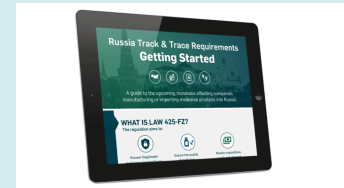




RESOURCES

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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

Product at secondary & tertiary packaging levels



VERIFY

Receipt



VERIFY

Receipt



VERIFY

Receipt



VERIFY

Receipt



AGGREGATE

Document secondary & tertiary packaging



AGGREGATE

Document primary & secondary packaging



REPORT

Product Report

Product Data

Chain Data



REPORT

Sampling



REPORT

Product Report



REPORT

Product Report

Receipt

Receipt

Product Report

Product Data

Chain Data

Product Report

Product Data

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WHICH PRODUCTS ARE INCLUDED?

All drugs manufactured or imported into Russia are subject to the requirements:



Prescription drug products



Over-the-counter (OTC) products

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:



1. Product code / GTIN
2. Serial number
3. Crypto key
4. Crypto code



What is encryption?
Encryption encodes data using an algorithm to cipher. A key string of data, called a cryptographic key, is used to encrypt the data. The key is used to decrypt 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 setting, the retail aggregation event and new relationship 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.



Proven compliance solutions implemented with workflow triggers and automated data integration for seamless compliance monitoring in conjunction with 30+ data sources.

10.2 Billion

Serial numbers commissioned in 2019



Compliance solutions implemented for more regulated pharmaceuticals 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

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