Industry Poll: Russia Requirements are Most Complex of Any Market

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.

Pharmaceutical manufacturers that do business in Russia know they'll have to comply with upcoming serialization and reporting requirements but according to results from our recent Understanding Russia Compliance Complexities and Preparation Timeline webinar, there is a significant lack of clarity around the deadlines and other specifics.

Over 140 attendees, representing close to 100 unique companies, gathered during the live webinar to understand more about Russia compliance requirements. Here are the top four poll findings on the requirements, readiness, and more:

8 in 10 companies see Russia as having the most complex regulations.

82% of the respondents feel that Russia compliance regulations are more complex

than they've seen for any other country, and only 2% feel that Russia compliance has the same or less complexity. In addition, the remaining respondents stated that they haven't yet looked into the requirements, so are unsure of the level of complexity.

4 of 10 respondents struggle to fully understand the requirements.

When asked what they find the most challenging about the Russia regulations, the responses were mixed:

- 42% of respondents stated that it's the complexity of the requirements.
- 28% feel they may not be able to track the several dozen required categories of events and messages.
- 17% are concerned with upgrading their current IT systems or installing new systems.
- 6% don't understand whether intermediate deadlines apply to their organization.
- 5% will be challenged with managing the changes in their day-to-day operations.

4 of 10 companies don't know if they're affected by early deadlines.

Companies that manufacture drugs on the 12 Nosologies list have early compliance deadlines in July and October of 2019. There will also be an earlier deadline for drugs on the overall Vital and Essentials Drug (VED) list, but that date has yet to be disclosed by the Russian government.

When asked, close to 46% of respondents said they don’t know if the drug they manufacture is on the 12 Nosologies or VED lists. 4% of the respondents do manufacture products on the 12 Nosologies list, while 17% manufacture one on the VED list. Close to 33% of respondents stated that they do not have a drug on either list.

6 of 10 respondents aren't ready to comply with Russia requirements.

Attendees overwhelmingly indicated that they haven't started preparing for Russia compliance. In fact, 60% said they either are unsure what to do for compliance or are still investigating their options, but haven't started preparation. 35% of respondents have started preparations and will work with a solution partner, while 5% are preparing to use internal resources for compliance.

If you are still planning for Russia compliance, watch the on-demand webinar to hear about the requirements, get answers to your peers' top questions, and understand how to manage the new requirements.

Ready to get started?

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.

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