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PHARMA LEGISLATIVE DEVELOPMENTS REVIEW

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I. LEGISLATIVE INITIATIVES

1. Amendments in relation to medicines for orphan diseases

The Federal law "On health protection" sets forth that procurement of drugs for the patients suffering from orphan diseases is effected at the level of Russian regions and regional budgets.

In April 2013 the Cabinet of Ministers has considered the legislative initiative to transfer the powers to effect the relevant procurement from regional to federal authorities. The Cabinet of Ministers rejected the above initiative due to the fact that it violates the balance between federal and regional budgets.

2. Amendments to the Federal Law "On Medicines"

(a) Amendments discussed with the FAS

In the beginning of April 2013 amendments to the Federal Law "On Medicines" (including amendments to article 333.32.1 of the Russian Tax Code), suggested by the Ministry of Health, were submitted for approval to other federal authorities (the Federal Antimonopoly Service, the Ministry of Economic Development, the Ministry of Finance). The document is planned to be submitted to the Russian Government by the end of April 2013.

The relevant amendments set forth, ***inter alia***, new definitions aimed to regulate circulation of biological and orphan drugs and determine interchangeable drugs and methods of drugs comparison.

The Ministry of Health also works on by-laws, which must facilitate the implementation of the relevant amendments. The Ministry of Health plans to enact 15 such documents in relation to specific procedures and expertise.

The Federal Antimonopoly Service (the FAS) strongly disagrees with amendments, suggested by the Ministry of Health. The FAS refused to approve the initiative and sent its comments to the Ministry of Health. The FAS believes that the proposed amendments can introduce additional barriers for the Russian pharmaceutical market and its development.

The current ideological conflict between two governmental bodies may result in two alternative consequences: the Ministry of Health might agree with the FAS objections and modify suggested amendments; or the Ministry of Health might make a discrepancy report which will be further discussed in the Russian Government.

(b) Amendments regarding price regulations

The Ministry of Health also prepared amendments to the Federal Law "On Medicines" in relation to the price regulations on vital and essential drugs (published on 15 March 2013). According to the explanatory note, the amendments are aimed at improvement of the system of price regulation, ***inter alia***, through introduction of reference pricing. The relevant amendments also provide for separation of the procedure of registration and re-registration of prices.

II. REGULATORY CHANGES

1. The Federal Law "On Federal Contractual System"

The President of the Russian Federation has signed the Federal Law dated 5 April 2013 N 44-FZ "On contractual system in state procurement". The aim of the document is to change the system of state procurement procedures in Russia. Most of the provisions of this law will enter into force on 1 January 2014.

The document contains a number of provisions specifically related to the drug procurement:

- the tender documentation must be based on international nonproprietary names of the drugs or indication of their chemical or group names;
- the trade names of the drugs may be indicated in the tender documents, if such drugs are included into specific list to be approved by the Russian Government;
- a tender participant, whose price offer is 25 % below initial price of the contract, must justify the relevant price, e.g. through submission of a guarantee letter from the drug manufacturer or other evidence;
- in case of urgent purchase of the drugs vitally necessary for a particular patient it is allowed to choose the supplier through issuing an offer for commercial proposals.

2. The Strategy for Drug Provision until 2025

The Ministry of Health has approved the Strategy for Drug Provision until 2025 (the Strategy), aimed at improving the availability and access of drugs for the country's population as well as the plan for the implementation of the Strategy.

The document lists five main tasks: (i) ensuring the rational use of drugs; (ii) improving the procedure of forming the list of drugs, provided within the framework of governmental programs; (iii) safety, efficacy, and quality of products for medical use; (iv) improving state regulations of prices for drugs; (v) increasing the qualifications of medical and pharmaceutical workers.

The financing of the Strategy is to come from funds allocated from the federal budget, regional budgets, and extra-budgetary funding. The funding for the third stage of the Strategy is to be decided following the implementation of the first two stages.

3. Administrative regulation on authorization of drugs importation

On 31 March 2013 the Administrative regulation of the Ministry of Health on authorization of drugs importation for the purposes of clinical trials, expertise and urgent supply to the patients has entered into force.

In particular, the Administrative regulation sets forth that the Ministry of Health must approve the import of specific parcel of registered or unregistered drugs for the purposes of clinical trials within 5 working days from the application date.

III. PUBLIC DISCUSSIONS

1. Interchangeability of medicines

During the press-conference held on 27 March 2013 by "A&F" the head of the FAS department for trade and social sphere Timofey Nizhegorodtsev emphasized the necessity of explaining to patients that the majority of medicines are interchangeable. He stated that the stereotype that only the original medicine has necessary quality should be broken to increase the level of medical services in Russia.

Timofey Nizhegorodtsev has also suggested to introduce the definition of "interchangeability" into specific laws. Interchangeability should mean that different drugs have comparable therapeutic effect and may be used for treating the same symptoms of the same group of patients. Thus drugs containing the same active substance (INN), in the same dosage form and manufactured according to the established standards of manufacturing practice (or GMP) must be considered as interchangeable.

2. Penalties for manufacturers and distributors of counterfeit drugs

Two deputies of the Russian State Duma, Alexander Prokopev and Irina Yarova, plan to submit to the State Duma a draft law, aimed at stiffening the administrative and criminal liability for production and sale of counterfeit drugs.

Alexander Prokopev emphasized that the market share of counterfeit drugs in Russia amounts to 10-20 %, whereas only 1 % of such drugs is withdrawn from circulation by the governmental authorities.

The initiative is supported by Sergey Kolesnilov, the councilor of presidium in Russian Academy of Medical Science, who noted that it is necessary to introduce definitions of counterfeit and pirate medicines to the Federal Law "On Medicines".

3. Consolidated governmental body for control of the pharmaceutical market

The State Duma Committee on Healthcare announced the initiative to create the consolidated authority with the powers to control the whole pharmaceutical market. This issue was discussed on the parliamentary hearings. If the initiative is met positively by the Cabinet of Ministers, necessary amendments to the Federal Law "On Medicines" and Federal Law "On health protection" will be prepared.

4. Discussions on biologic drugs in State Duma

On 20 March 2013 the State Duma held the roundtable in relation to registration and marketing of biosimilars.

Deputies of the State Duma stated that after the launch of drugs into the market the manufacturers of biosimilars must provide to the state control authorities the data of pre-clinical and clinical trials and programs of risk-management for the purposes of permanent collection of information regarding biosimilars safety.

The discussion revealed the need to amend the existing Federal Law "On Medicines" in order to introduce the effective system of control of biosimilars safety.

IV. COURT PRACTICE

"Irvin-2" vs. FAS

The Supreme Arbitration Court of the Russian Federation in its decision N VAS-505/13 has ruled that two participants of the state auction for drug procurement have participated in concerted practices and thus breached the Federal Law "On protection of competition".

This case creates a dangerous precedent, where the courts of all instances accepted the indirect evidence of concerted practices. There was no other evidence except the "objective behavior of participants, which itself shows the presence of oral agreement between them".

This decision was also reported by the FAS as new precedent which helps to preclude unlawful behavior during state procurement of drugs.

CONTACT INFORMATION:

JULIA
TORMAGOVA

Head
of Commercial Group

Tormagova@vegaslex.ru

MARIA
BORZOVA

Senior associate
Commercial group

Borzova@vegaslex.ru

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RECOMMENDATIONS & RECOGNITION:

- European Legal Experts 2012
- Best Lawyers 2012
- International Financial Law Review 2012
  - Restructuring and insolvency
  - Corporate and M&A
  - Project finance
- Chambers Europe 2012
  - PPP
  - Competition/Antitrust
  - Dispute Resolution
  - Tax
- PLC which lawyer? 2012
  - Competition/Antitrust
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- The Legal 500 EMEA 2012
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- Russia's leading rankings "Pravo.ru-300", 2012
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COOPERATION:

Ministry of Economic Development, Ministry of Transportation of the Russian Federation, Ministry of Regional Development, Federal Antimonopoly Service, Federal Tariff Service, Federal Financial Markets Service, Committees of the State Duma and the Federation Council, Vnesheconombank, various federal agencies, PPP and Investment Commission of the Russian Union of Industrialists and Entrepreneurs, Protection Committee of the National Securities Market Association, Agency of Strategic Investments and Initiatives, IMEDA, Agency for Strategic Initiatives (ASI), etc.

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