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 7 HCN/Nosologies 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 widespread shortages are subject to serialization, reporting, and verification requirements as of December 31, 2019:

- **7 HCN/Nosologies drugs:** treatment for rare medical conditions with expensive treatments, such as haemophilia, cystic fibrosis, pituitary dwarfism, Gaucher disease, multiple sclerosis, and immunosuppressive therapy for organ transplant patients.

WHO DOES IT AFFECT?

Everyone in the pharmaceutical supply chain is involved:

Pharmaceutical Manufacturer/MAH*	Importer	3PL	Distributor	Dispenser
SERIALIZE Product at secondary & tertiary packaging levels	**VERIFY**	**VERIFY** Accept order	**VERIFY** Accept order	**VERIFY** Accept order
AGGREGATE Document parent-child relationships		**AGGREGATE** Document parent-child relationships		
REPORT • Foreign shipment • Product data • Pack data	**REPORT** • Sampling	**REPORT** • Move destruction • Withdrawal	**REPORT** • Move order	**REPORT** • Retail sale

Note: CMOs, distributors or dispensers could be a marketing authorization holder (MAH) for one or more products.

REPORTING AND NOTIFICATIONS

Companies report to a central system via electronic documents in XML format. Compliance reporting will be time bound and must be submitted in the correct sequence: a company can't submit its report until the previous company in the supply chain has submitted its report.

In addition to submitting reports to a central regulatory system, Russian regulations also require that companies be able to manage upstream and downstream notifications between trade partners triggered by a wide range of compliance events.

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 (saleable unit) and tertiary (case) levels. This is a 2D Data Matrix barcode and must include 4 encrypted data elements:

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

What is encryption?
Encryption scrambles data using an algorithm or cipher. A long string of data, called a cryptographic key, works like a password to protect the file. The only way to read it is by using the key to decrypt (unscramble) the data.

A NOTE ON AGGREGATION

The Russian regulation will require 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 a unit removed for sampling, the related 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.

Manufacturer/MAH → Russia Regulatory System

Categories of Events & Messages

- Commission / Decommission
- Aggregation / Disaggregation
- Quality Shipment / QC Release
- Shipment / Receipt / Transfer
- Import / Export
- Withdrawal / Recall
- Destruction
- Processing / Query Results
- Notifications

UP TO 35 EVENTS
For 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

Russia Compliance

- Business Logic for Events
- Regulatory Document Creation
- Electronic Document Signature
- Send & Receive Documents from Russia Authority
- Document Archive

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NETWORK FOR GREATER GOOD

The Most Proven Track and Trace Solution Worldwide

TraceLink is already helping more than 800 customers across the supply chain achieve compliance in the U.S., EU, and other markets around the world.

Existing compliance platform instrumented with workflow triggers and business logic to accelerate the development of a Russia Compliance module in conjunction with 20 pharma customers.

10.2 Billion
Serial numbers commissioned *(as of April 2020)*

Country-specific compliance software for more regulated geographies than any other provider.

Experts dedicated to following developments to Russia track and trace requirements

5 offices in Europe, Asia, and the U.S., offering local support and expertise in 29 languages.