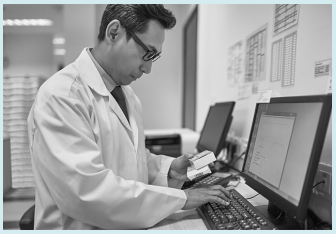
EAEU and Uzbekistan Track-and-Trace Regulatory Update: An Interview with TraceLink's Pavel Lotkov



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Pavel Lotkov

For pharmaceutical manufacturers, the key to ensuring compliance as more countries require track and trace or update existing regulations is using a single platform capable of quickly responding to new requirements. TraceLink is that platform. For example, TraceLink continuously monitors new and emerging track-and-trace regulations in the Eurasian Economic Union (EAEU) and Uzbekistan region to determine the best way to extend the TraceLink Global Compliance platform to accommodate them. TraceLink also established the **TraceLink EAEU+Uzbekistan Innovation Forum**, where customers work together to understand regulations, share experiences, and solve problems.

In this interview, Pavel Lotkov, an EAEU and Uzbekistan regulatory compliance expert and Customer Success Director for Track-and-Trace Compliance at TraceLink, provides an update on emerging serialization and track-and-trace regulations in Uzbekistan and the EAEU, which includes Russia, Kazakhstan,

Kyrgyzstan, Belarus, and Armenia. He also explains how TraceLink works with customers, governments, and regulatory system operators to help pharmaceutical manufacturers ensure continuous compliance across multiple regions, with a commitment to providing support for new countries in the future.

What do pharmaceutical manufacturers need to know about the development of serialization and track-and-trace regulations in the EAEU region and Uzbekistan?

Pavel Lotkov: One thing that manufacturers need to be aware of is that this region produced the most complex serialization and traceability requirements in the world and the governments in these countries were unwavering in following through with the implementation of these compliance mandates. Hardly anyone believed that Russia's complex crypto code-based compliance mandate would get implemented as originally proposed, but it was, with additional complexities added throughout the implementation process. With its global view to compliance, TraceLink built the crypto capability as a standard component of the platform, anticipating other countries in this region would require it. All of the countries in the region but Kyrgyzstan require crypto codes.

What else can you tell us about serialization in the region?

Lotkov: Another important point is that serialization in this part of the world was first mandated for non-pharma products, such as alcohol, tobacco, appliances, milk products, bottled water, and clothes. As a result, the respective regulators and the government systems operators became experienced with the deployment of serialization and traceability requirements across whole industry segments. Yet, when it comes to pharma, they discovered newfound complexities, and what it is like having to deal with the GxP-conscious industry. When TraceLink starts working with government system operators, we bring forward a lot of the pharma-specific use cases and practices that the operators did not encounter when implementing non-pharma mandates.

Can you provide a summary of what is happening with new and emerging track-and-trace regulations in the EAEU and Uzbekistan?

Lotkov: All of the countries in the EAEU and Uzbekistan currently serialize other products, and in some cases, they also serialize pharmaceutical products. Russia has required serialization for pharmaceutical products since July 2020. Uzbekistan's mandate to serialize pharmaceutical products went into effect in September 2022 and they are in the process of adding new requirements for compliance reports and supply chain segments. TraceLink's commitment to continuous compliance ensures that TraceLink Global Compliance solutions will be updated before new regulations go into effect.

What is happening with track-and-trace requirements in Kazakhstan and Kyrgyzstan?

Lotkov: Kazakhstan's first phase of pharmaceutical serialization was supposed to go into effect in July 2022. It did launch after a brief delay with about 90 products requiring serialization and aggregation. Traceability requirements were officially delayed until July 2024 and will include the remaining 1,287 medicines. Kyrgyzstan started this year. Kyrgyzstan's requirements offer the most flexibility. For example, the country is allowing the importation of medicines that come in packs with artwork that is different from those registered with the government until the end of December 2025.

What about Belarus and Armenia?

Lotkov: The Belarus Ministry of Health announced in May 2023 that they are launching a pilot program for pharmaceuticals, and the country already has product marking requirements in place for over two dozen product groups. Armenia is currently running a pilot for the serialization of alcoholic drinks, while mandatory serialization for tobacco products started in March 2023. Armenia has not yet announced its intention to start serializing pharmaceuticals, but in my opinion, it's just a matter of time.

Country	Is serialization required?	Is aggregation required?	Is traceability reporting required?	Are crypto codes required?
Russia (Pharmaceuticals)	Yes	Yes	Yes	Yes
Uzbekistan (Pharmaceuticals)	Yes	Yes, up to the case level	Yes	Yes
Kazakhstan (Pharmaceuticals)	Yes	Yes	Yes	Yes
Kyrgyzstan (Pharmaceuticals)	Yes	No	Yes	No
Belarus (Pharmaceuticals)	Pilot announced			
Armenia (Pharmaceuticals)	To be determined			

Are there any key significant commonalities or differences in how the countries of the region approach compliance?

Lotkov: All countries currently have serialization requirements compliant with the GS1 industry standard, most with crypto codes as a part of the encoded information in the DataMatrix. All of them have traceability regulations of some sort, usually tied to the electronic invoicing process. For example, in the case of Russia's pharmaceutical compliance mandate, full traceability is already in place, and it is leveraged by the government to plan for shortages, get real-time data about product availability, obtain prices, and identify any diversions that may be happening.

What stands out to you about the Russian mandate?

Lotkov: In my opinion, the most intriguing aspect of the Russian pharmaceutical mandate is that the Manufacturing Authorization Holder has access to a wide range of information about their products as they travel through the supply chain. For example, the quantity of products held by each of the downstream entities all the way to the pharmacy or hospital level. The government also encourages consumers to partake in uncovering non-compliance by scanning their purchases using a mobile application to report suspect products. It remains to be seen if other

countries in the region will be adopting this approach in whole or partially. Despite the many similarities, when we dig into the regulatory aspects and technical specifications, we are sure to find significant differences, and they will remind us and our customers that we are, indeed, dealing with very different mandates.

What advice do you have for pharmaceutical manufacturers that want to ensure continuous compliance in the region as new traceability regulations go into effect?

Lotkov: It's always good to start early and partner with TraceLink by joining the TraceLink EAEU+Uzbekistan Innovation Forum as the new regulations are still evolving. As soon as a draft regulation is released, or a regulation is passed into law, TraceLink examines the regulation and the government system specifications closely to make sure that the documentation is complete, and that it does not have any glaring gaps or contradictions. Developing and pending regulations are always discussed at TraceLink Innovation Forums and feedback is included in our commentary back to regulatory agencies.

What are some of the challenges that come with ensuring continuous compliance?

Lotkov: There will always be situations where some regulations are open to interpretation or unclear. For these types of things, it's very important to align early on with our customers because there is a lot of planning that needs to happen in these early stages of implementation. By participating in the Innovation Forum, you can quickly identify gaps, risk areas, and the best plan of attack for meeting new regulation requirements together. Oftentimes, customers can also leverage our communication channels with government system operators when they get stuck in other processes that may not be strictly in TraceLink's scope, but still impact our customer's ability to make progress toward compliance.

What are TraceLink Special Interest Groups and how do they help

customers stay informed about emerging regulations in the EAEU and Uzbekistan?

Lotkov: At TraceLink, we have multiple Special Interest Groups and Innovation Forums to provide coverage for nearly 40 compliance mandates that we are tracking all around the world. Customers should join the applicable forum or forums as soon as they subscribe to our Global Compliance solution. These Special Interest Groups and forums ensure that each customer's use case is covered in the groups. They are a key component of our TraceLink Community offering.

What happens in the Special Interest Groups?

Lotkov: In those groups, we share the news about the status of evolving regulations, technical specifications, and requirements. We also discuss and prioritize various use cases, share what we hear through many information channels about the readiness of the industry and its different supply chain segments, and highlight blockers or breakthroughs that we uncover in the process of compliance mandate monitoring. In our **EAEU+Uzbekistan forum**, we cover compliance mandates related to pharma, food supplements, and medical devices for Russia, Kyrgyzstan, Kazakhstan, Uzbekistan, and now Belarus. We are monitoring official documents, such as regulations and specifications. We also monitor "industry chatter" via a multitude of channels such as the industry Telegram and WhatsApp groups, as well as articles, and interactions with our customers' in-country affiliates, so we are very well grounded in reality.

How interactive are the TraceLink Community forums?

Lotkov: While we always have a packed agenda, the forums are designed to be very interactive. A customer may share a specific problem they are experiencing in working with government officials or an issue they encountered trying to register in the government system. Then several other customers immediately speak up, sharing how they were able to overcome these problems. As an added bonus,

sometimes government system operators are invited to our innovation forums to cover burning industry questions that are of relevance to our customers. The TraceLink forums are invaluable resources for our customers, the pharmaceutical industry, and regulatory agencies because it helps ensure that regulations achieve their goals with minimal disruptions across the pharmaceutical supply chain.

Learn more about the TraceLink EAEU+ Uzbekistan Innovation Forum and join today

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