1. General Information about Serialization in Russia

The Russian Federation is a pioneer in serialization. They have already launched mandatory serialization for some product categories – for example: tobacco and furs. Serialization supports market transparency, quality of the products and protection of consumers from illegally produced goods.

The necessity to implement serialization applies to perfumes, cameras, lamps, tires, coats, jackets, capes and milk. Some of them are already at pilot stage. However, the most important pilot project is the serialization of medicaments.

Serialization of Medicaments will be mandatory from January 2020. The System for Russian Serialization, called Monitoring Dvijenia Lekartsvennikh Preparatov (MDLP), was developed by the Russian Technology Provider CRPT. Unlike other countries’ process serialization, the Russian system not only provides unique identification codes to mark every box of medicaments, it will also track every movement of them. This full Track & Trace approach makes aggregation a basic necessity.

Because of the fact that the Governmental Degree about obligatory identification code was implemented, it is very important that pharma producers are ready to print the Russian Identification Codes (including the Crypto Code) on the packages of medicaments that are distributed in the Russian market.

Russian Requirements in a Nutshell:

- Russian Track & Trace regulations are postponed to 2020
- All medicines are effected incl. over the counter (OTC) products
- A 2D code on every secondary pack or bottle is required
- Serial number will be enriched by a crypto code
- Aggregation is required due to supply chain reports
- Up to 70 notification messages are required to report
2. Arvato Systems' Footprint in Serialization

Arvato Systems is one of the leading Serialization Software Solution providers having a very long experience in this field. Arvato Systems offers with its Corporate Serialization Database (Arvato CSDB) a solution which brings all the elements of serialization for pharma applications together. The solution can be integrated into existing ERP systems, creating interfaces with production lines, suppliers, production sites and verification systems. With this solution Arvato Systems supports since 2011 the top 20 pharma companies as well as midsize and small pharma companies to comply with local Track & Trace regulations in various countries all over the world. Beside this, Arvato Systems is providing the National Verification Systems for 17 countries across Europe and connects them with the EU Hub.

3. Arvato CSDB Russian Pharma Track & Trace Package

The Arvato CSDB Russian Pharma Track & Trace Package covers scenarios like exporting to Russia without a local representative or MAH Business in Russia as further detailed in the below table:

<table>
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<tr>
<th>Business Model</th>
<th>Description</th>
<th>Relevant Processes</th>
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| European MAH without Russian        | • The foreign MAH has to be registered due to Russian Legislation  
                    Representative office                                                  | Custom Clearance  |
|                                     | • The foreign MAH has to send import messages about emission of medications, shipping the medications  
                    • Further work is being done by the Importer                                                                                                     | Import Message    |
|                                     |                                                                                                                                                | Shipping Message  |
|                                     |                                                                                                                                                | Packaging Message |
|                                     |                                                                                                                                                | Market Messages   |
| Export to Russia with local          | • The foreign MAH has to be registered due to Russian Legislation  
                    representative                                                                                                                                | Prod. incl. Crypto |
|                                     | • The foreign MAH has to send export messages about emission of medications, shipping the medications to  
                    Representative Office, which forwards them to MDLP  
                    • Representative Office is responsible for Description of Medicament in MDLP  
                    • In case if the Representative office is authorized by Law it can also act as an Importer or further on as a Wholesaler | Code              |
|                                     |                                                                                                                                                | x                  |
| Wholesaler Russian resident         | • The wholesaler transports Medicaments from Customs Warehouse to Retail  
                    • Every Medicament status change should be reported by the Wholesaler, until he is the owner of the Medicament | x                  |
| Russian Producer                    | • Produces the Medicament, prints Cryptocodes  
                    • Puts it into circulation as Wholesaler  
                    • He is responsible for all the messages until he is the Owner of Medicament                                                                 | x                  |
| Import to Russia Business            | • The Importer is responsible for Medicaments Custom Crossing Processes  
                    • Import and Shipping messages are being sent by Importer                                                                                     | x                  |
|                                     |                                                                                                                                                                           | x                  |
|                                     |                                                                                                                                                                           | x                  |
4. Solution Overview

To cover the various business models, Arvato Systems offers an IT solution architecture which supports reporting, manufacturing and logistical processes. The heart of the architecture is the Arvato CSDB product family, as further detailed in the figure below:

![Figure 1: The architecture of the Arvato CSDB Landscape.](image)

All harmonized working components in the architecture support a pharma company within its business model. Depending on which business model and in which combination a pharma company is acting on the Russian market Arvato Systems can “Mix & Match” the different modules to a customer required specific solution package. Each module is covering and supporting specific processes within the supply chain.

- Mobile application fast & easy to install on existing IT landscape & mobile devices
- Business application monitors and controls operational processes
- Process transparency in real time

Arvato Smart Logistics Platform - Healthcare Suite
5. Arvato Systems’ Experts for being compliant with Track & Trace Regulation

As the Russian Track & Trace requirements are connected to multiple supply chain processes, Arvato Systems’ experts are pleased to support you on your process fitting compliance package, answering your questions or provide you with further information. Please get in contact with us and we will draw you how our solution will look for your business model and IT landscape.

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Global IT specialist Arvato Systems supports major companies through digital transformation. More than 2,600 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.