RUSSIAN DESK

Dear readers,

Under Article 14 of the Procurement Law[1], the so-called national regime applies to state procurement; this involves the establishment of a number of prohibitions, restrictions, and conditions on admission for certain goods, work, and services of foreign origin. The nuances are disclosed in subsidiary legislation. The Ministry of Industry and Trade (MIT) has submitted a draft Government resolution that establishes new rules for applying the national regime. These rules are expected to come into force on 1 January 2020 (hereinafter the "**Draft Changes**").

The Ministry of Finance has also prepared changes to the list of goods that are subject to the admission rules. The order implementing these changes has already entered into force.

This newsletter is dedicated to these restrictions and conditions on the admission of foreign medical goods to state procurements.

Best regards,

Kamil Karibov
Ph.D. | Partner

New rules for complying with the national regime in the state procurement of medical products

THE STATUS QUO

Medical products are currently subject to the restrictions established by Government Resolution No. 102[2], as well as the conditions on admission established by Order No. 126n[3].

The essence of the restrictions is that, for the purposes of the state procurement of medical products listed in the Annex to Resolution No. 102, the purchasing agency should reject all offers to supply goods of foreign origin (except for those of the member states of the Eurasian Economic Union (EAEU)), provided that at least two offers to supply goods have been received from the EAEU that meet the requirements of the relevant procurement. This "odd man out" principle means that, in such a case, offers to supply foreign goods are simply rejected.

If a proposal involving foreign goods has not been rejected and turns out to be the best proposal, admission conditions still apply. These involve the conclusion of contracts under competitive bidding with a price reduction of 15% off the price proposed by the winner, in cases where the winner's bid contains an offer to supply goods, where the country of origin of at least one of these goods is a foreign state (other than an EAEU member).

Thereby Russian suppliers receive preferential treatment in state procurements.

[1] Federal Law No. 44-FZ dated 5 April 2013 "On the Contract System in the Field of Procurement of Goods, Work, and Services for State and Municipal Needs".

[2] Russian Government Resolution No. 102 dated 5 February 2015 "On Restrictions and Conditions on Admission of Certain Types of Medical Goods Originating in Foreign States for the Purposes of Procurements for State and Municipal Needs".

[3] Ministry of Finance Order No. 126n dated 4 June 2018 "On Conditions on the Admission of Goods Originating in a Foreign State or a Group of Foreign States for the Purposes of the Procurement of Goods for State and Municipal Needs".

BEITEN BURKHARDT

NEW RESTRICTIONS

The Draft Changes affect 17 categories (sub-categories) and 1 sub-group of medical products under NC 034-2014 (CPA 2008). Russian National Classification of Products by Type of Economic Activity.[4]

The list of products attached to the Draft Changes contains references to the same categories (sub-categories) and sub-groups of medical products as in Resolution No. 102. However, Resolution No. 102 lists specific types of medical products in these categories (sub-categories) and sub-groups that are subject to the restrictions. For example, sub-category 26.60.11.111 under the Classification includes CT scanners, and is presented in this way in the list attached to the Draft Changes. In the list attached to Resolution No. 102, the same sub-category is understood to be CT scanners with 1 to 64 slices, i.e. only certain types of CT scanners. In addition, the sub-categories indicated in the list attached to the Draft Changes include only one type of equipment that coincides with those given in the Classification, whereas the list attached to Resolution No. 102 under the same sub-category number gives a different type of product (or several types).

In addition, neither Resolution No. 102 nor Order No. 126n will cease to be in force in connection with the passage of the Draft Changes. It is expected that they will be harmonised with the Draft Changes. On the whole, we note that the list of medical products to which admission restrictions or conditions apply will expand as a result of the Draft Changes.

Clause 5 of the Draft Changes expressly stipulates that admission restrictions extend to the procurement of work and services that involve the procurement of goods indicated in the Annex to the Draft Changes. This is in line with the positions taken in court practice. For example, the Supreme Court applies the restrictions established by Resolution No. 102 not only to sale and purchase agreements for the corresponding goods, but also to contracting agreements and service agreements containing elements of the sale and purchase (supply) agreements for such goods.[5] If the Draft Changes will enter into force on 1 January 2020, this position will be enshrined in law and will become mandatory for state and municipal purchasing agencies.

According to the Draft Changes, registration of certain types of goods in the register of industrial products manufactured in the Russian Federation will also serve as confirmation of the country of origin. This register will be created and maintained using the State Information System for Industry (GISP) according to the procedure to be approved by the MIT. It is planned to transfer the operation of the GISP from the MIT to the Federal State Autonomous Institution "Russian Foundation for Technological Development"[6].

In the application to participate in procurements, the procurement participant must disclose information on the country of origin of goods (with the submission of supporting documents, if necessary) which will serve as confirmation of compliance with the restrictions. When performing the contract, the supplier must provide an excerpt from the register of Russian industrial products or a copy of Certificate ST-1 (if the goods are not registered) (point 8 of the Draft Changes).

The Draft Changes also stipulate control over the implementation of innovations: The purchasing agency will be required to place information on the procurement results in the GISP within 10 business days after the conclusion of the contract. If no procurement took place, this information must also be placed in the system (point 10 of the Draft Changes).

WHAT STILL NEEDS TO BE EXPLAINED

As in the case of Resolution No. 102, the Draft Changes contain a rule (point 6) that one contract (one lot) cannot include both industrial products included in the corresponding resolution and products not included in the resolution. Taking into account the fact that neither Resolution No. 102 nor Order No. 126n cease to apply in connection with the adoption of the Draft Changes, a situation may arise in which various medical products will be purchased that are covered by the provisions of all three legal acts. Consequently, according to the logic of the lawmakers, the goods from each list will have to be purchased in a separate lot. As a result, the purchasing agency will have to purchase medical products from various Russian manufacturers separately even if this is not economically justified. The additional work of forming separate lots and preparing procurement documentation also falls to the purchasing agency.

The Draft Changes do not give an absolutely clear-cut description of the procedure for confirming compliance with the restrictions. For example, point 8 indicates that to confirm compliance the procurement participant must provide the document stipulated in point 6. However, point 6 does not contain any information on this. Even if this is a clerical error, and what is really meant is point 7, the ambiguity remains: according to point 7, the entry of goods in the register of industrial products manufactured in the Russian Federation or Certificate ST-1 may serve as confirmation of the country of origin. The grounds for entering goods in this register are the availability of a confirmation statement on the manufacture of industrial products in the Russian Federation. This leads to the question of whether a reference to the goods in the register is sufficient, or whether the aforementioned statement or Certificate ST-1 must be submitted.

CHANGES TO ORDER NO. 126N

The Ministry of Finance has added to the list of goods subject to the conditions on admission.[7] The amendments to Order No. 126n entered into force on 12 November 2019.

[4] Approved by Order No. 14-st of the Federal Agency on Technical Regulating and Metrology dated 31 January 2014.

[5] Clause 29 of the Judicial Review of the Supreme Court of Russia No. 2 (approved by the Presidium of the Supreme Court on 17 July 2019).

[6] Draft Order of the Ministry of Industry and Trade of Russia "On Transferring the Functions of the Operator of the State Information System for Industry to the Federal State Autonomous Institution ‚Russian Foundation for Technological Development'" (as of 30 September 2019) (prepared by the Ministry of Industry and Trade of Russia).

[7] Order No. 165n of the Ministry of Finance of Russia dated 14 October 2019 "On Introducing Amendments to the Annex to Order No. 126n of the Ministry of Finance of the Russian Federation dated 4 June 2018 'On the Conditions on Admission of Goods Originating in a Foreign State or a Group of Foreign States to Procurements of Goods for State and Municipal Needs'".

The medical equipment included in the list was expanded: Instead of the current 14 items, all items of group 26.60 of the Classification related to medical equipment are included in the list (with the exception of sub-group 26.60.9). These items include all electrical medical diagnostic and therapeutic radiation equipment, with the exception of services on the manufacture of medical tools, and certain operations during the manufacture of radiation equipment and tools, rehabilitation equipment, and electrical medical diagnostic and therapeutic equipment performed by a subcontractor (26.90.9). Therefore now 42 items of medical equipment fall under the conditions on admission instead of the current 14 items.

The new list of goods subject to the conditions on admission also overlaps with the list attached to the Draft Changes and the current list of types of medical products given in Resolution No. 102. These overlaps lead to uncertainty in the application of the restrictions and conditions on admission to foreign products contained in different lists. For example, if the restrictions could not be applied, pursuant to clause 2(1) of Resolution No. 102 the conditions on admission should be applied. However, neither the law nor court practice contains clear explanations on whether the conditions on admission will apply to the goods included in the list attached to Resolution No. 102 but missing on the list attached to Order No. 126n. It would be useful to harmonise these lists.

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