Andrey Gorodissky & Partners

Newsletter

on Limitation of Government and Municipal Procurements of Foreign-Manufactured Essential Medicinal Drugs

December 2015

*On November 30, 2015 the RF Government adopted Regulation N 1289 "On Limitations and Requirements for Admission of Foreign-Manufactured Medicinal Products Included in the List of Vital and Essential Medicinal Drugs for the Purpose of Government and Municipal Procurements" (the "**Regulation**"). The Regulation goes into effect on December 10, 2015*[1].

Below we offer a brief review of the said Regulation.

Limitations on Government Procurements of Foreign-Manufactured Medicinal Drugs

The referenced Regulation introduces limitations on government procurements of foreign-manufactured medicinal products in conformity with the so-called "third is a crowd" principle: where for the purpose of government and municipal procurements of medicinal drugs, included in the list of vital and essential medicinal drugs ("**Essential Drugs**")[2], at least 2 different[3] bids for supplying medicinal drugs manufactured in Eurasian Economic Union (the "**EEU**")[4] have been tendered, all other bids for supplying medicinal drugs *manufactured in foreign countries* (other than EEU) are to be rejected by the customer. This rule also applies where the contract (lot) provides for supplying of two or more medicinal drugs and the country of origin of at least one of medicinal drugs specified in the bid is a non-EEU country.

Furthermore, the Regulation emphasizes that the said limitation applies to medicinal drugs with one and the same international non-proprietary name (the **INN**)[5] or, if there is no such name, with one and the same chemical or common name[6]. Therefore, in case 2 or more bids for supply of

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[1] This Regulation will take effect upon the expiry of 7 days after its first publication on December 02, 2015 (on the official legal information web portal at http://publication.pravo.gov.ru).

[2] The List of essential drugs for human use for the Year 2015 was approved by Regulation of the RF Government of December 30, 2014 No 2782-p.

[3] Bids are to include medicinal drugs manufactured by different manufacturers not included in one and the same group of related parties, as defined in the competition legislation (See Art. 9 of the Federal Law of July 26, 2006 N 135-FZ "On Protection of Competition").

[4] Besides the Russian Federation, the Eurasian Economic Union includes Armenia, Belarus, Kazakhstan and Kirgizia.

[5] International non-proprietary name of a medicinal product is the name of active ingredient of a pharmaceutical substance recommended by the World Health Organization (See Art. 4(16) of the Federal Law No. 61-FZ of 12 April 2010 "On Circulation of Medicinal Products").

[6] Common name of a drug is a name of a medicinal drug which does not have an international non-proprietary name, or of a combination of medicinal drugs, used for grouping them under a common name

EEU-manufactured generics and at the same time a bid for a reference medicinal drug originating from a third country have been tendered, the Regulation requires that the choice should be made in favor of one of the generics.

Please note that this limitation does not apply to:

- Procurements of medicinal drugs by private healthcare and pharmacy organizations;
- Procurements of medicinal drugs not included in the list of vital and essential medicinal drugs.

The limitation established by the Regulation also extends to actual performance of obligations to supply medicinal drugs in context of a relevant purchase (replacement of a medicinal drug specified in the bid or change of the country of its origin during making of a contract or performance thereof is not allowed).

Origin of Medicinal Drugs

The fact that medicinal drugs were manufactured in EEU is to be proved by a certificate of origin, issued by authorities EEU countries in accordance with Rules used to determine the country of origin (the "**Rules**"), being an integral part of the Agreement on Rules for Determining the Country of Origin of Goods within the Commonwealth of Independent States (Yalta, November 20, 2009; the "**Agreement**").

Under the above Agreement, as a general rule[7], the country of origin of a product is a EEU country within the territory of which the product was completely manufactured and sufficiently processed/refined in accordance with the said Rules.

Exceptions

The Regulation provides for three exceptions from the general rule of limitation of government procurement of foreign-manufactured medicinal drugs. The limitation is not applicable in case:

- Information about government procurement of medicinal drugs (notice of procurement or invitation to take part in a limited tender) was posted on the web site at http://www.zakupki.gov.ru[8] before the effective date of the Regulation (December 10, 2015);
- Procurement of medicinal drugs is made by diplomatic missions or consulates of the Russian Federation, Russian Federation's trade missions, its official missions at international organizations and other customers operating within the territory of another country, for the purpose of supporting of their own operations;

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on the basis of identical composition of active ingredients (See Art 4(17.1) Federal Law No. 61-FZ of 12 April 2010 "On Circulation of Medicinal Products").

[7] See Section 2 of the Rules.

[8] Official web site for publication of information about the Russian Federation's orders for supplies of goods, performance of work, or provision of services.

– A bid has been made for supply of non-EEU medicinal drugs which are packed on a primary and secondary retail packing basis, or secondary retail packing basis with release quality control, within the territory of EEU countries[9] (before December 31, 2016, inclusive).

Contact information

Alexey Gorodissky
Partner, Attorney-at-Law, Trademark Attorney

Jose K. Tobar Kirillov
Lawyer

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Andrey Gorodissky & Partners

Znamenka 13, bldg. 3, 3rd floor, Moscow, 119019, Russia.
Tel.: +7 (495) 933-75-67, 691-98-13 Fax: +7 (495) 697-92-26.
E-mail: office@agp.ru. Internet: http://www.agp.ru.

[9] Primary package is individual package, i.e. such package in which the drug is immediately contained; secondary package is a group or external package of medicinal drugs: boxes, etc.; retail package is a package in which goods are purchased by consumers and which is an integral part thereof and is included in their value.