KPMG

Track & Trace of pharmaceuticals in Russia: comprehensive advisory support

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KPMG in Russia

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Pharmaceutical serialization in Russia: law-making stages and key events

Starting from July 1, 2020 all pharmaceuticals circulating in the Russian Federation are subject to mandatory labeling (serialization), and their flow in the market is subject to monitoring via the statutory information system “Labeling of Pharmaceuticals” (FGIS MDLP).

The main goal of the track & trace introduction is combatting counterfeit products, as announced by the regulators.

FGIS MDLP is supposed to allow pharmaceutical producers and other data exchange participants track the route of their products up to the end-consumer.

2016

Start of project

25.10.2016:

Priority project passport
Protocol # 9 of the Presidential Council for Strategic Development and Priority Projects

2017

Preparing to Implement

01.02.2017:

Serialization Experiment launch
Government Resolution # 62

28.02.2017:

Methodological Recommendations on Serialization implementation, approved by MoH

28.12.2017:

Framework serialization requirements
Federal Law # 425-FZ

2018

Specifying Requirements and IT System Development

23.04.2018:

Methodological Recommendations update, approved by MoH

28.04.2018:

Functional model of products labeling/serialization
Government Resolution # 791-p

30.07.2018:

Draft Regulation on identification tool's characteristics, printing properties and requirements to structure and format

28.08.2018:

Prolongation of Serialization Experiment
Government Resolution # 1018

01.11.2018:

Approving CRPT as FGIS MDLP operator

14.12.2018:

Methodology of T&T reporting and FGIS MDLP functionality
Government Resolution # 1556

25.12.2018:

Final concept and principles of T&T with crypto-protection
Federal Law # 488-FZ

2019

Testing

CRPT's methodological guidelines update

08.05.2019:

Fee for T&T crypto-code approved (50 kopecks per code)
Government Resolution # 577

30.08.2019:

Crypto-code length reduced to 44 chars
Government Resolution # 1118

05.09.2019:

Template contract for supply of emission registrars approved
Order of the Ministry for Industry & Trade # 3325

11.09.2019:

Template contract for crypto-code emission approved
Order of the Ministry for Industry & Trade # 3381

01.10.2019:

Mandatory labelling for 12 Nosologies products

31.12.2019:

Deadlines during the transition period affirmed
Government Resolution # 1954

2020

Transition period and Launch

29.02.2020:

Mandatory FGIS MDLP registration for all participants of pharmaceuticals circulation

01.07.2020:

Mandatory Track & Trace for all newly produced pharmaceuticals

Key risks and uncertainty areas

Risks

Risk management methods

Risks	Risk management methods
FGIS MDLP development is still in progress	Direct interaction with FGIS MDLP Operator to clarify data flows and IT systems requirements
Rules are more complicated as compared to EU Track & Trace: ~60 reporting events, additional cryptocoding, financial data reporting	Elaborated planning and execution of data exchange processes redesign and IT systems integration, including external ones
Changes to identifier (labeling code) structure negatively impact the production process, leading to cost and/or defective rate increase	Upfront testing of high-density identification codes on the existing equipment
FGIS MDLP failures and disruptions while big data processing; lack of information on the data protection level and tools within FGIS MDLP	Developing back-up solutions for data transfer to corporate repository
Existing IT solutions (especially international ones) are not customized to the Russian T&T requirements	Upfront assessment of IT solutions capacity/functionality and cost-benefit analysis of the improvements required

Areas for in-depth analysis and risk assessment:

- Changes to business processes
- Unclear accounting issues (in particular, accounting and reporting on prices)
- IT systems changes
- Reporting changes

Areas to expect most significant changes:

- Printing and scanning of identification tools considering the crypto-protection requirements, data security requirements and setup of the data exchange with emission and disposal registers
- Business processes and requirements to IT systems based on the necessary reporting events sequence and requirements to formats of data submitted to FGIS MDLP

Implementing Track & Trace: what you have to do?

Planning and analysis → **Implementation**

Mobilization → **Diagnostics & Analyses** → **Development** → **Testing & Launch**

Mobilization

- Appoint working group, project manager, project schedule
- Assess the regulatory framework impact, including its uncertainties, upon your business processes
- Sign up and create a personal account in FGIS MDLP and register at FGIS MDLP API server

Diagnostics & Analyses

- List the products subject to labeling, with account to the manufacturing localization degree
- List the business processes affected by Track & Trace
- Develop To-Be business processes considering requirements to the reporting events and interaction with FGIS MDLP
- Identify necessary organizational changes while implementing To-Be business processes
- Determine To-Be IT architecture with account to integration of systems and data flows (interaction with WMS module and other external IT systems)
- Develop IT functional requirements considering reporting events format for FGIS MDLP and requirements to crypto-protection
- Set requirements to printing and scanning equipment considering the requirements to identification tools for secondary and tertiary packaging
- Decide upon engaging external IT specialists/ solutions

Development

- Make necessary updates of IT systems which transfer/ exchange data to/with FGIS MDLP
- Tune printing and scanning equipment
- Ensure that necessary upgrades are made in external IT systems
- Develop testing scenarios based on the To-Be business processes

Testing & Launch

- Test printing and recognizing the labeling codes for secondary and tertiary packaging
- Test data transfer to FGIS MDLP for reporting events and getting system response via the personal account and via API
- Test integrated modules while interacting with WMS module and other IT systems
- Complete end-to-end testing based on To-Be business processes and testing scenarios for all reporting events
- Complete all other organizational and technical steps necessary for commencing commercial operation

Project execution control throughout all stages; coordinating and managing the working group; monitoring timing, deadlines and dependencies

Monitoring updates and changes of regulatory framework; setting up the decision-making process in the situation of regulatory uncertainties; "what-if" scenarios analyses

A complex Track & Trace project: KPMG services

Project management

Planning

- Analyzing project status, project plan and interim results, proviging recommendations on improvements
- Improving the existing schedule and roadmap of T&T implementation project; functional planning
- Help with selecting the automated IT solution for T&T (for own or external IT systems)

Ongoing execution

- Coordinating global and local project teams' activities
- SPOC function for all the project participants
- Cross-functional work and communication management
- Support while interacting with external project participants (3PL provider, customs broker, etc.)

Control and reporting

- Progress monitoring and control
- Regular reporting, proactive identification of risks and challenges; risk management solutions
- Regular communications and presenting the status/ results to the project management/ steering committee

Business processes

- To-Be business processes catalogue considering T&T requirements, reporting events and interaction with FGIS MDLP
- To-Be business process maps considering requirements for inputs/outputs, stages, responsibilities allocation, paper and e-documents workflow
- List of necessary organizational changes resulting from the business processes changes

Developing requirements to IT systems (SMA L3, L4):

- Recommendations on To-Be IT architecture and IT systems integration
- Developing functional requirements to IT systems transferring/exchanging data to/with FGIS MDLP
- Developing controls to be implemented into IT systems

Laws and Regulations

- Consulting and developing technical position on ambiguous matters and matters not addressed by law, including other affected regulatory areas (statutory and tax accounting, transfer pricing, customs and legal issues)
- "What-if" analyses focused on regulatory and fiscal risks
- Operational and legal support while interacting with 3PL providers and other data exchange participants
- Developing controls and processes to ensure transparency and compliance with the regulatory requirements

Results *(depending on the scale of KPMG involvement selected by you):*

- Effective and flexible project management; coordinated efforts of all local and global participants; meeting deadlines and quality demanded
- Integrated IT systems and smoothly functioning data exchange with FGIS MDLP
- Harmonized approaches to interaction with the project's external participants
- Technical position on complicated/unclear regulatory matters and understanding of existing risk scenarios

Why KPMG?

Experience of serialization and labeling of pharmaceuticals

Complex projects on serialization/labeling realized for pharmaceutical companies in Russia; availability of solutions tested in practice and action

Management and IT consultancy capabilities

Many years of experience in business processes modeling, IT systems requirements development, their configuration and integration

Industry-specific experience

Broad experience of advising pharmaceutical companies; Life Sciences center-of-excellence in Russia and the CIS

Availability of profound international track & trace expertise

KPMG runs an international center-of-excellence for Track & Trace in Life Sciences

Multi-profile expertise

Availability of specialty teams and experts within KPMG who could be immediately onboarded to the project as necessary (to address customs, legal, compliance, cyber-security and other matters)

Involvement in law-making activities

Active participation in sessions/roundtables and direct contacts with the Ministry of Healthcare, Federal Service on Surveillance in Healthcare and Social Development, Ministry for Industry and Trade, CRPT, business associations, experts and etc.

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