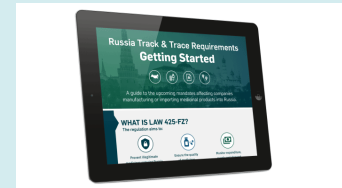




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Russia Track and Trace Requirements: Getting Started



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:



CRITICAL DRUG CATEGORIES
Critical 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.

- 71 HCN/Novologes drugs: treatment for rare medical conditions with expensive treatments, such as chemotherapy, cancer therapy, diabetes therapies, Crohn's disease, multiple sclerosis, and immunosuppressive therapy for organ transplant patients.

WHO DOES IT AFFECT?

Everyone in the pharmaceutical supply chain is involved:



REPORTING AND NOTIFICATIONS
Companies report to a central system via electronic documents in XML format. Compliance reporting will be time-based and must be submitted to the central system in compliance with the report until the previous company in the supply chain has submitted its report. In addition to submitting reports to a central regulatory system, Russian regulators also require that companies be able to change system and document verification between master 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 (retailable unit) and tertiary (case) levels. This is a 2D Data Matrix barcode and must include encrypted data elements:

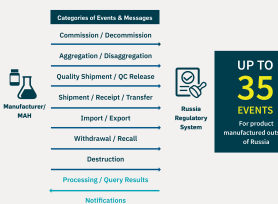
- Product code / GTIN
- Serial number
- Crypto key
- Crypto code

What is encryption?
Encryption scrambles data using an algorithm to create a key string of data, which a cryptographic key, which is a password to protect the file. The data key is used to by using the key to decrypt unscrambled 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 sent to another setting, 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.



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.



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- 100+ countries** covered for their regulated products (as of Jan 2020)
- 200+ employees** dedicated to helping pharmaceutical, biotech, food, and consumer products.
- 20 offices** in Europe, Asia, and the U.S., offering local support and expertise in 20 languages.

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