WORLD LEGISLATION MAP 2020

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

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BRAZIL

Track-and-Trace with Aggregation

In Brazil, the national agency ANVISA implemented the following Law No. 13,410 of December 28, 2016, together with RDC 319 of November 12, 2019, establishes that the pharmaceutical industry has until April 2022 to implement traceability for prescription drugs. To further detail the contents within the law, the 'Instrução Normativa' is expected to be released in 2020.

Serialization Requirements

2D Data Matrix encoded with GTIN, ANVISA drug number, S/N, lot number and expiration date. This data should also be available in human-readable format. Mandatory from April 28, 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

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

TURKEY

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

2D GS1 barcode, S/N type: SGTIN (item level), SSCC (case and pallet levels).

RUSSIA

Track-and-Trace with Aggregation

Full Track-and-Trace system with a national database including pre-importation events. Aggregation from secondary to tertiary is mandatory.

Serialization Requirements

Secondary packs: 2D GS1 Data Matrix with with GTIN, serial number, expiration date, lot number and crypto code (TBC) as of October 1, 2020. GS1 128 with SSCC or GTIN.

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 parent-child 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.

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

SAUDI ARABIA

Track-and-Trace with Aggregation

New labeling practices became mandatory 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 2019, all stakeholders (manufacturers, importers, distributors, dispensers) must register with the Saudi pharmaceutical Track-and-Trace system (DTTS) and report all transactions involving drugs packs.

Serialization Requirements

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

CHINA

Track-and-Trace

On October 10, 2020, the China National 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 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

TAIWAN

Track-and-Trace with Aggregation

Serialization regulations are being 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.

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

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