Regulatory environment
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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

= country accepts GTIN

= no input available
Serialisation of pharmaceuticals

- country developing requirement or requiring serial number

Bahrain
GS1 DataMatrix on pharmaceuticals

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

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In the EU - the Falsified Medicine Directive

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

EU Commission Delegated Regulation 2016/161

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

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

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**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:

<table>
<thead>
<tr>
<th>GTIN</th>
<th>Batch</th>
<th>Expiry</th>
<th>S/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>(01) 07046261398572</td>
<td>(10) TEST5632</td>
<td>(17) 130331</td>
<td>(21) 19067811811</td>
</tr>
</tbody>
</table>

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.
High level of activities in the MENA region

**Egypt**
serialisation reporting: guideline to be published, uses EPCIS

**Jordan**
Change from 1D 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

Ethiopia
See next slide

Angola
Discussions on traceability

Rwanda
Discussions on traceability

Nigeria
Discussions on traceability

OCEAC
Conference on PH traceability
Ethiopia – 2018 / 2025

Proposed timeline for implementation regulatory requirements (draft)

Phase 1: Medicine uniquely identified, barcodes available on labels and associated master data shared.

Phase 2: Implementation batch traceability

Phase 3: Implementation of traceability based on unique items

Use of traceability data to improve patient safety and efficiency (continuous work)

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
- **All drugs will be in the traceability system in 2022**
# And also in Asia Pacific

<table>
<thead>
<tr>
<th>Country</th>
<th>Status and Initiative</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>India</strong></td>
<td>For export: barcoding since 2013; reporting: on hold; For domestic market: ongoing discussions on right approach and technology</td>
</tr>
<tr>
<td><strong>Indonesia</strong></td>
<td>Draft regulation</td>
</tr>
<tr>
<td><strong>Pakistan</strong></td>
<td>Federal Regulation adopted Barcoding and serialisation</td>
</tr>
<tr>
<td><strong>South Korea</strong></td>
<td>Barcoding and serialization plus reporting</td>
</tr>
<tr>
<td><strong>Malaysia</strong></td>
<td>Full track &amp; trace under development</td>
</tr>
<tr>
<td><strong>Russia</strong></td>
<td>Serialisation, central database, pilot</td>
</tr>
<tr>
<td><strong>Kazakhstan</strong></td>
<td>Serialisation pilot</td>
</tr>
</tbody>
</table>
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