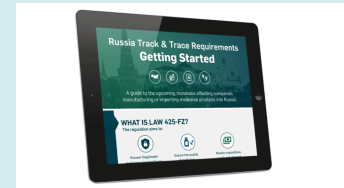




RESOURCES

Home
Resources
Resource Center

Russia Track and Trace Requirements: Getting Started



If your company manufactures, ships, or distributes products for the Russian market, you may be struggling to understand the upcoming track and trace requirements: the regulation introduces the most complex and comprehensive serialization and reporting mandates the industry has seen to date.

Start your planning with this overview infographic, covering the regulation, its scope, and who it affects, including:

- The deadlines for different products.
- The events that must be reported on.
- What companies will need to do in order to comply.

Russia Track & Trace Requirements Getting Started

A guide to the upcoming mandates affecting companies manufacturing or importing medicinal products into Russia.

WHAT IS LAW 425-FZ?

The regulation aims to:



Prevent illegitimate medicines entering Russia



Ensure the quality of medicines



Monitor expenditure, supply and demand

KEY DATES & DEADLINES

Based on the most recent updates to the law, these deadlines are now in effect:



December 31, 2019

Compliance deadline for the T-HCN/Novologes drugs.



July 1, 2020

Compliance deadline for all medicines being manufactured in Russia or imported into Russia.



CRITICAL DRUG CATEGORIES

Certain categories of drugs deemed as being critical to specific treatments or at risk of withdrawal shortages are subject to serialization, reporting, and verification requirements as of December 31, 2019.

- T-HCN/Novologes drugs: treatment for rare medical conditions with expensive treatments, such as hemophilia, cystic fibrosis, sickle cell disease, Gaucher disease, multiple sclerosis, and immunosuppressive therapy for organ transplant patients.

WHO DOES IT AFFECT?

Everyone in the pharmaceutical supply chain is involved:



Pharmaceutical Manufacturers



Importer



Distributor



Dispenser



SERIALIZE



VERIFY



VERIFY



VERIFY



AGGREGATE



AGGREGATE



REPORT



REPORT



REPORT



REPORT



REPORT



REPORT



REPORT



REPORT



REPORT



REPORT



REPORT



REPORT



REPORT



REPORT



REPORT



REPORT



REPORT



REPORT



REPORT



REPORT

WHAT INFORMATION IS REQUIRED?

Pharmaceutical manufacturers must apply a serialized barcode to the packaging of their products at the secondary (retailer unit) and tertiary (case) levels. This is a 2D Data Matrix barcode and must include a encrypted data element:



- Product code / GTIN
- Serial number
- Crypto key
- Crypto code



What is encryption?
Encryption scrambles data using an algorithm to cipher. A key string of data, called a cryptographic key, acts as a password to protect the file. The file key is used to decrypt (unscramble) the data.



A NOTE ON AGGREGATION

The Russian regulation requires products to be aggregated, and that changes to the parent-child relationships be tracked through the supply chain. For example, if a case is opened up and sent to another country, the retail aggregation events and new relationships must be reported to the government.

WHAT KIND OF EVENTS NEED TO BE TRACKED? AND HOW MANY?

The Russian Law requires the tracking of several dozen events which vary based on the manufacturer's business operations.

Categories of Events & Messages

Commission / Decommission

Aggregation / Disaggregation

Quality Shipment / QC Release

Shipment / Receipt / Transfer

Import / Export

Withdrawal / Recall

Destruction

Processing / Query Results

Notifications



Russian Regulatory System

UP TO 35

EVENTS

Per product manufactured outside of Russia

WHAT CORE CAPABILITIES ARE REQUIRED?

In order to meet Russian regulations, a compliance solution will need to incorporate company-specific business logic and complex reporting functionality.

Core Serialization

Master Data Management

Serial Number Generation

Serial Number Allocation

Event Repository

Russian Compliance

Business Logic for Events

Regulatory Document Creation

Electronic Document Signature

Send & Receive Documents from Russian Authority

Document Archive

TraceLink is already helping more than 600 customers across the supply chain achieve compliance in the U.S., EU, and other markets around the world.



Enabling compliance solutions implemented with workflow triggers and automated data integration for seamless compliance monitoring in conjunction with regulatory partners.

10.2 Billion

Serial numbers commissioned in 2019



Compliance solutions implemented across more regulated markets than any other provider.



Experts dedicated to following developments in Russian track and trace requirements.



5 offices in Europe, Asia, and the U.S., offering local support and expertise in 20 languages.

Russia PharmaceuticalsRussia

Contact Us

Contact Us

Contact Us