



# Track & Trace of pharmaceuticals in Russia: comprehensive advisory support

September 2020

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*

# 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*

# 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

# 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*

# 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:**

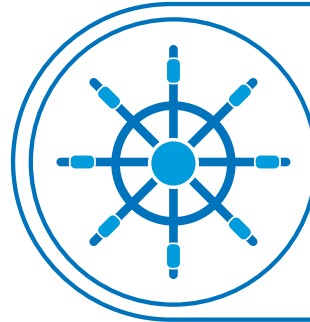
Mandatory labelling for 12 Nosologies products

**31.12.2019:**

Deadlines during the transition period affirmed  
*Government Resolution # 1954*

# Key risks and uncertainty areas

## Risks



## Risk management methods

- FGIS MDLP development is still in progress
- Rules are more complicated as compared to EU Track & Trace: ~60 reporting events, additional cryptocoding, financial data reporting
- Changes to identifier (labeling code) structure negatively impact the production process, leading to cost and/or defective rate increase
- FGIS MDLP failures and disruptions while big data processing; lack of information on the data protection level and tools within FGIS MDLP
- Existing IT solutions (especially international ones) are not customized to the Russian T&T requirements

- Direct interaction with FGIS MDLP Operator to clarify data flows and IT systems requirements
- Elaborated planning and execution of data exchange processes redesign and IT systems integration, including external ones
- Upfront testing of high-density identification codes on the existing equipment
- Developing back-up solutions for data transfer to corporate repository
- Upfront assessment of IT solutions capacity/functionality and cost-benefit analysis of the improvements required



## Areas for in-depth analysis and risk assessment:

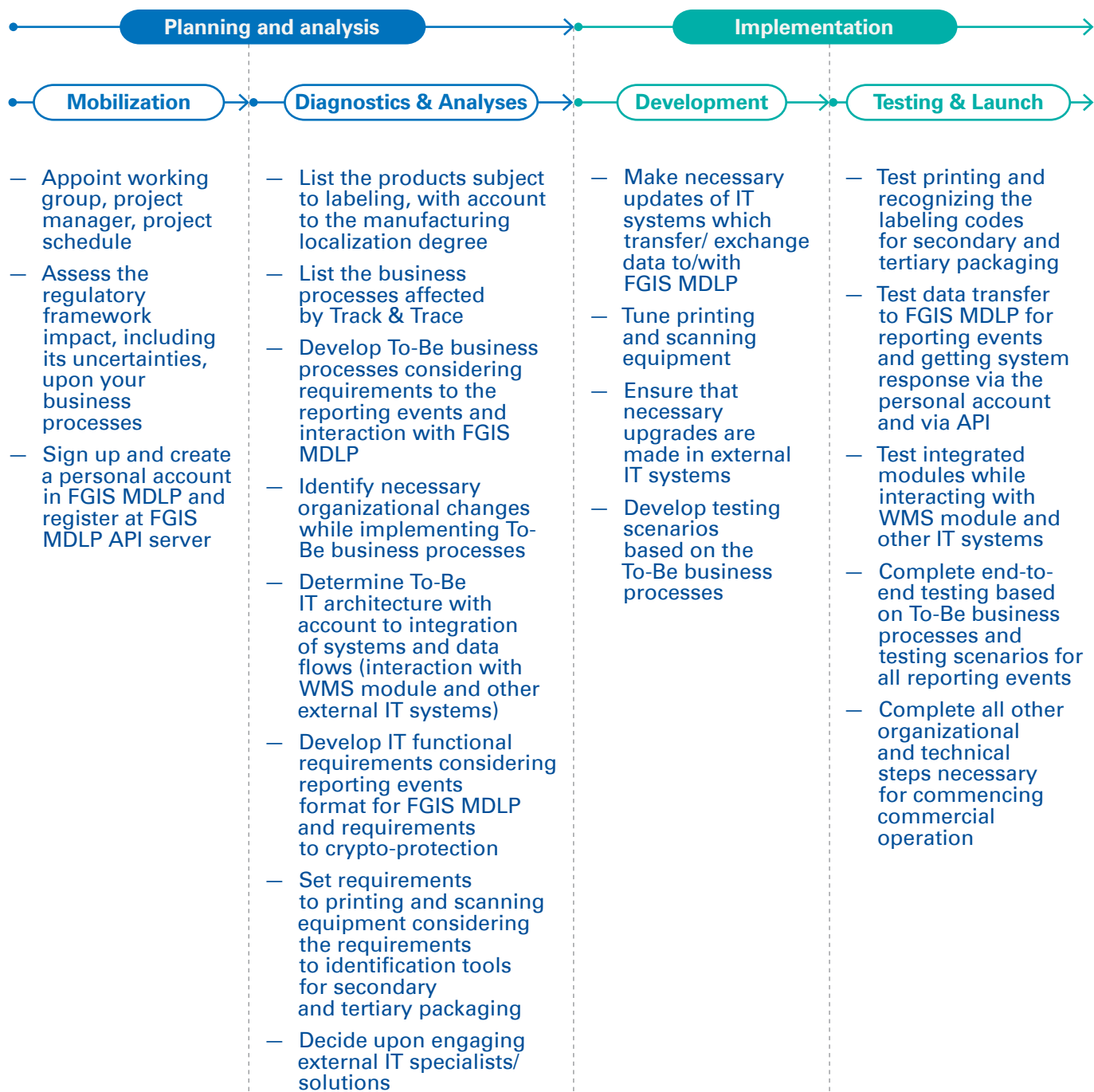
- Changes to business processes
- Unclear accounting issues (in particular, accounting and reporting on prices)
- IT systems changes
- Reporting changes



## 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?



**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, providing 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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