$\mathcal{M}(\mathcal{R})$ LEGISLATION MAP 2020

BRAZIL

Track-and-Trace with Aggregation

In Brazil, the national agency ANVISA

implemented the following Law No.

establishes that the pharmaceutical

detail the contents within the law, the

'Instrução Normativa' is expected to be

2D Data Matrix encoded with GTIN,

Mandatory from April 28, 2022

ANVISA drug number, S/N, lot number

be available in human-readable format.

and expiration date. This data should also

Serialization Requirements

released in 2020.

13,410 of December 28, 2016, together

industry has until April 2022 to implement

traceability for prescription drugs. To further

with RDC 319 of November 12, 2019,

USA

Track-and-Trace with Aggregation

With traceability regulations already in place, the United States is now regulating serialization. As of November 24, 2017, the Drug Supply Chain Security Act (DSCSA) requires that manufacturers mark packaged with a product identifier, serial number. lot number and expiration date. By 2023, all manufacturers will also have to implement an interoperable, aggregation-ready Track-and-Trace system.

Serialization Requirements

2D Data Matrix encoded with Standardized Numerical Identifier (SNI), lot number and expiration date.

COLOMBIA

Track-and-Trace with Aggregation - TBC

Colombian authorities, in partnership with industry associations, initiated a national plan for medicine traceability at the end of 2017. A pilot project was initiated using RFID technology with mitigated results. Draft regulations have been discussed with local associations.

Serialization Requirements

Identificador Único de Medicamento (IUM) assigned by INVIMA.

ARGENTINA

Track-and-Trace with Aggregation

New labeling policies were introduced in 2015. Manufacturers now serialize every saleable unit in accordance with GS1 standards for both the serial number and harcode format

Serialization Requirements

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SOUTH AFRICA

Track-and-Trace and Serialization

In 2018, the South African government replaced EAN-13 barcodes on tertiary packaging (e.g., shipping cases) with GTIN-14 Data Matrix codes containing GTIN. batch/lot and expiration date. South Africa plans to phase in and then fully implement serialization of secondary and tertiary packaging by 2022 to mitigate the counterfeiting of medicines.

System Requirements

GTIN (01), Batch/Lot (10), Expiration Date (17), Serial Number (21) Batch coding: September 1, 2020 Serialization June 30, 2022 Aggregation: June 30, 2022

EUROPEAN UNION

EU FMD – Verification and Decommissioning

As of February 2019, all manufacturers and dispensers are required to comply with the European Union's Falsified Medicines Directive (EU FMD), which requires all prescription medications destined for sale in the EU to have a unique product identifier and an anti-tampering feature, and to be verified and decommissioned before being dispensed to patients.

Serialization Requirements

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SAUDI ARABIA

Track-and-Trace with Aggregation

in 2015. Since March 12, 2017, all

domestically produced and imported

pharmaceutical products intended for

human use are required to carry a 2D GS1

Data Matrix barcode, Effective 7 February

importers, distributors, dispensers) must

Track-and-Trace system (DTTS) and report

GS1 Data Matrix encoded with GTIN, S/N,

2019, all stakeholders (manufacturers,

register with the Saudi pharmaceutical

all transactions involving drugs packs.

Serialization Requirements

lot number and expiration date.

New labeling practices became mandatory

GS1 Data Matrix encoded with GTIN or NTIN, S/N, lot number and expiration date.

RUSSIA

Track-and-Trace with Aggregation

Full Track-and-Trace system with a

secondary to tertiary is mandatory.

Serialization Requirements

importation events. Aggregation from

Secondary packs: 2D GS1 Data Matrix

with with GTIN, serial number, expiration

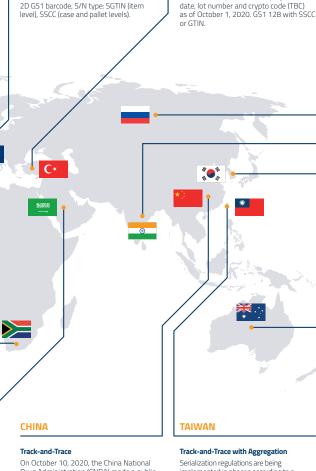
national database including pre-

Track-and-Trace with Aggregation

Turkey has one of the longest-standing Track-and-Trace systems in the world. All pharmaceutical products are subject to serialization and government reporting requirements, including aggregation at the unit level.

Serialization Requirements

TURKEY



- implemented in phases according to a detailed schedule set by the Taiwan Food and Drug Administration (TFDA): January 1, 2018: GTIN/Batch, expiration
- date on secondary and tertiary packages January 1, 2019: Add S/N
- January 1, 2020: Add traceability platform login and aggregation

January 1, 2021: Add API S/N

Current Serialization Requirements

2D GS1 Data Matrix barcode.

INDIA

Track-and-Trace with Aggregation

India's Directorate General of Foreign Trade (DGFT) announced on November 1, 2018, that it would postpone the requirements for aggregation and for data submission to the Drugs Authentication and Verification Application (DAVA) portal to July 1, 2019.

Primary Pack Serialization

Still exempted from labeling with a 2D barcode encoded with a GTIN 14, batch number, expiration date and serial number; however, the primary level must have this information printed in human-readable format

Primary Pack Serialization on Mono Carton

(contains only one primary pack) Optional until further notice.

Aggregation Requirements

Secondary to tertiary only; primary to secondary not required until further notice.

Data Upload

As of October 1, 2015, manufacturers must maintain the data in the parentchild relationship for all three levels of packaging as well as their movements along the supply chain. Manufacturers must upload the data to the government's central portal. All export consignments should have barcodes (on secondary and tertiary packs) and data must be uploaded to the portal.

SOUTH KOREA

Track-and-Trace

As of January 1, 2015, serialization had to be implemented at 50%. In 2016, serialization requirements in South Korea covered 100% of pharmaceutical drug product manufacturers. On July 1, 2017, reporting enforcement was introduced for wholesale distributors.

Serialization Requirements

GS1 Data Matrix or GS1 - 128 linear barcodes encoded with GTIN, S/N, lot number and expiration date

AUSTRALIA

Track-and-Trace and Serialization

A new barcode identification system for all medicines in Australia was set up in 2016. In September 2016, new regulations were issued for the Australian market, requiring labeling developed for all medicines, but these regulations do not apply to serialization, which will become mandatory for all supply chain items on September 1, 2020.

Serialization Requirements

GTIN (AI 01), Expiration Date (AI 17), Batch/Lot Number (AI 10)

No Aggregation requirements

and collect traceability information throughout the entire process, for products such as the national drug centralized procurement, narcotic drugs psychotropic drugs, and blood products.

System Requirements

N/A

Drug Administration (CNDA) made a public announcement confirming the deadline 31st December 2020, for the drug market authorization holders to complete the construction of the traceability system