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

Turkey has one of the longest-standing 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. As of February 2019, all 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 meta data must be uploaded to the portal.

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

2D Data Matrix encoded with GTIN, ANVISA drug number, S/N, lot number and expiration date. By 2023, all manufacturers will also have to implement an interoperable, aggregation-ready Track-and-Trace system.

Serialization Requirements

Identifier Único de Medicamento (IUM) assigned by INVIMA.

EUROPEAN UNION

Track-and-Trace with Aggregation

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Serialization Requirements

GS1 Data Matrix encoded with 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

Secondary packs: 2D GS1 Data Matrix with GS1, serial number, expiration date, lot number and crypto code (TBC) as of October 1, 2020. GS1 128 with S55C or GTIN.

INDIA

Primary Pack Serialization

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

Serialization Requirements

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

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 salable unit in accordance with GS1 standards for both the serial number and barcode format.

Serialization Requirements

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

SAUDI ARABIA

Track-and-Trace with Aggregation

No Aggregation requirements

Serialization Requirements

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