RESOURCES

Russia Update: 12 Nosologies Deadlines and Crypto Coding Confirmed



April 2020 Update: The current compliance deadline for all medicines manufactured in Russia or imported into Russia is July 1, 2020. As of December 31, 2019, medicines that fall under the government's HCN/7 Nosologies guidelines are expected to comply with the current serialization requirements, which comprise 4 elements: Product Code (GTIN), Serial Number, Crypto Key, and Crypto Code. Expiry Date and Batch Number are no longer required. See the latest Russia Regulatory Updates for news on Russia Track and Trace regulations.

Last week, the Russian government published two official declarations related to Federal Law No. 425-FZ and serialization, clarifying timelines for 12 Nosologies drugs and finalizing cryptographic coding. For companies that produce or distribute medicines within Russia, these deadlines and the confirmation of complex coding requirements underline the need to quickly finalize compliance plans.

12 Nosologies Medicines

Decree # 1577 was officially published on December 24, documenting the specifics

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for implementing the system of monitoring the movement of medicines for medical use. Certain key dates were highlighted, including:

- **July 1, 2019:** Companies/organizations with 12 Nosologies products will have to register with the government monitoring system and pass certain tests for the systems involved.
- **October 1, 2019:** All medicines in the 12 Nosologies list will have to be labeled/serialized. Further, all entities in the drug circulation system will have an obligation to report required operations and events related to these medicines to the government system.

Cryptographic Coding

On December 28, government order # 2963-p for the system of marking and traceability of goods was signed and published. This order finalized requirements—including cryptographic coding—for the products covered across multiple industries along with medicines. Cryptographic keys and codes were not part of the original Russian medicines marking regulations and were proposed as a new addition to the standard GTIN, serial number, and other product identifier data.

Several organizations and associations across the pharmaceutical industry pushed back on this new requirement. But, with the publication of this order, cryptographic requirements will be firmly required for medicines as part of the marking and reporting regulations, which begin to be phased in 2019.

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TraceLink's Russia Compliance application features the same proven core serialization, integration, and compliance functionality trusted by more than 1,000 manufacturers, distributors, and healthcare providers around the world. TraceLink’s Russia Compliance solution lets you manage up to 35 distinct serialization events, including commissioning/decommissioning, aggregation, and destruction. Contact us to learn more.

Every week, we post an update of what's new in global compliance, along with a page of updates specific to Russian compliance. Check back for additional updates.

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