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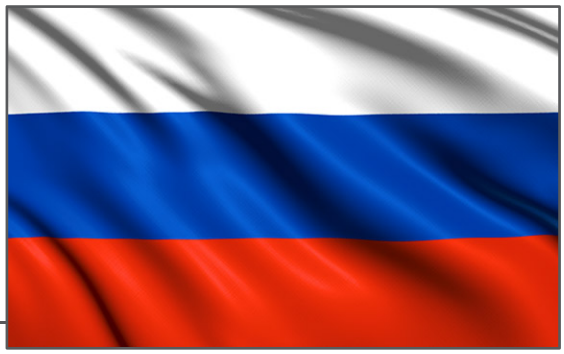
Russia Pilot and Serialization Requirements



Regulatory Update

August 2020

Regulatory Agency	Ministry of Health of the Russian Federation
Regulation Name or System Name	Pilot: "federal government information system for monitoring the circulation of medicinal products from the manufacturer to the end consumer with labeling", or, FGIS MDLP
Compliance Dates	Pilot runs from Feb 1, 2017 to Dec 31, 2019 According to a memo from the Ministry of Health, a stage-by-stage quarterly deployment of the monitoring system of medicinal product movement in 2018 was proposed. In 2018 these dates appear to have been pushed out by one year. They were again adjusted in a formal government decree on December 14, 2018 and again in a decree in December 2019: • July 1, 2019 through July 8, 2019: Drug companies supplying products for the twelve high-cost nosologies (hemophilia, cystic fibrosis, pituitary dwarfism, Gaucher disease, malignant neoplasms of lymphoid, hematopoietic, and related tissues, and multiple sclerosis and individuals after organ and (or) tissue transplant) must register with the government monitoring system and within 21 days, perform onboarding tests; Then, within two months of the successful completion of the tests, begin interacting with the system (in production?); • Starting on October 1, 2019: All other manufacturers must register with the government monitoring system and within 21 days, begin applying the tracking code on primary packages of the medicinal product (if the secondary package is not provided) and on the secondary (consumer) package of the medicinal product; Dispensers which do not carry on retail trade of medicinal products, and ensure withdrawal of medicinal products from circulation by dispensing medicinal products free of charge or at a discount on prescription, apply with the monitoring system operator to obtain withdrawal recorders within 21 calendar days after their registration with the monitoring system; • December 31, 2019: Labeling coverage and data upload to government service for the twelve high-cost nosologies released into circulation. • July 1, 2020: Labeling coverage of 100% of medicinal products and data upload to government service

	released into circulation. However, on June 3, 2020 the State Duma factional working group decided that they would establish a six month "stabilization/transition" period where they would not enforce the serialization and reporting requirements. This period ends on January 1, 2021. • Products produced prior to the dates above are exempt through the end of their shelf-life.
Applies to	Prescription drug registration-holders (manufacturers, repackagers and importers), wholesale distributors and pharmacies.

Unit-level Packaging ("units of sale")

Barcode Symbology	Data Matrix ECC200
Barcode Contents	The "Control Identification Sign" (CIS) • GTIN-14; • Serial Number (13 alphanumeric characters); • a "Crypto-code", supplied by a government service or a government supplied piece of hardware. The request for a Crypto-code must include the GTIN-14 and the Serial Number data elements because the Crypto-code are specific to those data elements; – a 4 digit "key" – a 44 character "signature" The Crypto-code must be obtained either through a piece of hardware provided by the government, installed locally, or through a government web service. The manufacturer must supply the GTIN + serial number for each crypto-code request. CRPT has indicated that these requests may come from an enterprise level system or a site- or even a line-level system. Only the GTIN and serial number data elements must appear on the package in human readable form (that is, the crypto-code does not need to be printed in human readable form).
Serial Number Randomization	No
Serial Number Reuse	5 years after issuance, or 1 year after the expiration date of the last use, whichever is later
Human Readable Expiry Date Format	DD.MM.YYYY recommended for the pilot
Barcode Data Encoding	GS1 standard
Product Code notes	In January 2018 GS1 Healthcare claimed that the regulatory agency in Russia has mandated that the product GTIN be unique to the location it was packaged as a way of combining GTIN and GLN without including a GLN. So if the identical product is packaged in more than one place, it will need to be assigned more than one GTIN—one for each packaging location. This would be a violation of the GS1

	General Specifications so GS1 is arguing they should just include a GLN. January 2019: I have not heard this as a potential issue since it was originally raised a year ago. In the recent Decree #1556 I don't see this issue in my reading of Annex 3 (information provided by the manufacturer when introducing drugs into the supply chain). GS1 Healthcare continues to keep this requirement in their summaries. I'm keeping it here for awareness that this could still be an issue. –Dirk.
Free Samples must be marked?	Yes
Stickering after manufacturing allowed?	No

Logistics Units (tertiary packaging)

Barcode Symbology	Code-128 "…in accordance with GOST ISO/IEC 15417-2013"
Logistics Units Must be Serialized?	Yes
Barcode Contents	• AI "00" • "Group code extension symbol" • "Registration number of the subject of medicines circulation obtained in the information resource which ensures the accounting and storage of reliable data on the goods according to the corresponding nomenclature of goods" • individual serial trade item number • check sum This sounds like a standard GS1 SSCC, but it's hard to tell because it is not clear who will issue the "Registration number of the subject medicines". For an SSCC, that would be one of the GS1 Member Organizations. Also, the "Group code extension symbol" for a true SSCC would be an extension of the serial number field. This may just be a simple translation issue.

Data Capture

Unit-to-Case Aggregation Capture?	Yes but mixed-lot shippers and pallets are not allowed at the reporting level. This seems to be limitation of the technical reporting system and not a regulatory requirement

Data Exchange

Send Unit Data to Government Repository?	Yes
Send Unit Data to Third-Party Repository?	No
Send Unit Data to Trading Partner?	Not clear, probably not
Send Aggregation Data to Government Repository?	Yes

Send Aggregation Data to Third-Party Repository?	No
Send Aggregation Data to Trading Partner?	Not clear, probably not

Authentication

Who Offers Data Repository for Authentication?	Government (third-party under contract)
Manufacturers Must Register Shipments in Repository?	Yes
Downstream Trading Partners Must Authenticate on Receipt?	Not clear, probably not
Downstream Trading Partners Must Authenticate on Shipment?	Not clear

Government Reporting

Manufacturer Activity Reported?	Yes (registration-holder), within 5 days
Downstream Trading Partner Activity Reported?	Yes, within 5 days

Challenges

- Spotty notification of new documents related to regulations and accurate translations are difficult to produce.
- Information from government decrees and CRPT, the government contractor used to develop the government's central repository, sometimes conflict.
- There are reports that some vendor solutions cannot recognize the full character set that CRPT will use for crypto-codes. There is some confusion over the cause of this problem and who will need to fix it, but it should be fixable.

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About Systech

Systech provides digital product authentication and traceability solutions to combat counterfeiting, prevent diversion and meet regulatory compliance. Built on decades of experience as the leader in pharmaceutical serialization, our comprehensive brand protection suite delivers the real-time insight, actionable product data, digital connectivity and consumer engagement functionality needed to fight supply chain threats.

Global brands across industries rely on us to keep their products authentic, safe and connected—from manufacturing to the consumer's hands. Together we are revolutionizing brand protection!

Regulatory Questions?

Contact us at info@systechone.com or visit us online here.