The Serialization of Medications in Russia

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1. The Problem of Counterfeit Medications in Russia

Counterfeit products naturally pose a major problem in the pharmaceutical sector. This affects brand-name and generic products as well as OTC (over-the-counter) products. According to the World Health Organization (WHO), counterfeited medications can range from cheap painkillers, to "lifestyle" supplements, right through to expensive medication used in HIV and cancer treatment.

Imitation medication is not just brought into circulation through non-authorized pharmacies and online portals, but also successfully planted in the legal distribution chain via wholesalers and the pharmacy network. To this end, counterfeiters falsify sales and supplier documents so that the "medications" are sold to legal wholesalers.

This applies to Russia as well as other countries in the Eurasian Economic Union (EAEU). EAEU member states Russia, Armenia, Belarus, Kazakhstan, and Kyrgyzstan have currently united to form a domestic market with a customs union.
Similarly to the EU nations and the United States, Russia has also developed a system for serializing medication.

In this whitepaper, we will explain what companies in the pharmaceutical industry are doing to fulfill ambitious requirements so that they can continue operating in Russia.

1.1 The impacts of counterfeit medications

Counterfeit medications are products whose origin, identity, and contents are falsified. Generally speaking, the following categories of medication are typically counterfeited:

- Products without active ingredients
- Products with too high or too low quantities of active ingredients
- Products with fake or counterfeit ingredients
- Products with correct quantities of active ingredients, but falsified packaging and package leaflets
- Products with a high degree of impurities
- Copies of an original product

1.2 The risks posed by counterfeited medication

The risks posed by counterfeited medication are clear to see. Some counterfeited medications are toxic by their very nature, either because of fatal doses of a real or fake active ingredient, or other poisonous chemicals. They are also often manufactured in very poor, unhygienic conditions by non-qualified individuals, can thus contain unknown impurities, and are sometimes impacted by microbiological contamination.

Another cause for concern is that counterfeited medications can impede the treatment of illnesses for which they are intended, or even cause it to fail. This is a consequence that does not reflect the quality of the original medication when it is used in a routine medical procedure. This results in both a loss of faith in medicine and the healthcare system, not only within professional circles, but also among patients. Recalls of counterfeited medications can ultimately give rise to supply shortages.

2 Fighting counterfeit medications in Russia

Russia and other countries in the EAEU have been implementing serialization systems for a large number of product categories for years. Systems for serializing furs and alcoholic beverages have already been put in place. Pilot projects are currently being carried out for tobacco products and medications. Other categories that are set to be implemented in the near future include fragrances and drugstore products, cameras and lamps, tires, beer, milk, clothes, and textiles.

An increase in market transparency and consumer protection against illegally manufactured goods and goods of questionable quality are the most important aims of this scheme. The long-term goal is to map the total value stream of imported products.

Russia has also worked within the scope of a public/private partnership (the "Markirovka Project") to develop a system for digitally labeling and ensuring the traceability of goods.

2.1 Legislation and deadlines – a major challenge

On January 1, 2019, the law on serializing medication with crypto coding entered into force. This means that serialization will be mandatory pursuant to Russian law from January 1, 2020.

The legislation stipulates that legal persons who carry out the manufacturing, import, storage and distribution, sales, use, or disposal of medication in Russia must provide information about these processes in the system designed for this purpose. This places pharmaceutical companies that want to export goods to countries in the EAEU under enormous pressure – firstly because of the system's high requirements, and secondly because of the extremely tight schedule. Companies that cannot make changes in line with the currently applicable schedule will no longer be able to export to Russia and other countries in the EAEU that are involved in the Markirovka Project.

2.2 A system for tracking every transaction

The "Monitoring Dvijenia Lekartsvennikh Preparatov" system (MDLP) was specifically developed within the framework of the Markirovka project as a technological method of serializing medications.

Unlike serialization systems in other countries, such as those in the EU, the Russian system not only requires unique identification codes for labeling each individual package of medication, but also tracks the products' every movement across the entire value chain.

Aggregating packages in shipping cartons is a crucial prerequisite for making this possible. Each shipping container has its own serial number, which the serial numbers of the individual packages in the carton refer to. This is the only way of securely recording the shipping process.

The Russian system is unique across the world in terms of its scope and complexity. Below you will find an overview of its main characteristics:

- All medicines, including OTC products and organic products, are recorded
- Much more data is recorded, including purchasing and manufacturing prices, composition, and much more
- A 2D code is required on every secondary packaging or bottle
- A crypto code signature and key must be included in addition to the Global Trade Item Number (GTIN) and serial number
- The aggregation of serialized products is necessary to guarantee an optimal recording process across the entire supply chain
- Up to 70 notifications are currently required for reporting

2.3 Crypto Code ensures verification

An important aspect of the law that came into force on January 1, 2019 is "crypto code," a sequence of alphanumeric characters that is generated via a secret encryption process based on Russian crypto technologies. While the GTIN and serial number are used for identification, the additional elements of the crypto code signature and key serve the purposes of verification (even offline). The crypto elements cannot be generated themselves, but are supplied by a closed IT system on request. The manufacturers transfer the GTIN and serial numbers and receive the corresponding crypto elements for the data matrix code to be printed on the packaging via a special device at the respective production site called the "issue recorder."

The data matrix code to be applied to the package is very complex due to its high data quantity – it consists of up to 44 x 44 modules. It is thus significantly more compact than conventional codes with 24 x 24 modules. For the code to be integrated on conventional packaging layouts, the modules have to be made significantly smaller. This places high requirements on the cameras and scanners used for recording the code, as well as printers for applying the code to the packaging.

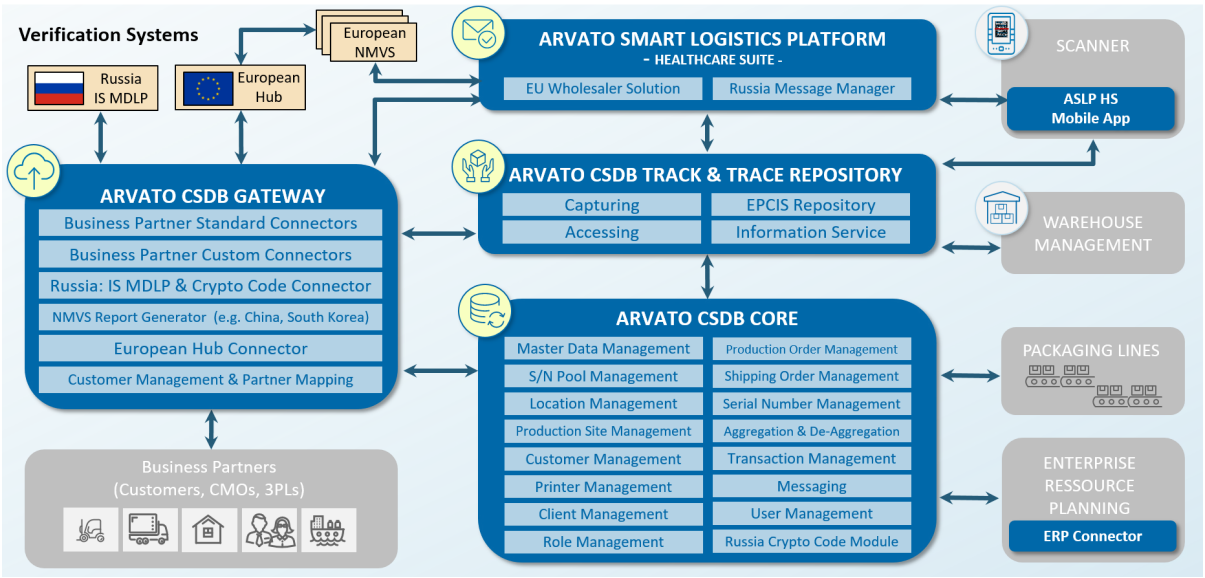
3 The Arvato CSDB Pharma Track & Trace Package

Arvato Systems offers the Arvato Corporate Serialization Database (Arvato CSDB), an IT solution that combines the various elements of serialization in the pharmaceutical industry. The solution can be integrated into existing ERP systems and offers interfaces to production lines, suppliers, production facilities, and verification systems.

The Arvato CSDB maps out a whole range of scenarios particular to medication serialization for Russia, including:

- Production as a CMO for the Russian market
- Exporting with and without a representative office in Russia
- Exporting with a proprietary import and sales organization in Russia
- International clients with production in Russia

In order to cover different business models, Arvato Systems has developed an IT solution architecture that optimally supports reporting, manufacturing, and logistics processes. The Arvato CSDB (CORE) represents the heart of the Arvato CSDB Russian Pharma Track & Trace Package.



The Arvato Smart Logistics Platform, Arvato CSDB Track & Trace Repository, and Arvato CSDB Gateway are further modules that can be combined and configured around the Arvato CSDB (CORE) in line with the client's specific scenario.

Depending on the business model (or combination of business models) used by a pharmaceutical company active on the Russian market, Arvato Systems can combine the various modules into a client-specific solution package. Each module maps specific processes and functions within the supply chain and supports them.

The main advantages of Arvato CSDB include:

- Support for the regulatory requirements of the respective country
- Extensive functions for the flexible and secure management of serialization data
- Flexible adjustment to different company sizes and business situations
- Flexible integration of external value-adding partners such as logistics partners
- Generation and provision of country-specific reports (such as for China or South Korea)
- Integration of verification and tracking systems (such as the EU Hub, Russian IS MDLP system)
- Certified first-class security standards for data storage and transfer
- Reliable reporting on serialization incidents
- Integration of internal systems and processes for the seamless exchange of the relevant data
- Integration in existing IT environments, including ERP and warehouse management systems
- Highly available infrastructure and redundant components ensure ongoing operation

4 How medication serialization is implemented

As illustrated above, the authorities in Russia are reluctant to make compromises when it comes to the planned implementation of serialization. In light of this very tight schedule and the system's complexity, it is important that the time required for introducing serialization is not underestimated – after all, developing a comprehensive information system is a tricky task. This challenge is almost insurmountable without a top-performing and highly experienced partner to accompany you through each stage of the process.

4.1 Partner requirements

Both the project and the markets within the Eurasian Economic Union are unique. For that reason, a few important points in particular should be borne in mind when selecting a consultancy and IT partner. The partner should have good connections in countries within the EAEU and local regulatory bodies, as this is the only way of accessing current specifications and finding out about any changes at the earliest stage possible.

Cooperative agreements with renowned hardware providers are also important, as they are particularly advantageous for integrating the entire system and validation in order to map an effective overall process.

The partner should also be able to observe and analyze entire business processes "end-to-end," as well as competently support the client from the initial consultation through to implementation.

4.2 The strategy

The early implementation of all involved departments within the company – such as purchasing, production, quality assurance, logistics, and IT, as well as marketing, sales, and regulatory affairs and, where applicable, the verification team – are of the utmost importance in successfully implementing a serialization solution.

Setting up an interdisciplinary project team is recommended to accelerate the processes. External partners, such as packaging suppliers, as well as printing companies and wholesalers where applicable, should also be included from the outset to prevent friction losses.

The first step must be a comprehensive requirements analysis. This should factor in the following questions:

- Which stakeholders and departments have to be included?
- What is the status of existing production systems with regard to introducing serialization?
- Are the IT systems prepared for this?
- Which interfaces are necessary?
- Which training and instruction courses are required?

Early registration with the respective authorities in Russia and participating countries of the EAEU is also a top priority. In addition, tests must be conducted at the earliest stage possible to determine whether existing or planned hardware such as cameras and scanners meets the requirements.

It is also recommended to define a manageable pilot project; for example, in relation to a selected production line. The experience gained through this can then be transferred to the overall project so that serialization can be introduced more rapidly.

4.3 Arvato Systems' expertise

Arvato Systems is one of the leading suppliers of serialization solutions, and has years of experience in this sector. Arvato Systems has supported renowned and internationally operating small- and medium-sized pharmaceutical companies since 2011 in complying with local track and trace regulations in different countries across the world – including Europe, the United States, South Korea, and China – with the aid of its solutions. It also supplies national verification systems to 17 countries in Europe and connects them to the EU-Hub. Arvato Systems has been selected as an official service provider by the European Medicines Verification Organisation (EMVO). We rely on our own team of serialization experts, which has already implemented numerous projects in the international environment.

Arvato Systems incorporates its team's expertise in serialization and supply chain management, and is able to map the entire value chain of the pharmaceutical industry. Its advisors boast extensive technological expertise, and also act as business consultants who support the client in addressing regulatory issues.

- ✓ One of the market leaders in Europe for corporate solutions and national verification systems
- ✓ Implementation experience: systems for 17 countries and over 70 pharmaceutical manufacturers
- ✓ Projects completed in Russia
- ✓ Proven serialization solution Arvato CSDB, which can be adapted to your business model
- ✓ Can be customized to fit specific requirements
- ✓ Integrated communication to Russian platforms
- ✓ Comprehensive implementation of reporting requirements

More information about serialization in Russia:
arvato-systems.com/serialization-russia-en

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Global IT specialist Arvato Systems supports major companies through digital transformation. More than 2,700 staff in over 25 locations epitomize in-depth technology expertise, industry knowledge and focus on customer requirements. Working as a team, we develop innovative IT solutions, transition our clients into the Cloud, integrate digital processes and take on IT systems operation and support.

In the healthcare segment, Arvato Systems covers the entire end-to-end process chain with its own serialization solutions. These solutions support both individual manufacturing companies and national verification systems. Arvato Systems has been selected as an official service provider by the European Medicines Verification Organisation (EMVO). We rely on our own team of serialization experts, which has already implemented numerous projects in the international environment.

As a part of the Bertelsmann-owned Arvato network, we have the unique capability to work across the entire value chain. Our business relationships are personal; we work with our clients as partners, so that together we can achieve long-term success.

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