RUSSIAN GOVERNMENT SETS RESTRICTIONS ON AND CONDITIONS FOR MEDICINES WHICH ARE ON THE LIST OF VITAL AND ESSENTIAL MEDICINES TO BE ADMITTED FOR PUBLIC PROCUREMENT

FAO: Russian and foreign manufacturers and distributors of medicines which are on the list of vital and essential medicines

Pepeliaev Group advises that, on 10 December 2015,[1] a Resolution of the Russian Government (the 'Resolution')[2], will take effect that sets restrictions on and conditions for the medicines which are on the list of vital and essential medicines to be admitted for the purposes of state and municipal procurement.

Main new developments

According to the Resolution, when purchasing medicines which are on the list of vital and essential medicines and have one international non-proprietary name (a chemical or generic name) under one contract, the customer must dismiss applications containing proposals to supply any medicines which originate from foreign countries, except member states of the Eurasian Economic Union. This includes applications containing proposals to supply one or more medicines if at least one medicine originates from any country which is not a member state of the Eurasian Economic Union.

The customer has the right to dismiss such application under the following conditions:

1. The customer receives at least two applications which comply with the requirements specified in the procurement documentation;
2. Such applications at the same time:
   - contain proposals to supply medicines which originate from member states of the Eurasian Economic Union;
   - do not contain proposals to supply medicines of the same manufacturer or manufacturers included in one group of entities[3].

It appears that the Resolution will be more widely applied than Resolution No. 102 of the Russian Government dated 5 December 2015 (what has become known in Russian as the 'Three's A Crowd' Resolution with respect to medical devices). Thus, medicines, with rare exceptions, are subject to a general requirement that they be purchased based on their international non-proprietary name (a chemical, generic name) taking account of dosage forms[4]. Thus, purchasing medicines is subject to a more substantial restriction at the stage of placing an order compared with purchasing medical devices. Moreover, it is worth mentioning that, compared with the medical device sector, the Russian pharmaceutical industry is more diverse and more prepared for the import substitution.

If the purchaser does not dismiss the application containing a proposal to supply a medicine which originates from a foreign country pursuant to the rules provided for by the Resolution, the rules will be applied which are set out in Order No. 155 of the Ministry for Economic Development dated 25 March 2014

[1] http://publication.pravo.gov.ru/Document/View/0001201512020026.
[2] Resolution No. 1289 of the Russian Government dated 30 November 2015 'On restrictions on and conditions for the medicines which originate in foreign countries and which are on the list of vital and essential medicines to be admitted for the procurement purposes for state and municipal needs'.
[3] According to the definition set out in article 9 of Federal Law No. 135-FZ 'On protecting competition' dated 26 July 2006.
[4] The specific procurement practice relating to such groups of biological products as, for example, insulins, deserves special attention.

'On terms and conditions for products that originate from foreign countries to be admitted for the purposes of the procurement of goods, work or services to provide for state and municipal needs' (according to which a 15 % preference applies).

Moreover, the latest amended version of article 14 of the Federal Law 'On the contractual system'[5], provides that the above Resolution does not allow for a medicine of another manufacturer or for a medicine which originates from another country to be substituted (the Federal Law 'On the the contractual system' allows such substitution according to the general rule should the purchaser agree that the seller will supply a product of improved quality).

The country of origin of a medicine is confirmed by a country of origin certificate issued by an authorised body (organisation) of a member state of the Eurasian Economic Union in accordance with the approved form and established criteria for determining the country of origin of products[6].

It is obvious that the State Register of Medicines (the 'SRM') does not include data on the country of origin, and thus it is required to arrange an additional expert review and obtain an ST-1 certificate. Taking account of our experience in advising the medical sector[7], we believe that manufacturers and distributors may face technical issues relating to obtaining ST-1 certificates and arranging an expert review, which is done first. Currently, there is no set procedure for issuing certificates with respect to medicines (such procedure is determined only for medical devices[8]). Thus, for the Resolution to be applied in full, a special procedure for issuing ST-1 certificates with respect to medicines is required. The issue of applying the ad valorem share rule to the production of generics stipulated by the Agreement is also topical[9]. According to this rule, goods are deemed to be sufficiently reprocessed if the cost of foreign goods used for the production of the end product does not exceed 50 % of the price of such end product. In the majority of cases, pharmaceutical substances of generics are produced outside the member states of the Eurasian Economic Union, and their cost may account for a substantial share of a medicine's ultimate price. In this regard, although a medicine undergoes the packaging stage and the stage of release quality control, in a number of cases, it may not be acknowledged to be local owing to the ad valorem share rule being applied to it.

Exceptions from the rule

The Resolution provides for a number of exceptions to which **it does not apply**. Such exceptions are as follows:

- procuring medicines which originate from foreign countries and which are subject **only** to the following procedures within the member states of the Eurasian Economic Union:
  - primary and secondary (consumer) packaging followed by ensuring release quality control, or
  - secondary (consumer packaging) of medicines followed by ensuring release quality control - up to 31 December 2016, inclusive.

This exception is actually the first preference for companies that have started localising the production of pharmaceuticals. However, in our opinion, this preference is not an incentive, but rather a compensating measure for manufacturers who either have already transferred these production stages to the member states of the Eurasian Economic Union or have taken sufficient steps in this direction. We assume that the SRM data relating to manufacturing sites may serve as confirmation of a company's specific status.

[5] Federal Law No. 44-FZ dated 5 April 2013 'On the contractual system in the area of procurement of goods, work and services to provide for state and municipal needs'.
[6] See the Rules for Determining the Country of Origin, which constitute an integral part of the Agreement regarding the Rules for Determining the Country of Origin within the Commonwealth of Independent States dated 20 November 2009 ('the Agreement').
[7] When applying a similar procedure with respect to medical devices, those involved in procurement faced difficulties relating to obtaining an ST-1 certificate in respect of Russian products, which sometimes made offering Russian goods more problematic than offering foreign goods.
[8] Order of the Chamber of Commerce and Industry of the Russian Federation No. 29 dated 10 April, 2015 'On Regulations on the procedure for issuing ST-1 certificates for procurement purposes to ensure state and municipal needs (for individual types of medicines)'.
[9] Decision No. 515 of the Commission of the Customs Union dated 18 November 2010 'On the procedure for using the ad valorem share rule as a criterion of sufficient processing of goods manufactured using foreign goods placed under the free customs zone customs procedure or under the free warehouse' customs procedure.

The above stages are treated individually as grounds for granting preferential status owing to the simplified procedure for confirming that these stages have been transferred to the member states of the Eurasian Economic Union (e.g. by providing a reference to the SRM data). At the same time, medicines that have been localised to a greater extent require an ST-1 certificate. This makes the procurement procedure more complex for companies offering such medicines. In any case, the wording of the Resolution suggests such an interpretation. However, the practice may be different.

- the Resolution does not apply if the orders for supplying medicines or forwarding invitations to participate in selective tendering were placed before the Resolution took effect;

- the Resolution does not apply if the medicines are purchased by diplomatic missions, consular offices, trade representations, official representations of the Russian Federation in international organisations and other purchasers operating in a foreign state.

Conclusions

The content of the Resolution is rather "general". There are individual technical and conceptual flaws. Analysing administrative and judicial decisions will help to fill in the gaps and eliminate the technical flaws.

It appears that the issues relating to the implementation of the Resolution may be partly similar to the issues relating to the 'Three's a Crowd' Resolution when it was applied to medical devices. For example, one potential issue is the requirement to dismiss the application of a participant if the first part of it contains a proposal to supply a product which originates from member states of the Eurasian Economic Union, but no ST-1 certificate has been supplied. Another difficulty could be applying the Resolution when one lot contains requests for several medicines, one of which is not on the vital and essential medicines list.

Nevertheless, not all the issues arising out of the application of the 'Three's a Crowd' Resolution to medical products are to affect the pharmaceutical sector (applying the codes of the All-Russian Classifier of Products, avoiding restrictions in the tender documentation, etc.).

What to think about and what to do

The Resolution is bound to change the competitive balance on the public procurement market. Market players should analyse the localisation extent of both their own medicines and those of their competitors. On this basis, market players should evaluate the described changes.

Manufacturers of medicines from member states of the Eurasian Economic Union should make all the organisational arrangements to prepare for the potential inspection of their production process.

Distributors should take into account that medicines produced in member states of the Eurasian Economic Union require ST-1 certificates (except for medicines localised at the packaging and release quality control stages).

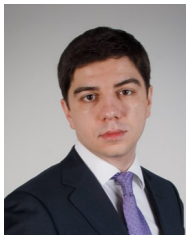
Manufacturers who have not considered localising their medicines in the member states of the Eurasian Economic Union should reassess the issue and analyse whether it is reasonable for them to transfer production either by deploying their production facilities in member states of the Eurasian Economic Union or by starting contract manufacturing.

Help from your adviser

Pepeliaev Group's lawyers will readily provide comprehensive legal support regarding issues relating to the public procurements of medicines. This includes providing legal advice and drafting documents, as well as representing companies in court and before the antimonopoly authority.

Pepeliaev Group's lawyers also have experience in supporting localisation of production in the member states of the Eurasian Economic Union (construction of production facilities, contract manufacturing, and out-licensing).

Contact details



Sergey Klimenko
Head of Life Sciences Group
Pepeliaev Group
T.: +7 (495) 967-00-07
s.klimenko@pgplaw.ru

Anna Shibanova
Associate
Pepeliaev Group
T.: +7 (495) 967-00-07
a.shibanova@pgplaw.ru