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STATE REGULATION OF PRICES HAS BEEN INTRODUCED FOR CERTAIN TYPES OF MEDICAL DEVICES

For the attention of Russian and foreign manufacturers and distributors of medical devices

Pepeliaev Group offers a brief overview of Federal Law No. 33-FZ[1] (the "Law") dated 8 March 2015, which establishes state regulation of prices for medical devices which have been included in the list of medical devices that are implanted in a human body when medical care is provided in the context of the programme of state guarantees of providing medical care to citizens free of charge.

The Law will come into force on 9 May 2015.

Background

This Law was adopted mostly in response to the uncertain situation that has existed in Russia for the last several years with regard to foreign trade. The Law has been developed as a part of the measures in the area of healthcare and providing medicines and medical devices which are set out in the Plan of Priority Actions for Providing a Sustainable Development of the Economy and Social Stability in 2015[2]. It aims to stabilise the economic situation in the medical devices market, preventing unjustified price growth and any forms of price speculation under the pretext of an unstable economic situation, including the consequences of the recent sanctions against Russia.

Main New Developments

The Law has introduced state regulation of prices for medical devices (the **"Devices"**) that are implanted in a human body when medical care is provided in the context of the programme of state guarantees of providing medical care to citizens free of charge. At present the list of such Devices is approved by the Russian Government's Directive No. 2762-r dated 29 December 2014.

In accordance with the Law, state regulation of prices will be implemented by identifying the limits for manufacturers' prices and the limits for wholesale and retail markups on the actual manufacturers' prices for the Devices in accordance with the procedures approved by the Russian Government. Therefore, the authors of the Law have used the existing approach to state regulation of prices for medicines.

The Federal Service on Surveillance in Healthcare (**"Roszdravndzor"**) will perform state registration or re-registration of the limits for manufacturers' prices for the Devices and will keep the state register of such prices.

It should be noted that, unlike the state regulation of prices for medicines from the vital and essential medicines list, the Law does not impose restrictions on:

a) selling, disposing of or releasing Devices for which no limits have been registered with regard to manufacturers' prices;

[1] Federal Law No. 33-FZ "On amending article 80 of Federal Law "On the fundamentals of healthcare for citizens in the Russian Federation"" dated 8 March 2015.

[2] Approved by Directive No. 98-r of the Russian Government dated 27 January 2015.

b) disposing of and releasing Devices by manufacturers for prices which exceed the registered limits for manufacturers' prices for the Devices;

c) disposing of and releasing Devices by wholesale and retail traders for prices which, taking into account the limits of the wholesale and retail markups, exceeds the amount of the actual selling price[3].

However, despite there being no such restrictions, the Law does not set any special or transitional provisions that would apply if any manufacturers of the Devices fail to register limits of their prices for the Devices by the time the Law comes into force or afterwards. This may entail legal uncertainty for a public sector customer that may wish to acquire the Devices through a public procurement system. In accordance with article 22(8) of Federal Law No. 44-FZ "On the contractual system in the area of procurement of goods, work and services to provide for state and municipal needs" dated 5 April 2013 (the **"Law on the Contractual System"**), if the prices of the acquired products are subject to state regulation, a public sector customer shall define the starting (maximum) price of the public contract (**"SMPC"**) using a method based on a schedule of rates.

(i) If none of the manufacturers of a certain type of the Devices have registered their prices for the Devices as of when the auction documentation is drafted.

In our opinion, the customer may establish the SMPC using a basic method of comparable market prices (market analysis)[4]. In this case the customer should be prepared to justify the use of this method.

(ii) *If some of the manufacturers of a certain type of the Devices have registered their prices as of when the auction documentation is drafted.*

At present we believe that in this case the customer would still have to use a method based on a schedule of rates and also include in the auction documentation a requirement that the price for the Device be registered and that the documents be provided that confirm the price was registered (a price negotiation memorandum and an extract from the order of Roszdravnadzor concerning the registration of the price to the Device). In our opinion, the public sector customer will most likely have to dismiss bids to supply the Devices where the limit has not been registered for the price or to refuse to enter into the contract with the winner (similar to the rules for medicines from the vital and essential medicines list, for which no limit of the selling price is registered[5]).

At present the Russian Government is expected to adopt several regulations to implement the Law in practical terms:

a) The procedure for identifying the limits for manufacturers' prices and wholesale and retail markups on the actual manufacturers' prices for the Devices (the **"Procedure for defining prices"**, currently undergoing through public consultation[6]);

b) The procedure for Roszdravndzor to use its powers to perform state registration (re-registration) of the limits for manufacturers' prices for the Devices and to keep the register of limits for manufacturers' prices (has passed the public consultation stage[7]).

It is expected that the Russian Government will adopt these documents by the time the Law comes into force. However, these documents do not remove the legal uncertainty mentioned above. This situation needs to be regulated through amendments to the legislation or official clarifications by competent state authorities.

[3] Regulation of prices for medicines from the list of vital and essential medicines includes these restrictions (article 61(2) and 61(3) of Federal Law no. 61-FZ "On the circulation of medicines" dated 12 April 2010).
[4] Article 22(1) and 22(12) of the Law on the Contractual System.
[5] Article 31(10)(1) of the Law on the Contractual System.
[6] http://regulation.gov.ru/project/22385.html?point=view_project&stage=2&stage_id=17155
[7] http://regulation.gov.ru/project/22387.html?point=view_project&stage=2&stage_id=16666

What to think about and what to do

We recommend that companies continuously monitor regulatory acts that are being adopted in pursuance of new legislative provisions regarding state regulation of prices for medical devices implanted in a human body.

In order to bring companies' activities in line with the requirements of the Law, those active on this market are advised to take certain preparatory steps including:

- To define 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 analyse the company's current pricing policy with regard to the Devices;
- After the corresponding regulatory acts come into force, to calculate the limits for manufacturer's prices and wholesale and retail markups in accordance with the Procedure for defining prices;
- To apply to Rozdravnadzor in accordance with the prescribed procedure to have the limit registered for the manufacturer's price for the Device;
- To bring in line with the new legislative requirements the company's documents connected with the pricing policy regarding the Devices.

Help from your adviser

Pepeliaev Group's lawyers are ready to provide advice on any matters connected with identifying, calculating and registering the limits for manufacturers' prices for medical devices implanted in a human body as well as identifying the limits for the wholesale and retail markups on such medical devices. We are also ready to draft all necessary internal documents of a company.

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