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COMMERCIAL POLICIES OF PHARMACEUTICAL COMPANIES AND MEDICAL DEVICE MANUFACTURERS: NEW LESSONS FOR MARKET PLAYERS

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MARCH 2014

Federal Antimonopoly Service (FAS) and Russian court practice in addressing unreasonable refusals to enter into a supply agreement continues to develop. Several new cases considered by the FAS and the courts at the end of 2013/beginning of 2014 have enabled the identification of new trends in legal implementation policies[1].

Who is at risk?

In undertaking a competition analysis the FAS will evaluate the following:

(a) conditions of market access;

(b) market shares of market players;

(c) the balance between the market shares of the sellers and purchasers of a particular product; and

(d) the timeframe in which a company is able to influence the functioning of a particular market.

Therefore, the following market participants may potentially be at risk:[2]

(a) wholesalers with a market share exceeding 50% within the geographical boundaries of Russia;

(b) manufacturers whose market share allows them to influence the functioning of a particular market; and

(c) exclusive distributors to international companies who are also the sole sellers of a particular product in Russia.

How is market share determined?

Different factors can influence the determination of the market share of a particular company. For instance, the following factors may be regarded as an indication of a company's dominant position:

(a) the inability of a customer to substitute the expendable MD materials of one manufacturer for the expendable materials of another manufacturer;

(b) lack of an analogous drug on the market; and

(c) the inability of a customer to substitute one drug with another due to the specific therapy appointed by his or her doctor.

During its competition analysis the FAS also analyses on which market a particular company operates (i.e. wholesale or retail). For the purposes of market analysis the FAS may additionally refer to expert opinions.[3]

What exactly may reveal a restraint on competition?

Based on current practice we can conclude that the following factors may occasion a finding of unreasonable refusal to enter into a supply agreement:

(a) If a company's internal policies and procedures:

- do not provide clear and transparent selection and approval criteria for potential distributors;
- do not set forth the exact timeframe and procedure for processing a potential distributor's commercial proposal, as well as failing to set forth the procedure and conditions for the commencement of cooperation and for the termination of contractual relations;
- set forth the need to conduct due diligence in relation to a potential distributor, but fail to clarify the due diligence procedure to be followed and the criteria for assessing the due diligence results; or
- allow a refusal to enter into an agreement with a potential distributor on the basis of corruption risks without the company having any evidence of the existence of such a risk (For example, a decision from a government authority confirming a violation by the current or potential distributor of Russian laws and regulations (including anticorruption provisions) or an examination of alleged violations by the current or potential distributor by a government authority may be accepted as such evidence).

(b) Acts or omissions by a company and/or its official distributors in which:

- a commercial proposal from a distributor is processed within an unreasonably long time period and/or a refusal to enter into agreement is repeated several times without due justification;
- no official order or any other document is issued by the company's governing body on termination of contractual relations with a distributor (provided that the framework cooperation agreement is valid);
- notwithstanding a currently valid framework cooperation agreement, the company asks its distributor to go through a due diligence procedure in order to restore the actual supply of products, where the timeframe and procedure for such due diligence are not transparent; or
- the company's official distributors also refuse to enter into a supply agreement with the company's potential partner, or fail to reply to such a potential partner without reasonable explanation;

[1] See at: http://fas.gov.ru/solutions/solutions_38702.html, http://kad.arbitr.ru/Card/b3bad694-2a11-4755-a713-9937ea6bbfa8.

[2] Please note however, that the FAS has its own methodology for determining market shares, set forth in the Order of the FAS dated 28 April 2010 No. 220.

[3] For example, in one of the cases the FAS applied to the Russian Public Nephrologist Organization (within the Russian Dialysis Community), which certified that the drug of one of the foreign pharmaceutical companies belongs to the category of special solutions and may not be substituted by any other drug.

(c) The possible consequences of the refusal to enter into a supply agreement, whereby:

- the distributor is involved not only in the sale of the product but also in the production, storage and distribution of the product in Russia, and the refusal to enter into a supply agreement with this distributor leads (or may lead) to the total termination of all of the distributor's listed activities in relation to the product;
- the refusal to enter into a supply agreement with the distributor leads (or may lead) to the distributors' inability to participate in the state auction resulting (or possibly resulting) in the inability of patients to receive necessary life-saving treatment; or
- the refusal to enter into a supply agreement with the distributor results (or may result) in a need to replace life-saving therapy for patients (which may entail additional distributor or budgetary expense) and may adversely influence the medical treatment of patients.

Taking a practical approach, in order to secure equal market access and healthy competition between suppliers at state auctions, a company-exclusive supplier of a product must provide conditional approval of the commercial proposals of all its potential distributors and enter into a supply agreement with the auction winner. If such a company unreasonably refuses to enter into a supply agreement with a distributor, this may:

(a) create additional barriers to market access for certain distributors;

(b) influence the market negatively;

(c) pre-determine the terms and conditions for the circulation of certain products; and/or

(d) cause damage to current or potential market players.

What to do next?

In connection with the above outlined development of administrative and court practice, we recommend that market participants examine their commercial policies and procedures in order to make sure that they reflect the recent trends in legal implementation policies. Internal corporate trainings may serve as a useful tool to adopt the results of such an audit. It might be also necessary to adjust internal compliance regulations to the new requirements.

CONTACT INFORMATION:

JULIA TORMAGOVA

Head of
Commercial group

tormagova@vegaslex.ru

MARIA BORZOVA

Projects manager of
Pharmaceutical sector

borzova@vegaslex.ru

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MOSCOW
Tel.: +7 (495) 933 0800
Fax: +7 (495) 933 0802
vegaslex@vegaslex.ru

VOLGOGRAD
Tel.: +7 (8442) 266 312/313/314/315
Fax: +7 (8442) 266 316
volgograd@vegaslex.ru

KRASNODAR
Tel.: +7 (861) 274 7408
Fax: +7 (861) 274 7409
krasnodar@vegaslex.ru