



Germany

Bionorica ensures compliance with Russian serialisation law ahead of official deadline

<p>Challenge Bionorica had to ensure compliance with the Russian serialisation law before the 1 July 2020 deadline.</p> <p>Approach Movilitas' fully compliant set of services and solutions helped Bionorica handle the complex serialisation requirements. An integration of the company's SAP® Advanced Track and Trace for Pharmaceuticals (ATTP) solution with the Russian Order Management System (OMS) was established to enable the request of required crypto codes. Additionally, a direct integration from Bionorica's SAP ATTP solution to the Russian Drug Circulation Monitoring System (MDLP) was created using Movilitas.Cloud for monitoring and legal reporting of all transactions. GS1 standards provided the foundation for the traceability system.</p>	 <p>“By 2024, the unified national track & trace digital system will cover all industries, from cigarettes and medications, to clothing and child nutrition.”¹</p>	<p>30% faster reporting process through automation</p>
	<p>52% reduction in implementation costs since all involved systems are based on GS1 standards</p>	 <p>Compliance would not have been possible without GS1 standards</p>



Bionorica is one of the world's leading manufacturers of scientifically researched herbal medicines. As the premier supplier for the phytomedicine market in Russia, the company faced the country's regulatory deadline of 1 July 2020. All new medications released must comply with Russia's Federal Law No. 425-FZ, which dictates the requirements of drug serialisation that manufacturers must meet. The goal of this regulation, as with others in the EU and around the globe, is to reduce the occurrence of counterfeit medications that could negatively impact patient health. Bionorica needed to ensure compliance with the pending regulation and tight timeframe to maintain its current supply levels.

Marco Steinkamp

Track and trace in Russia

The Chestny ZNAK is a national track and trace system created by the Centre for Research in Perspective Technologies (CRPT) in Russia. The system's purpose is to protect customers from fake goods, including medicines, by ensuring authenticity and declared quality. “By 2024, the unified national track and trace digital system will cover all industries, from cigarettes and medications, to clothing and child nutrition.”¹

Five steps cover the product journey—from a manufacturer assigning a digital code, to a store scanning the item before placing it on the shelf, to a customer scanning the code on the mobile app. This process creates a record of the entire value chain and helps prevent counterfeit goods from getting into the hands of consumers, which ultimately protects consumers' health and rights. Additionally, full product traceability supports businesses with optimising their supply chain processes and reducing costs, while increasing revenue and competitive advantage.

¹ Source: <https://chestnyznak.ru/en/business/#footer-link-two>

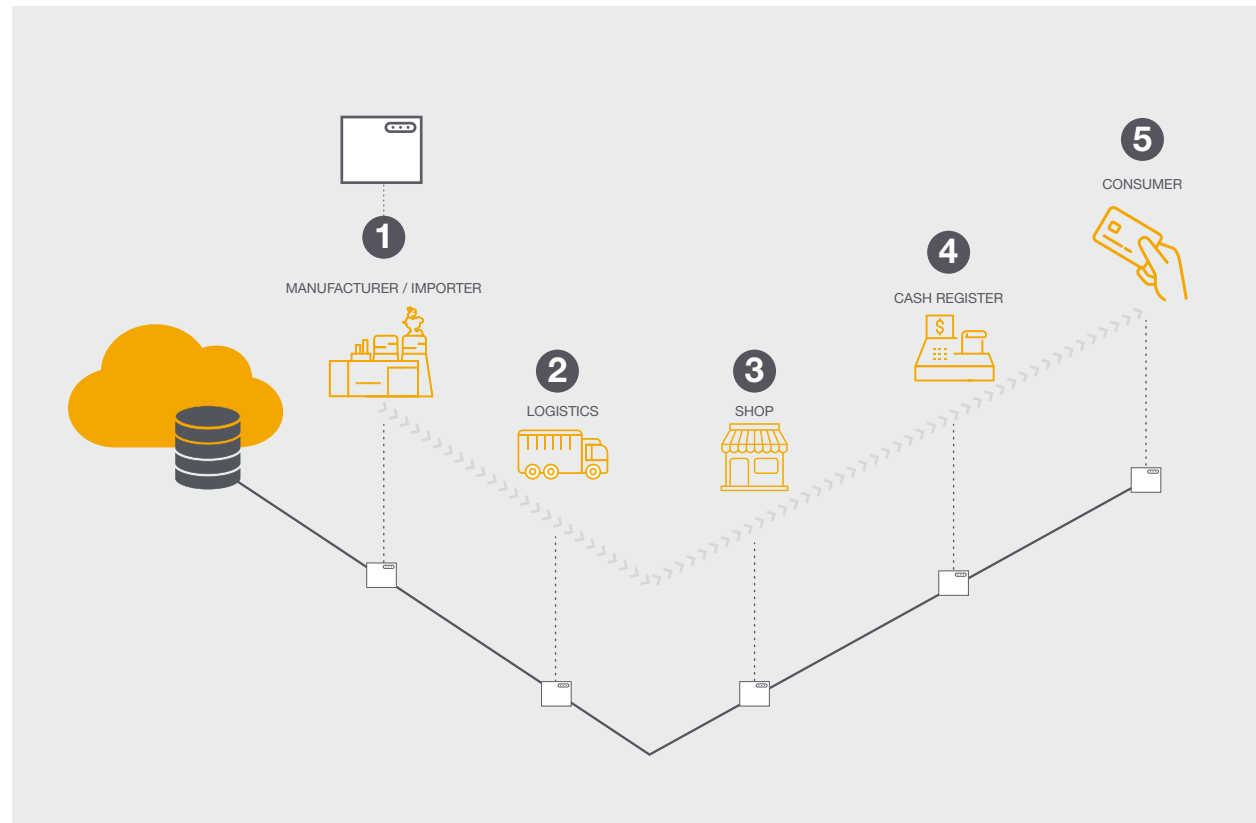


Figure 1: Track and trace in Russia covers the complete product journey - from production to consumption - Source: chestnyznak.ru

Serialisation and traceability for medicine in Russia

After a federal law was enacted in April 2010, Russia developed a dedicated track and trace information system called IS MDLP to monitor pharmaceutical products. In February 2017, an experiment was initiated to implement and monitor the identification of specific pharmaceutical products. In December 2017, Federal Law No. 425-FZ passed, amending the original law. It specified a deadline of 1 January 2020, which was later extended until 1 July 2020, and states the requirements of drug serialisation that manufacturers and other pharmaceutical stakeholders—such as distributors, pharmacies and healthcare providers—must meet.



Bionorica required a solution that established a direct connection to the Russian Order Management System and automated the reporting process, while taking its needs as a global manufacturer of herbal medicines into account.

The challenge

The pharmaceutical industry has found the Russian serialisation regulation difficult to meet based on its complex requirements. Meeting the regulation requires a different approach to the technology solutions implemented for the EU Falsified Medicines Directive (FMD) and other countries' regulations.

In order to be compliant, healthcare stakeholders must gather additional key data and communicate with the Russian systems. In addition to a two-dimensional (2D) barcode and randomised serial numbers, the regulation requires a cryptographic key that is requested

from the Russian Order Management System for each order. Therefore, technology used in compliance solutions must be able to handle the longer codes from data exchange to aggregation.

Additionally, the law specifies that more than 50 transactions must be monitored and reported, from manufacturing to dispensary. The reports, which must be encrypted and signed, are uploaded to the MDLP. This process is manual, which is resource intensive and can have a higher risk of errors. Thus, Bionorica required a solution that established a direct connection to the OMS and automated the reporting process, while taking its needs as a global manufacturer of herbal medicines into account.

How Bionorica ensured compliance with the Russian serialisation law

To ensure compliance with Russia's serialisation law before the deadline, Bionorica needed a direct connection between its SAP ATTP solution and the Russian OMS to be able to request crypto codes. The company also required the solution to automate the extensive reporting process.

By taking advantage of the Movilitas fully compliant set of services and solutions, Bionorica was able to handle the complex serialisation requirements. Based on its successful technical expertise, extensive traceability experience and detailed understanding of Russia's Federal Law No. 425-FZ, Movilitas, a GS1 Solution Partner, was selected by Bionorica to tackle the complexity of the regulation.

To automate the reporting process, it was necessary to implement a communication bridge that would help streamline the bidirectional flow of information, including up to 50 reports that are required of the marketing authorisation holders (MAHs) and contract manufacturing organisations (CMOs).



Only by taking advantage of Movilitas' fully compliant set of services and solutions, Bionorica was able to handle the complex serialisation requirements.

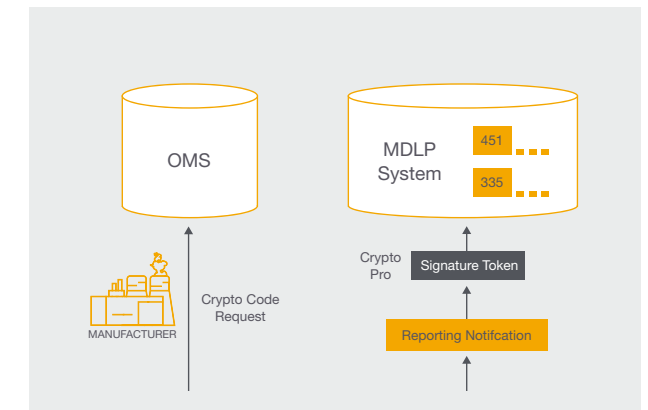


Figure 2: A cryptographic key is requested from the Russian Order Management System (OMS) for each order. The reports, which must be encrypted and signed, are manually uploaded to the MDLP.

Using Movilitas.Cloud for monitoring and the legal reporting of all transactions, a direct integration from Bionorica's SAP ATTP solution to the Russian MDLP system was created.

Movilitas.Cloud was easily implemented, because it did not require local installations or modifications to the production line. It is a GAMP 5 validated software-as-a-service (SaaS) solution that streamlines compliance by enabling communication between SAP ATTP and the Russian MDLP system for message processing and retention. Movilitas.Cloud provides both foreign and domestic connections in accordance with industry best practices.

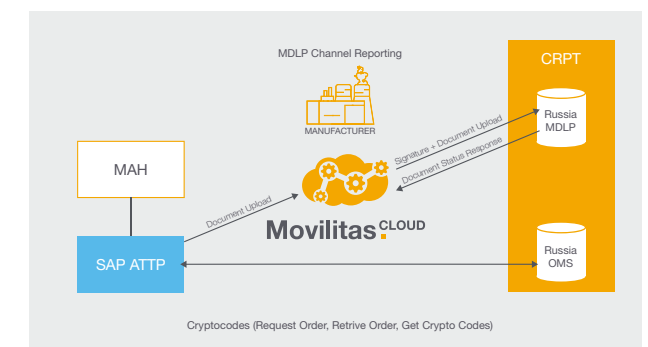


Figure 3: The integration of SAP ATTP and OMS enables the request of crypto codes. The reporting process is automated through the direct connection of SAP ATTP and MDLP using Movilitas.Cloud.

Bionorica requested and managed the cryptocodes through the direct integration of SAP ATTP with the Russian OMS. In the automated reporting process, the necessary documents are generated in SAP ATTP, uploaded to Movilitas.Cloud via Bionorica's own middleware and exchanged with Russia's MDLP system via the latter. With Movilitas.Cloud, Bionorica tracked and managed the status of reports.

The role of GS1 standards

Global GS1 standards provide the needed foundation for such an authentication and traceability system. They are an integral part of national regulations like Russia's Federal Law No. 425-FZ, significantly improving the integrity and visibility of local and global healthcare supply chains. Bionorica's case shows that global GS1 standards are crucial when securing a global supply chain and tackling national serialisation regulations, thereby preventing counterfeiting, the resale of medicines and the sale of expired medicines, as well as reducing drug shortages.

Bionorica was able to increase its patients' safety while maintaining compliance, because all systems involved in the project (the Russian OMS and MDLP, SAP ATTP, Movilitas.Cloud) adhere to GS1 standards and, therefore, are interoperable.

This facilitated a 30% faster reporting process as the standards allow for an easier exchange of information. Bionorica was also able to reduce the adjustment and implementation costs by 52% and to achieve compliance with a go-live date ahead of the deadline.



Bionorica's case shows that global GS1 standards are crucial when securing a global supply chain and tackling national serialisation regulations, thereby preventing counterfeiting, the resale of medicines and the sale of expired medicines, as well as reducing drug shortages.

Bionorica was able to increase its patients' safety while maintaining compliance, because all systems involved in the project (the Russian OMS and MDLP, SAP ATTP, Movilitas.Cloud) adhere to GS1 standards and, therefore, are interoperable.



About the author



Marco Steinkamp
European Sales Director
Movilitas

Marco Steinkamp studied Logistics at the Fontys University of Applied Science in Venlo (NL). In 2005, he joined British American Tobacco (BAT). During his 10+ years with BAT, he held several positions and was a member of BAT's local and global supply chain organisation. For more than four years, Marco also supported BAT's Global Track & Trace Program as Senior Project Manager in logistics as well as manufacturing environments. With this end-to-end supply chain track & trace experience and expertise, he joined Movilitas as the European Sales Director for Track & Trace in May 2015. After moving into the role of the Global Sales Director for Track & Trace in 2017, Marco became European Sales Director in December 2019.

About the organisations



Movilitas is a technology leader delivering the next generation of solutions and consulting services across multiple industries to advance smart supply chain ecosystems. We are recognized as a trusted SAP partner for digital supply chain transformation. We help businesses realize new growth opportunities, adapt to today's on-demand economy and maintain compliance. Through services, such as Movilitas.Cloud, or extensions and accelerators for SAP solutions, our clients unlock data to realize greater efficiencies and new revenue streams.
movilitas.com

Bionorica, located in Neumarkt, Bavaria, is one of the world's leading manufacturers of scientifically researched herbal medicines. Doctors, pharmacists and patients in more than 40 countries trust in Bionorica's products. In 2019, the Bionorica Group achieved sales of EUR 333 million. Based on the "phytoneering" strategy, Bionorica decodes the extensive active ingredient potential of plants (phytos) using cutting-edge research and technology (engineering). The result: highly effective medicines with few side effects. Bionorica's research and development priorities involve the treatment of symptoms in the respiratory tract, urinary tract, women's health and the immune system.

bionorica.de