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Changes in the procedure for admission of foreign medical devices and medicines to public procurement in Russia

On 1 January 2019, amendments to the Resolution of the Government of the Russian Federation No. 102 of 05.02.2015 that provides for restrictions and conditions for the admission of certain types of medical devices originating from foreign countries for the purpose of procurement for state and municipal needs ("Resolution No. 102") [1] and the Resolution of the Government of the Russian Federation dated November 30, 2015 No. 1289 that establishes the restrictions and conditions for admission for the purposes of procurement to ensure the state and municipal needs of medicinal products originating from foreign countries included in the list of vital and essential drugs (VED) ("Resolution No. 1289") [2], came into force.

1. Admission to public procurement of foreign medical devices

According to the amendments, when conducting public procurement tenders for certain types of medical devices included in the list of disposable medical devices from polyvinyl chloride plastics originating from foreign countries ("list No. 2") attached to Decree No. 102, the customer shall reject all the bids containing proposals for the supply of relevant medical devices originating from foreign countries (with the exception of the member states of the Eurasian Economic Union (EAEU)), provided that at least two bids that meet the requirements specified in the notice on the procurement and (or) the documentation for the purchase are submitted, which at the same time:

1) contain proposals for the supply of medical devices:

- the country of origin of which is only the member states of the EAEU;

- in the price of the final product of which the percentage of the cost of used materials (raw materials) of foreign origin corresponds to that specified in the Appendix to the Resolution of the Government of the Russian Federation of August 14, 2017 No. 967 [3];

- for manufacturing of which there is a document confirming the compliance of manufacturing with the requirements of GOST ISO 13485-2017 "Interstate standard. Medical devices. Quality management systems. Requirements for regulatory purposes";

2) do not contain proposals for the supply of the same type of medical device from one manufacturer or manufacturers belonging to the same group of persons, corresponding to the characteristics provided for by the Federal Law "On Protection of Competition".

The percentage of the cost of used materials (raw materials) of foreign origin in the price of final products is confirmed by an examination certificate issued by the Chamber of Commerce and Industry of the Russian Federation containing information on the share of the cost of foreign materials (raw materials) used to manufacture one unit of a medical device, or a similar document issued authorised body (organisation) of the EAEU member state.

In the event the customer rejected based on the above-mentioned restrictions the bids containing proposals for the supply of disposable medical devices made of polyvinyl chloride plastics included in the list No. 2 and originating from foreign countries, in the course of performance of the respective contract concluded upon results of the public procurement tender it is not allowed to replace:

- the medical device for the one the country of origin of which is not a member state of the EAEU or a percentage of the cost of used materials (raw materials) of foreign origin in the price of the finished product of which is higher than specified in the Annex to the Resolution of the Government of the Russian Federation № 967 dated August 14, 2017 for the corresponding year, and

- the manufacturer of the medical device.

2. Admission to public procurement of foreign medicines

The amendments to Resolution No. 1289 are aimed at supporting manufacturers of medicines with a high degree of production localisation in Russia and other EAEU member states.

Resolution No. 1289 provides that when procuring a medicinal product included in the VEM list (with one international non-proprietary name or, in the absence thereof, with a chemical or group name) that is the subject of one contract (one lot), the customer must reject all bids for supply of medicines originating from foreign states (except for the member states of Eurasian Economic Union (EAEU)), if there are at least two bids that meet the requirements of the notice of procurement and/or procurement documentation, which simultaneously:

- include offers to supply medicines originating from Russia or other EAEU member states;

- do not contain offers to supply medicines of the same manufacturer or manufacturers belonging to the same group of persons, as defined by the Federal Law 'On Protection of Competition'.

According to the amendments, in the event upon rejection of the bids by the customer at least one bid contains an offer to supply the medicines all manufacturing stages of which, including the synthesis of the active substance molecule in the production of pharmaceutical substances, are carried out in the territories of the EAEU member states, and information on such pharmaceutical substances is included in the registration files of the medicines in question, the admission conditions for the purpose of procurement of goods originating from a foreign state or group of foreign states established by the Ministry of Economic Development and Trade of the Russian Federation shall be applied to such medicines.[4]

The conformity of a medicinal product and pharmaceutical substance to the local content requirements shall be confirmed by declaring by the procurement participant of the information on:

- document confirming the manufacturer's compliance with the Rules of Good Manufacturing Practice of the Eurasian Economic Union approved by the Resolution of the Council of the Eurasian Economic Commission No. 77 dated 3 November 2016, or the Rules of Good Manufacturing Practice approved by the Ministry of Industry and Trade of the Russian Federation;

- document containing information on the stages of the technological process for manufacturing of medicinal products for medical use performed in the EAEU territory, issued by the Ministry of Industry and Trade of the Russian Federation.

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[1] Introduced by the Decision of the Government of the Russian Federation dated December 19, 2018 N 1590.

[2] Introduced by the Decision of the Government of the Russian Federation dated May 12, 2018 No. 572.

[3] Decision of the Government of the Russian Federation of August 14, 2017 N 967 "On the peculiarities of the purchase of disposable medical products (use) from polyvinyl chloride plastics for state and municipal needs".

[4] Order of the Ministry of Economic Development and Trade of the Russian Federation No. 155 'On the Conditions for the

Admission of Goods Originating in Foreign States, Works and Services Performed by Foreigners for the Purpose of Procurement of Goods, Works, Services for State and Municipal Needs', dated 25 March 2014, provides for the procedure for granting preferences in respect of the contract price to the procurement participants, whose applications or final offers contain offers to supply of goods produced in the territory of EAEU member states, in the amount of 15%, as well as the list of goods in respect of which these preferences are granted.

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