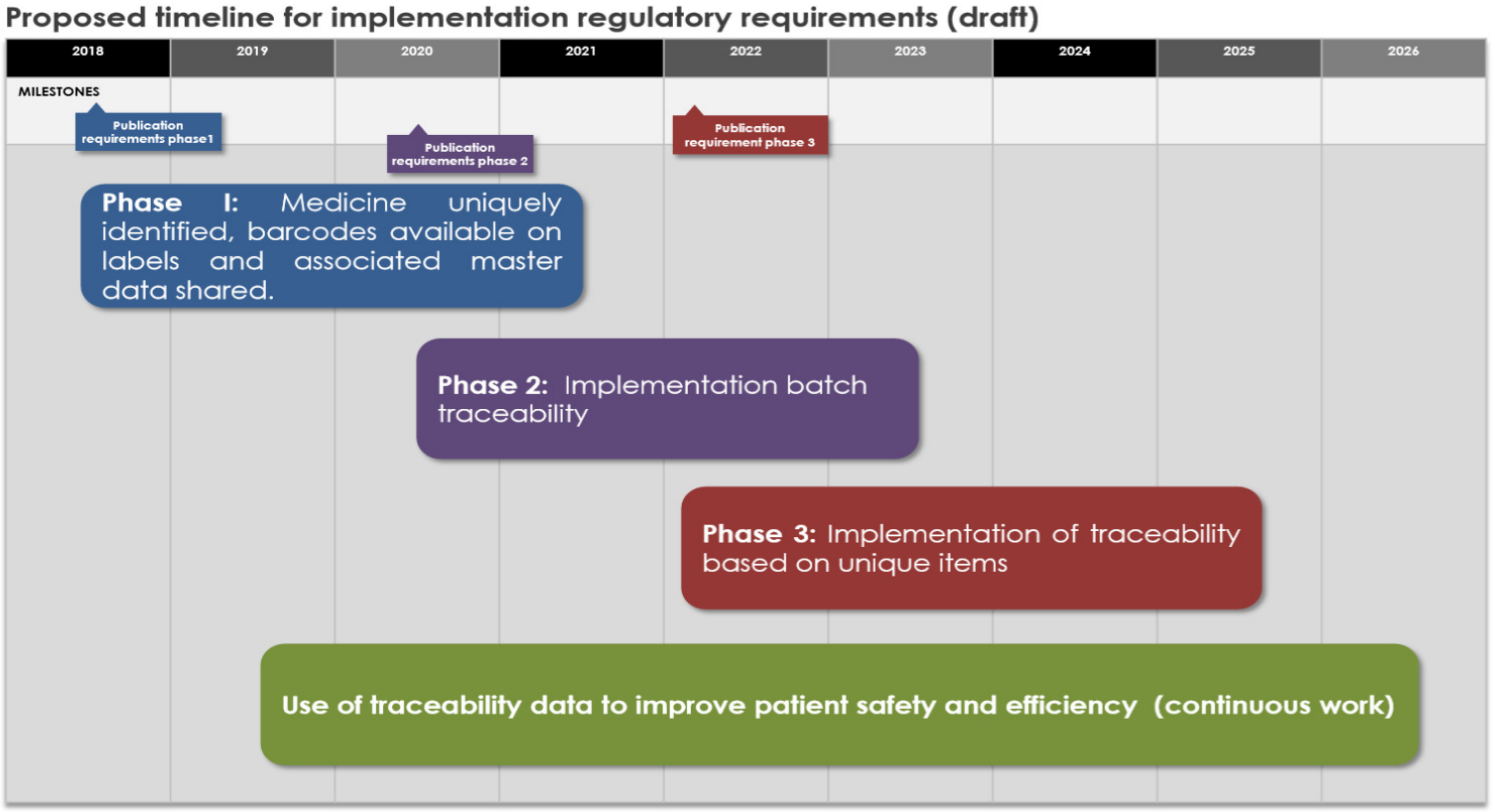
Ethiopia
See next slide

Nigeria
Discussions on traceability

Angola
Discussions on traceability

OCEAC
Conference on PH traceability

Ethiopia – 2018 / 2025



Source: EFMHACA

China – new system under development

- **CFDA suspended the drug monitoring system in Feb. 2016.**
- On 20 July 2016, the **new GSP regulation** has been released, confirming the transition for a "drug electronic supervision system" to a "drug traceability system" and allowing the use of GS1 standards.
- Beijing Workshop in December 2017 resulted in strong support and alignment around GS1 standards
- 2018: launch of a pilot project in which global and local manufacturers will showcase traceability with GS1 standards from manufacturer to wholesaler (Sinopharm) and retail pharmacies and hospitals. This is largely driven by PSM (Partnership for Safe Medicines), RDPAC (Local association of research-based manufacturers) and CPIA.
- August 24th 2018: CNDA published a drug traceability system guide
- November 2018: new guidance on drug traceability system implementation from China National Medical Products Administration (in Chinese): www.nmpa.gov.cn/WS04/CL2196/331501.html
- **All drugs will be in the traceability system in 2022**

And also in Asia Pacific

India
For export :barcoding since 2013
reporting: on hold
For domestic market:
ongoing discussions on right approach and technology

South Korea
Barcoding and serialization plus reporting

Russia
Serialisation, central database, pilot

Indonesia
Draft regulation

Pakistan
Federal Regulation adopted
Barcoding and serialisation

Malaysia
Full track & trace under development

Kazakhstan
Serialisation pilot

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