Restrictions on state procurement of foreign medical devices: practice and implications for other sectors

MARIA BORZOVA
Senior Associate, Manager of life sciences projects, VEGAS LEX law firm

Background

On 5 February 2015, the Russian Government adopted Resolution No. 102 "On Restricting the Access of Certain Types of Medical Devices Originating from Foreign Countries for the Purpose of Procurement for State and Municipal Needs" (Resolution No. 102). Resolution No. 102 contains a closed list of medical devices to which its provisions apply (the "List").

Resolution No. 102 became the formal implementation of the so called "three's a crowd approach". A similar approach is being discussed for implementation in the pharmaceutical sector.[1] Therefore, it is useful to look into the theory and practice of the application of relevant approaches based on the experience gained in the MDs sector.

Practical implications

Paragraph 2 of Resolution No. 102 states that the state purchaser must reject the tender offers of medical devices which are both included in the List and originate from foreign countries (except for Armenia, Belorussia and Kazakhstan) if at least two other bids are submitted, and the two or more tender bids meet the following conditions:

(a) the products offered in the bids satisfy the requirements of the tender documentation;

(b) the country of origin of the products is Russia, Belarus, Kazakhstan or Armenia; and

(c) the bids do not offer one and the same type of medical device from one manufacturer.

Current practice[2] states that the list of relevant preconditions for the application of Resolution No. 102 is closed. Therefore, if during the tender, a state purchaser needs to acquire medical devices which are not manufactured in the countries listed in paragraph (b) above, then the state purchaser has no grounds to apply the relevant restrictions. Please note, however, that it is necessary to monitor how this principle will be further applied towards expendable materials, reagents etc., which due to objective circumstances may not have any equivalent (in order to identify the practical guidelines determining the unique status of the product excluding the application of Resolution No.102).

The state purchaser may not include products subject to the above restrictions, and products that are not in the List into one tender procedure, as it may breach the imperative requirements of the procurement regulations and the principles of competition protection.[3]

Furthermore, according to current practice, the state purchaser may apply

[1] Go to: http://regulation.gov.ru/project/18147.html?point=view_project&stage=2&stage_id=12383.

[2] E.g. see the Decision of the FAS Kemerovo Region Department dated 26 May 2015, case No. 159/3-2015.

[3] E.g. see the Decision of the FAS Tula Region Department dated 3 June 2015, case No. 04-07/72-2015.

Resolution No. 102 and the Order of the Ministry of Economic Development dated 25 March 2014 No. 155 "On the conditions for releasing goods originating from foreign countries for the purpose of purchasing goods, work and services to meet state and municipal needs" simultaneously in the same tender procedure.[4]

At the same time, if the state purchaser applies the restrictions set forth in Resolution No. 102, the bidding company must provide a certificate confirming the product's country of origin. Otherwise, the state purchaser may reject the bid on formal grounds.[5]

Conclusions

We believe that the above regulatory trends will continue to develop (including the possibility of opposing practical interpretations). Moreover, some of the above approaches may have the same implications for other economic sectors where the "three's a crowd approach" is applied.

If we try to speculate on the possible implications for the pharmaceutical sector, we can identify the subsequent risks. For instance, the provision of a certificate of origin of a drug may be regarded as an excessive requirement, as information on the production stages and the manufacturer's origin is given in the registration certificate. If adopted, such an approach may create significant difficulties for tender participants.

Furthermore, many issues may potentially arise while determining the requirements for tender documentation and when taking decisions on product equivalence. Therefore, until the interchangeability regulations start working, it will be difficult to assess whether the state purchaser should actually apply the "three's a crowd approach", even if it believes that only one medical option is possible for patients (for instance, for those already established on certain medicines).

[4] E.g. see the Decision of the FAS Bryansk Region Department dated 8 June 2015, No. 60.

[5] E.g. see the Decision of the FAS Primorsk Territory Department dated 10 April 2015, case No. 123/04-2015; Decision of the FAS Murmansk Department dated 7 May 2015, case No. 06-10/15-112; Decision of the FAS Kemerovo Region Department dated 18 June 2015, case No. 223/3-2015 etc.