THE PROCEDURE HAS COME INTO FORCE FOR REGISTERING MANUFACTURERS' PRICES FOR MEDICAL DEVICES THAT ARE IMPLANTED IN A HUMAN ORGANISM

FAO: Russian and foreign manufacturers and distributors of medical devices

Law firm Pepeliaev Group advises that rules have been established for the state regulation of prices for medical devices which have been included in the list of medical devices that are implanted in a human organism when medical care is provided under the state programme guaranteeing that free medical care will be provided to the public ("medical devices implanted in a human organism").

The Resolution of the Russian Government (the "Resolution")[1] on this came into force on 16 January 2016.

The list of medical devices implanted in a human organism was approved by the Russian Government's Directive No. 2762-r dated 29 December 2014.

Content of the Resolution

The Resolution approves (1) the rules for the state registration of limits for manufacturers' prices for medical devices implanted in a human organism, (2) the method for establishing such limits and (3) rules for keeping the state register of limits for manufacturers' prices for medical devices implanted in a human organism. The Resolution entrenches the uniform approach to registration of limits for manufacturers' prices for medical devices implanted in a human organism which are produced abroad and in member states of the Eurasian Economic Union.

State registration of limits for manufacturers' prices for medical devices implanted in a human organism should be handled by the Federal Service on Surveillance in Healthcare (known in Russian by the abbreviation "Roszdravnadzor").

Before 12 February 2016 Roszdravnadzor should send to manufacturers of medical devices implanted in a human organism requests for information that is required for calculating the average weighted manufacturers' prices for medical devices by category in accordance with the nomenclature system for medical devices.

Manufacturers should send to Roszdravnadzor the required information not later than one month from when they receive the request, in other words, before 12 March 2016.

Before the end of June 2016 Roszdravnadzor is expected to calculate average weighted manufacturers' prices for medical devices, agree them with the Federal Antimonopoly Services (the "FAS") and publish this information on its official website.

[1] Resolution No. 1517 of the Russian Government dated 30 December 2015 "On the state regulation of prices for medical devices which have been included in the list of medical devices that are implanted in a human organism when medical care is provided in the context of the state programme guaranteeing that free medical care will be provided to the public" (together with the "Rules for the state registration of limits for manufacturers' prices for medical devices which have been included in the list of medical devices that can be implanted in a human organism when medical care is provided under the state programme guaranteeing that free medical care will be provided to the public", "Rules for keeping the state register of limits for manufacturers' prices for medical devices which have been included in the list of medical devices that can be implanted in a human organism when medical care is provided under the state programme guaranteeing that free medical care will be provided to the public" and the "Method for establishing limits for manufacturers' prices for medical devices which have been included in the list of medical devices that can be implanted in a human organism when medical care is provided under the state programme guaranteeing that free medical care will be provided to the public and limits for wholesale markups on the actual manufacturers' prices for such medical devices").

When the average weighted manufacturers' prices are actually calculated and registered, certain problems may arise. According to the Resolution, such prices should be established for medical devices which are purchased in Russia. This, however, leaves open the question of how the price should be calculated when a medical device is acquired abroad and in Russia it is sold not by the manufacturer but by the primary distributor.

Before 15 July 2016 manufacturers of medical devices implanted in a human organism should send to Roszdravnadzor:

- an application for the state registration of the limit for manufacturer's price, which should be drafted in the form set out by the Resolution in hard copy or as an electronic document signed by an enhanced encrypted and certified digital signature;
- a document that confirms the powers of the authorised representative of the manufacturer of the medical device.

The Resolution does not set any special provisions regarding the registration of limits for manufacturers' prices for medical devices implanted in a human organism, for which one registration certificate (an "RC") has been issued. In principle, a situation may occur when a manufacturer may establish different prices for medical devices of the same type registered under one RC.

Executive authorities of constituent entities of Russia are recommended to establish limits for wholesale markups on the actual manufacturers' prices for medical devices implanted in a human organism in accordance with the method approved by the Resolution.

When a limit for manufacturer's price for a medical device is submitted for state registration, it may not exceed the average weighted manufacturers' price established by Roszdravnadzor.

It is stated that initial (maximum) prices of contracts for the purchase of medical devices implanted in a human organism may not exceed the registered limits for manufacturers' prices, taking account of the established limits for wholesale markups on the actual manufacturers' prices and value added tax (for medical devices that are subject to VAT).

The Resolution does not set any transitional provisions for government procurement of medical devices implanted in a human organism, for which limits for manufacturers' prices have not been registered and/or limits for wholesale markups have not been set. It is clear that, even if the situation develops favourably, limits for manufacturers' prices will not be registered before summer 2016. Moreover, it is very difficult to suggest when will executive authorities of constituent entities of Russia set limits for wholesale markups. In view of this, it remains unclear what actions a public sector customer should take to purchase medical devices implanted in a human organism, under Federal Law No. 44-FZ "On the contractual system in the area of the procurement of goods, work and services to provide for state and municipal needs" dated 5 April 2013 before limits for manufacturers' prices are registered and limits for wholesale markups are set. We believe that this provision of the Resolution should not apply until limits for manufacturers' prices are registered for medical devices implanted in a human organism and limits for wholesale markups are set.

The Resolution does not set any rules for the re-registration of limits for manufacturers' prices for medical devices implanted in a human organism. However, it obliges the Russian Ministry of Healthcare (the "Health Ministry") together with Ministry of Economic Development, Ministry of Finance, Ministry of Industry and Trade, FAS and Roszdravnadzor to submit to the Russian Government before 1 October 2016 agreed proposals regarding the procedure for re-registration. These should take into account an analysis of the practice of the state registration of limits for manufacturers' prices.

What to think about and what to do

We recommend that Russian and foreign manufacturers and distributors of medical devices take a number of actions to ensure compliance with the Resolution:

- to identify which medical devices from the company's range of products are in the list of the devices approved by the Russian Government's Directive No. 2762-r dated 29 December 2014;
- to perform an analytical review of how the company sets its prices for medical devices implanted in a human organism and to evaluate the competitive environment;
- to send to Roszdravnadzor the information required for the regulator to calculate the average weighted manufacturers' prices;
- to calculate limits for manufacturer's prices;
- to apply to Roszdravnadzor in the prescribed manner before 15 July 2016 for the registration of a limit for manufacturer's price.

We recommend that parties operating on the market continuously monitor how subordinate legislation is developed and adopted in pursuance of the Resolution, and keep a close watch over regulatory acts of executive authorities of constituent entities of Russia as well as clarifications and practice of the FAS, Roszdravnadzor and the Health Ministry.

Help from your adviser

Pepeliaev Group's lawyers are ready to provide advice on any matters connected with registering the limits for manufacturers' prices for medical devices implanted in a human organism.

Pepeliaev Group's lawyers are also available to provide comprehensive legal support on any matters connected with state procurement of medical devices implanted in a human organism, including drafting legal advice and documents as well as representing companies before the antimonopoly authority and in court.

Contact details

Sergey Klimenko
Head of Life Sciences Group
Pepeliaev Group
T.: +7 (495) 967-00-07
s.klimenko@pgplaw.ru