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LT In Focus
Russia restricts government procurement of foreign medicine

On 10 December 2015, Russian Government Resolution No. 1289 of 30 November 2015 (hereinafter, "Resolution No. 1289"), which restricts the inclusion of foreign medical products on the list of Vital and Essential Medicines, was enacted. The resolution was published on the official website of the Government of the Russian Federation http://government.ru/docs/20833/ on 2 December 2015.

The resolution was prepared by the Ministry of Industry and Trade in 2015 as part of the implementation of the Plan of Priority Measures to Ensure Sustainable Economic Development and Social Stability. However, discussions on restricting imported medicines in government procurement have been ongoing since 2013.

According to Resolution No. 1289, state purchasers shall reject all offers to supply Vital and Essential Medicines (hereinafter, "VEM") originating from foreign states (except for member states of the Eurasian Economic Union[1] (hereinafter, "EAEU")) if:

1. At least two bids have been made for VEM originating from the EAEU (for example, if one bid has been made for a medicine originating from a foreign (non-EAEU) state, and at least two bids have been made for the medicine originating from the EAEU);
2. Such bids do not contain offers to supply VEM produced by the same manufacturer or manufacturers from the EAEU, defined as a single group of persons;[2]
3. Such bids comply with the requirements for a notice of procurement and/or procurement documentation.

Resolution No. 1289 applies to bids for the supply of VEM with one international non-patented name (hereinafter, "INN")/chemical or grouping name under a single lot/contract, but it is unclear how the resolution will apply in cases where the purchase of several products, including those not included in the list of VEM, is made under a single lot. Commenting on Resolution No. 1289, Industry and Trade Minister Denis Manturov said, "*The particular feature of tenders is that they will be held with respect to each specific INN and the restrictions will apply only to single lots*."[3] This conclusion, however, is not supported by the Resolution, and government procurement participants may have questions about the procedure for forming lots for the procurement of VEM.

It should be noted that the restrictions of Resolution No. 1289 relate to VEM produced by several manufacturers, at least two of which are EAEU members. For example, if there is only one foreign manufacturer, or one foreign and one EAEU manufacturer, of a VEM, no restrictions shall be applied to the procurement.

The restrictions provided for by Resolution No. 1289 are based on the provisions of Federal Law No. 44-FZ[4], which entitles the Government of the Russian Federation to impose restrictions on the admission of goods originating from foreign states and work and services performed by foreign persons, including restrictions on the procurement of the abovementioned goods, work and services.

It is also worth mentioning that Russian Government Resolution No. 102 of 5 February 2015 (hereinafter, "Resolution No. 102") provides for restrictions on government procurement of a number of medical devices included in the list specified in Resolution No. 102 in accordance with OKPD codes[5] originating from foreign

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[1] Russian Federation, Republic of Belarus, Republic of Kazakhstan, Republic of Armenia, and Republic of Kyrgyzstan

[2] The term "group of persons" is defined in accordance with Article 9 of Federal Law No. 135-FZ of 26 July 2006 *On the Protection of Competition*

[3] The information is published on the website of the Ministry of Industry and Trade of Russia http://minpromtorg.gov.ru/press-centre/news/#!pravitelstvo_utverdilo_postanovlenie_ob_usloviyah_dopuska_importnyh_preparatov_pri_gosszakupkah

[4] Federal Law No. 44-FZ of 05.04.2013 *On the Contractual System for Purchases of Goods, Work and Services for State and Municipal Needs*

[5] All-Russian Classifier of Economic Activity Types

states (other than the Republic of Armenia, Republic of Belarus and the Republic of Kazakhstan). The restrictions introduced by Resolution No. 102 are similar to the restrictions imposed by Resolution No. 1289.

According to Resolution No. 102 and Resolution No. 1289, countries of origin of the respective medical products/devices are confirmed by a certificate of origin issued by an authorized agency (organization) of a state not subject to restrictions.[6] The form of the certificate (ST-1) is stipulated in the Rules for Determining the Country of Origin of Goods, forming an integral part of the Agreement On Rules for Determining the Country of Origin of Goods in the CIS of 20 November 2009 (hereinafter, the" Agreement") in accordance with the criteria for determining the country of origin of goods specified by the mentioned Rules. The Chamber of Commerce and Industry of the Russian Federation issues the Certificates of Origin (Form ST-1).

On 21 December 2015, the Chamber of Commerce and Industry of the Russian Federation approved a provision on the issuance of certificates of origin for the purposes of government procurement (with respect to medical products included in the list of VEM)[7] and published it on its website. According to the approved provision, the certificate (Form ST-1) should be prepared and issued within three working days if the required documents are in place. The certificate shall cease to be effective after the completion of procurement procedures for the government needs. Only manufacturers of medical products may receive certificates for a period of up to six months, provided there is an annual expert examination report for such products.

According to the Rules for Determining the Country of Origin of Goods, the country of origin for goods originating from CIS member states shall be the member state of the Agreement where the goods were manufactured or sufficiently processed/modified.

If the production of finished goods requires the use of materials from a signatory state to the Agreement, supported by a certificate (Form ST-1) and subject to further multi-stage processing/modification, the country of origin of the goods shall be the country where such goods were processed/modified for the last time.

In the absence of the certificate of origin (Form ST-1) of the materials, the country of origin of finished goods shall be determined based on the criteria for sufficient processing/modification, which may include the following conditions:

- Changes in a tariff code under the Foreign Economic Activity Tariff Schedule (hereinafter – "FEATS") at the level of at least one of the first four digits (the main criteria);
- Fulfilment of the required conditions, performance of production and technological operations;
- *Ad valorem* percentage rule, where the value of used materials from foreign countries reaches a specified percentage of the price of the finished goods.

However, simple packaging operations including the filling of bottles, cans and boxes do not meet the criteria for sufficient processing/modification of goods, despite the fact that the packaging of medicines may involve changes in FEATS code at the level of the first four digits. According to Resolution No. 1289, enterprises performing only primary and secondary (consumer) packaging or the secondary packaging of medical products in the EAEU and ensuring their quality control will be admitted to tenders through 31 December 2016. It is still unclear which document is required in order to confirm the primary/secondary packaging of VEM in the EAEU in 2016.

Starting from 1 January 2017, an EAEU country that is the primary/secondary packaging location of VEM will not be recognized as the country of origin for the purposes of government procurement. According to state authorities, this change should support Russian VEM manufacturers and incentivize the localization of production of such products by foreign manufacturers.

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[6] EAEU countries for the purposes of Resolution No. 1289 and EAEU countries other than the Republic of Kyrgyzstan for the purposes of Resolution No. 102

[7] RF Chamber of Commerce and Industry Order No. 94 of 21.12.2015

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