Legal alert

pepeliaev group

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RESTRICTIONS HAVE BEEN SET IN TERMS OF ADMITTING CERTAIN CATEGORIES OF MEDICAL DEVICES TO STATE AND MUNICIPAL PROCUREMENT PROCESSES

For the attention of CEOs and heads of legal and commercial departments of companies involved in producing and distributing medical devices

Pepeliaev Group advises that Resolution No. 102 of the Russian Government "On restricting the admission of certain categories of medical devices originating in foreign countries for the purposes of procurement for state and municipal needs" dated 5 February 2015 (the "Resolution") was published on 6 February 2015 on the official legal information portal (www.pravo.gov.ru)[1].

The Resolution was drafted by the Russian Ministry of Industry and Trade at the instruction of the Russian Government and in accordance with the Plan of the First Priority Measures to Provide for Sustainable Development of the Economy and Social Stability in 2015[2].

Please note that Order No. 155 of the Russian Ministry of Economic Development "On the terms and conditions on which products originating in foreign countries are admitted for the purposes of procurement of goods, work and services for state and municipal needs" dated 25 March 2014 is still in force. This Order sets the terms and conditions on which foreign medical devices may be admitted to procurement procedures (regarding the 15% preference).

The Resolution will come into force 7 days after it is officially published, in other words on 14 February 2015.

The Main New Developments

The restrictions apply only to a limited number of medical devices.

The Resolution sets a list of medical devices originating in foreign countries, which are restricted in terms of being admitted to public procurement processes **(the "List")**. The list contains the name of the type of the medical device and the code from the Russian National Classification of Products by the types of Economic Activity (known, in line with its Russian acronym, as the **"OKPD"**)[3]. According to the information from the Russian Government's website, the List was compiled taking into account that, for each type of medical device, a minimum of two domestic producers should be available that can provide for the current needs of the healthcare industry in Russia and whose manufacturing process complies with the inter-state standard GOST ISO 13485-2011 "Medical devices. Quality management systems. System requirements for the purposes of the regulation".

[1] http://publication.pravo.gov.ru/Document/View/0001201502060001

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

[3] The Russian National Classification of Products by the types of Economic Activity OK 034-2007 (adopted and put into force by Order No. 329-r of the Federal Agency on Technical Regulation and Metrology dated 22 November 2007).

It is therefore assumed that the most high-technology and innovative medical devices for which no domestic equivalents exist have not been included in the List.

The restriction will apply to all bids containing offers to supply medical devices originating in foreign countries except for Armenia, Belarus and Kazakhstan. Ordering parties must reject such bids if at least two bids have been placed to identify a supplier which are consistent with the requirements of the procurement documentation and at the same time:

- contain offers for the supply of one or several types of medical devices which are on the List and originate in Russia, Armenia, Belarus or Kazakhstan;
- do not contain any offers for the supply of the same type of the medical device of the same producer.

The country of origin of a medical device which is on the List will be identified based on a certificate of origin issued by authorised agencies (organisations) of Russia, Armenia, Belarus or Kazakhstan. The form of such certificate is approved by the Rules for Identifying the Country of Origin of a Product in the Commonwealth of Independent States[4] and should be in line with the criteria for identifying the country of origin of a product which are set out in these Rules.

Having reviewed the Resolution, we believe that the restriction on admitting foreign medical devices will not apply:

- to procurement of those medical devices originating in foreign states which are not on the List;
- if along with the bid that includes the offer to supply the foreign product, one other bid has been placed that includes an offer to supply the product and which has as the country of origin Russia, Armenia, Belarus or Kazakhstan;
- if along with the bid including the offer to supply the foreign product two or more bids have been placed with an offer to supply the same type of a medical product with the same producer which originates in Russia, Armenia, Belarus or Kazakhstan;
- if only foreign products are offered in all bids that have been placed.

The legislation does not prohibit offers from being combined in one bid for the supply of domestic and foreign goods if they are interconnected. Therefore, one bid may at the same time include offers to supply both Russian and foreign medical devices (including those from Armenia, Belarus or Kazakhstan).

If the Resolution is interpreted literally, the restriction on being admitted to procurement seems to apply to all bids for the supply of foreign medical devices, except for those from Russia, Armenia, Belarus or Kazakhstan. However, the Resolution does not state how (and even whether) the restriction will apply for bids that offer to supply foreign medical devices at the same time as products from Russia, Armenia, Belarus or Kazakhstan.

In practice there is likely to be uncertainty as to how the ordering party may act in such a situation. It appears that the ordering party's actions in a specific situation will depend on the details of each individual bid and all of the bids taken as a whole. If the Resolution is not to be interpreted ambiguously and consistent enforcement practice is to be created, in our opinion, the Russian Government needs to step in with clarifications.

Also, in accordance with the Resolution, the restrictions on being admitted to procurement procedures do not apply to:

- notifications placed in the single procurement information system regarding procurement of medical devices and/or invitations to participate in a process of identifying a supplier when these were sent in a private form before the Resolution came into force;

[4] Approved by Agreement on the Rules for Identifying the Country of Origin of a Product in the Commonwealth of Independent States dated 20 November 2009.

– procurement of certain medical devices in the List by Russian diplomatic missions, consular offices, trade missions and official Russian missions to international organisations to support their activities in a foreign state.

What to think about and what to do

In view of these developments we recommend that you review your current strategy of offering medical devices for state and municipal procurement. If necessary, you should adjust it to take into account the restrictions introduced by the Resolution.

Help from your adviser

Pepeliaev Group's lawyers have significant experience in providing advice to and representing the clients in matters connected with procurement of medical devices. They stand ready to provide comprehensive assistance and legal support on these matters in connection with the developments discussed above. This may include drafting legal advice and documents as well as representing companies in procurement-related disputes.

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