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Brazil Serialization Requirements: Getting Started



In 2019 Brazil began the commercial implementation phase of its national drug control system. When completed in 2022, the Sistema Nacional de Controle de Medicamentos (SNCM) will be used by companies to transmit data about product movement and disposition to the Brazilian Health Regulatory Agency (ANVISA). This visual guide to serialization and data exchange requirements gives companies producing medicines for the Brazilian market a quick understanding of the basics of Brazil regulations. Learn more about:

- Timelines
- Which products are included
- Regulatory and serialization requirements
- Government reporting

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BRAZIL SERIALIZATION REQUIREMENTS

Getting Started



A guide to serialization and trade partner data exchange requirements affecting companies producing medicines for the Brazilian market.

On December 28, 2016, Brazil published Federal Law No. 13.410, which established serialization and traceability requirements for the country and officially amended the original Federal Law No. 11.903. In 2019, under this new law, Brazil began the commercial implementation phase of its national drug control system. When completed in 2022, the Sistema Nacional de Controle de Medicamentos (SNCM) will be used by companies to transmit data about product movement and disposition to the Brazilian Health Regulatory Agency (ANVISA).

NATIONAL DRUG CONTROL SYSTEM TIMELINE:



Since the passage of its serialization and reporting regulations in 2016, ANVISA has conducted testing and evaluation of the reporting system with a limited number of companies. The final implementation phase started in 2019, with a firm end date of May 2022.

WHICH PRODUCTS ARE INCLUDED?

All drug products subject to ANVISA registration are subject to the requirements:



REGULATORY REQUIREMENTS



SERIALIZATION REQUIREMENTS

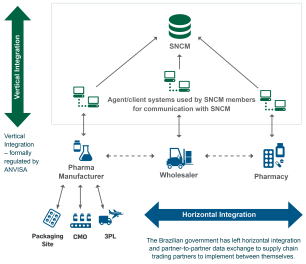
A Brazilian IUM is applied to each unit of product in a 2D data matrix (must be in this order)

1. GTIN - 14 digits
2. ANVISA Registry Number - 13 digits
3. SN <=20 digits (alphanumeric)
4. Expiry
5. Lot

Unit-level serial numbers must be unique and random

Any transport container with one or more medicines must also be serialized and aggregated

REPORTING AND COMPLIANCE CHOREOGRAPHY



TRACEABILITY AND REPORTING

Event Types:



Time parameters for reporting events to the central system



All members of the supply chain (manufacturer, wholesale distributors, pharmacies) must:



- Capture, store and transmit/report movements and events of drug products under their custody
- Store movement and event data for one (1) year after expiration date of drug product
- Use XML as the data exchange format for reporting purposes

The Most Proven Track and Trace Solution Worldwide

TraceLink has helped more than 1,200 customers across the supply chain commission more than 5.4 billion serial numbers and achieve compliance in the U.S., EU, and other markets around the world.



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