GRATA INTERNATIONAL

NEW SUPPORT MEASURES FOR MANUFACTURERS OF MEDICINAL PRODUCTS IN RUSSIA

Resolution of the Government of the Russian Federation No. 572 dated 12 May 2018 introduced amendments to Resolution No. 1289 dated 30 November 2015 that establishes restrictions and conditions for admission to the procurement for state and municipal need of medicinal products included in the list vital and essential medicines (VEM) originating from foreign states.

According to the current version of Resolution No. 1289, when purchasing 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'.

Resolution No. 1289 now provides that if 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 competent federal executive authority shall be applied to such medicines[1].

The conformity of a medicinal product and pharmaceutical substance to the local content requirements will 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 Decision 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.

Thus, the amendments are mainly aimed at supporting manufacturers of medicines with a high degree of production localisation in Russia and other EAEU member states.

The amendments become effective on 1 January 2019.

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[1] 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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Best Regards,

GRATA International Law Firm (Moscow)

Corporate and Commercial Law Department

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What we do:

- advising and legal support in participating in public and municipal procurement;
- advising on the statutory requirements and restriction regarding the import and circulation of various goods in Russia and other states;
- advising on compliance of advertising and marketing materials and events, marking, packing, and labels with regulatory requirements;
- development/review of distribution agreements, supply contracts, agent agreements, contract agreements, services and other contracts;
- development/review of the procedure for selection of counter-parties, commercial/trade policies, in view of the requirements of antitrust and tax authorities.

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