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ДЕЛОВЫЕ РЕШЕНИЯ И ТЕХНОЛОГИИ

BUSINESS SOLUTIONS AND TECHNOLOGIES

Russian Medical Devices Market Key Legislation

BST Consulting



Russian Medical Devices Market: Key Legislation (1/2)

01

Medical devices must be registered in accordance with the legislation of the Russian Federation.

Upon registration of medical devices, a market authorization is issued.

02

Invasive medical devices are subject to government price regulation.

The government regulates the maximum manufacturer's selling prices and the maximum wholesale mark-up to actual selling prices.

03

In the event of significant changes to a medical device, it is necessary to made changes in the market authorization.

In case the market authorization is not changed, the company can be subject to criminal legislation of Russian Federation.

04

Importation/sale of medical devices can be subject to VAT at the following rates depending of their type: 20 %, 10 %, or exempt from VAT

To confirm the 10 % VAT rate on import of medical device, it is necessary to use the codes for imported goods (TN VED code). To confirm the 10 % VAT rate for local sale of medical device it is necessary to use the code for locally produced goods (OKPD code). To apply the VAT exemption, the medical devices have to be complied with both codes for import and local sales.

05

There is a legislative initiative that introduces a 0 % VAT rate for medical devices.

To confirm the 0 % VAT rate, it is necessary that the medical device is in the register of industrial products manufactured in the Russian Federation and (or) the Eurasian register of industrial goods of the EAEU member states.

Russian Medical Devices Market: Key Legislation (2/2)

06

“Three’s a crowd rule” and “two’s a crowd rule” is applied to medical devices in state procurement.

“Three’s a crowd rule”: applications offering foreign medical devices are automatically rejected from state procurement if at least two applications are submitted with EAEU medical devices.

“Two’s a crowd rule”: applications with foreign medical devices are rejected from state procurement if at least one application are submitted with EAEU medical devices.

07

Medical device is treated as manufactured in the Russian Federation in accordance with scoring system.

Scores are granted for the use of the Russian raw materials and/or the use of Russian components and/or the implementation of technological operations during assembly and/or the volume of R&D.

08

The Russian Federation provides benefits for localization of medical devices.

For example, tax and customs benefits, preferential loans, advantages in state procurements.

09

Incentive payments (bonuses and services) are actively analyzed and challenged by tax authorities in current court practice resulting in additional tax costs up to 40% (20% profits tax, 20% VAT).

Therefore, these payments should be carefully structured.

10

8 August 2023 certain provisions of Double Tax Treaties with some unfriendly countries (including Japan) were suspended.

This suspension resulted in inability to apply reduced WHT rates to dividends, interest, royalties.

11

Russian Transfer Pricing rules changes starting from 2024

Increasingly under the spotlight, the proposed measures providing for a major clampdown on the transfer pricing rules are:

- to classify TP adjustments for controlled transactions with non-residents as dividends subject to withholding tax;
- to expand the related party criteria;
- to calculate arm’s length prices as the median of the arm’s length range;
- to expand the scope of reportable information on controlled transactions;
- to increase the fines for transfer pricing breaches;
- to change the safe harbor interest income/expense rates.

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