Track & trace solutions for pharmaceuticals
Track & trace of pharmaceuticals

Key dates:
• Starting from 1 January 2020, it will be mandatory to label pharmaceuticals and transfer information about their circulation to the Pharmaceuticals Monitoring System (SMDLP)
• Pharmaceuticals under the Seven Nosologies program are an exception: these pharmaceuticals must be labelled and information about their circulation transferred to the SMDLP from October 1, 2019

Key Requirements
• Serialization and aggregation of pharmaceuticals produced in Russia and abroad
• Reporting to the SMDLP at every stage of pharmaceuticals circulation, starting from production to the moment of sale in pharmacies and during public procurements, or disposal, including by healthcare providers.

Risks and costs
• Costs to set up and maintain the system
• Changes to business processes, document flow and internal controls
• Accessibility of track & trace data for regulators

Opportunities
• Analysis of reliable data in real time to assess the effectiveness of measures to market pharmaceuticals
• Electronic document flow and streamlining of the tax and accounts reporting process
Deliverables (key documents):
- Description of updated business processes to support the implementation of pharmaceutical track & trace (text and diagrams)
- Mapping table between data already contained in the company’s IT systems and data to be passed on to the SMDLP
- Review of the risks of implementing pharmaceutical track & trace and recommendations to eliminate them
- Updated internal policies and documents associated with implementing pharmaceutical track & trace

Our objectives:
- We make sure client employees have a complete understanding of changes to their functions and help develop an action plan to implement pharmaceutical track & trace
Below is a detailed breakdown of our services in each area:

**Business processes**
- Analyzing existing business processes
- Developing target business processes
- Preparing diagrams and textual descriptions for target business processes
- Developing and implementing monitoring procedures
- Assistance in implementing electronic document flow with a focus on the requirements of pharmaceutical track & trace and other compliance procedures (anti-monopoly, price regulations, etc.)
- Putting together an implementation road map for pharmaceutical track & trace based on the results of the analysis

**Tax, customs and other risks**
- Analyzing operational, financial, tax and customs risks associated with the implementation of pharmaceutical track & trace and developing recommendations to eliminate them

**Technical assistance**
- Developing mapping tables for the data required to generate reporting messages and the data already contained in the company’s IT systems
- Analyzing the current IT architecture and developing targeted improvements to it
- Developing the functional and technical requirements for IT solutions
- Developing an evaluation model for IT solutions and potential suppliers of these solutions

**Internal regulations**
- Updating and establishing internal policies/procedures for pharmaceutical track & trace

**Implementation support for track & trace**
- Providing project management office (PMO) services during the implementation of systems
- Joint participation in the pilot project run by the labeling system's operator (Center for Research in Perspective Technologies, CRPT) and representation of the company’s interests
- Quality control of system implementation, including the monitoring of business requirements

**Post-implementation support**
- Diagnostics of the newly implemented business processes and monitoring procedures
- Developing recommendations based on the diagnostics

**Staff training**
- Support in forming working groups to implement pharmaceutical track & trace within the company
- Conducting training sessions/seminars for employees on the legal requirements of pharmaceutical track & trace
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