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REGULATORY CHANGES

The new list of preferences for local products has entered into force

On 28 May 2013 the Russian Ministry of Justice has registered the order of the Ministry of Economic Development dated 17 April 2013 No. 211 «On the conditions of access of the goods produced in foreign countries for state procurement purposes» (registration number 28536).

Today it's the only document relating to implementation of localization concept in Russia. The document sets forth that during state procurement of certain products (including medicines) the tender participants may enjoy 15% price preference if they supply the goods produced in Russia or the Republic of Belarus.

Recommendations towards advertising of drugs, medical devices and medical equipment in CIS countries

On 24 May 2013 within the framework of the meeting of Coordination council on advertising of the CIS Interstate council on antimonopoly policy the representatives of the Republic of Azerbaijan, the Republic of Armenia, the Republic of Belarus, the Kyrgyz Republic, the Republic of Moldova, the Russian Federation, the Republic of Uzbekistan and Ukraine approved the following Recommendations towards advertising of drugs, medical devices, medical equipment, medical services, methods of medical treatment and biologically active additives in CIS.

1. Production, allocation and dissemination of advertising of drugs, medical devices, medical equipment, medical services and methods of medical treatment are allowed provided that:
   (i) a specific permit (license) for production and sale of drugs, medical devices and medical equipment, for rendering of medical services and usage of methods of medical treatment, issued in accordance with the national legislation of CIS countries, is obtained;
   (ii) strict rules in relation to advertising of drugs sold against medical prescription as well as advertising of medical devices, medical equipment, medical services and methods of medical treatment which require specific knowledge, specific education or medical prescription, are specifically set forth in the national legislative acts of CIS countries.
2. During advertising of drugs, medical devices, medical equipment, medical services and methods of medical treatment it is not allowed to:
   (i) apply directly to minors; indicate therapeutic effect in relation to incurable diseases or diseases hardly responding to medical treatment;
   (ii) inform that the positive curative effect is guaranteed;
   (iii) inform about actual recovery cases and gratitude of cured people; create an impression that it is not necessary to apply for professional medical help;
   (iv) induce healthy people to use the object of advertising.
3. The advertising of drugs must contain the full name of the medicine (including pharmacological name) and the name of manufacturer.
4. The advertising of drugs must not present the object of advertising as nutrition product.
5. The advertising of drugs, medical devices and medical equipment must contain the warning on contra indications and the necessity to read the instruction for use.
6. The advertising of biologically active additives must not create an impression that the object of advertising is medicine or has curable effect or positive influence on the course of disease.

The recommendations, prepared on the basis of the national regulations of CIS countries will be submitted to the Interstate council on antimonopoly policy in CIS.

Licensing of medical works and services

The Federal Service on Surveillance in Healthcare (Roszdravnadzor) has informed the market participants that on 26 May 2013 the Order of the Russian Health Ministry dated 11 March 2013 No. 121n «On approval of the requirements towards organization and performance of works (rendering services) during provision of primary healthcare, secondary (including hi-tech) care, palliative care, medical care during health resort treatment, during medical expertise, medical inspection, medical examination and sanitary antiepidemic (precentive) treatment within the framework of provision of medical help, during transplantation of organs and (or) telas, circulation of donated blood and (or) its components for medical purposes» has entered into force.

Therefore, the application for obtaining (re-issuance) of a license for medical activities from the moment the new order has entered into force must contain the list of works (services) corresponding to the new requirements. Roszdravnadzor also informed that in accordance with article 18 of the Federal law dated 4 May 2011 No. 99-FZ «On licensing of certain activities» a license must be reissued in case of changes in a list of works (services) for which a license is required.

LEGISLATIVE INITIATIVES

Russian Government asked the Ministry of Health to elaborate a new scenario of healthcare sector development

Deputy Chairman of the Russian Government Olga Golodets has asked the Ministry of Health to elaborate a new scenario of healthcare sector development for 2013–2016 within

the allocated budgetary funds in accordance with the assignment of the Chairman of the Russian Government Dmitry Medvedev.

The relevant scenario must reflect the actual changes of the program between 2013 and 2012, between 2014 and 2013 as well as between 2015 and 2014, must present the actual figures of expenditures, including those of federal budgetary enterprises.

The Russian Ministry of Economic Development held public consultations on the draft law amending the Federal law «On circulation of medicines»

The Ministry of Economic Development has arrived at the conclusion that the draft law «On amendments to the Federal law «On circulation of medicines» and article 333.32.1 of the Russian Tax Code» (the **Draft Law**) may introduce additional administrative barriers for market players and may entail additional increase in costs for pharmaceutical companies.

In particular the Ministry of Economic Development believes that it is not reasonable to conduct pharmaceuthcal expertise in relation to biological and biosimilar medicines before the Health Ministry takes decision on commencement of clinical trials. The Ministry of Economic Development concludes that procedure of pharmaceuthcal expertise repeats the procedure of quality control expertise which is conducted after the clinical trials are completed.

The Ministry of Economic Development also believes that substantial increase in timing of expertise and issue of clinical trials permit (it is estimated that the time period for issue of clinical trials permit may increase from current 115 calendar days to 6 months or one year) is likely to block the ability of participation of the Russian Federation in international clinical trials.

The Ministry of Economic Development noticed that in accordance with the generally accepted world practice for obtaining the clinical trials permit it is necessary to submit to the state authorities GPM certificates and similar documents for examination. The current international practice does not require the state authorities to examine the samples of drugs at this stage. Therefore, the Ministry of Economic Development does not see a particular necessity to change the current approach of the Federal law «On circulation of medicines» which is in line with the international practice.

The Draft Law suggests to introduce new powers of the Russian Health Ministry to approve: (i) the list of interchangeable medicines; (ii) the procedure for setting up and maintaining the relevant list. However, the Ministry of Economic Development believes that it is not necessary to create a separate list or register. It will be more convenient to include the data on interchangeability into the existing Register of medicines.

The Ministry of Economic Development has also outlined discrepancies in terminology used in the Draft Law.

The participants of public consultations also indicated that diagnostic radiopharmaceuticals remain out of the scope of the Draft Law and the Federal law «On circulation of medicines». The Ministry of Economic Development therefore suggested to introduce in the Draft Law a cross reference to a specific regulation on radiopharmaceuticals manufactured in the healthcare organizations.

The Russian Government has issued a number of assignments in relation to modernization of immunobiological industry

The Russian Health Ministry, the Russian Ministry of Finance and the Ministry of Economic Development must assess the possible ways to support the reconstruction and modernization of local production of immunobiological medicine, *inter alia*, in accordance with GMP standards and communicate the results to the Russian Government.

The Russian Health Ministry, the Ministry of Economic Development, the Russian Ministry of Finance and the Ministry of Justice must speed up the process of approval of the draft law on alteration of the Federal law «On the Immunoprophylaxis of Infectious Diseases».

The Russian Ministry of Finance and the Ministry of Economic Development must procure that from 2014 the money necessary to purchase the pneumococcal vaccine are included into the federal budget.

The Russian Ministry of Finance and Federal service on customers' rights protection and human well-being surveillance (Rospotrebnadzor) together with other executive bodies and RAMN must prepare their initiatives on modification of the National Calendar of Prophylactic Immunization up to 2020.

The Russian Ministry of Industry and Trade and Russian Health Ministry together with other executive bodies and RAMN must prepare their initiatives on localization of complete production cycle of vaccines pursuant to the Russian state program «Development of pharmaceutical and medical industry» during 2013-2020.

The Russian Health Ministry, Ministry of Industry and Trade, Federal Security Service, Ministry of Defense, Rospotrebnadzor and Federal Accreditation Service must enhance control over circulation of immunobiological medicine including quality control and submit to the Russian Government suggestions on unresolved issues.

The Ministry of Industry and Trade, Health Ministry, Rospotrebnadzor, Ministry of Economic Development and RAMN must elaborate a development plan for immunobiological industry with specific deadlines for its implementation.

Medical technology assessment is likely to be introduced in Russia

On 13-15 May 2013 during X congress of the Russian arthroscopic society the chairman of the Council of

Federation stated that the Council of Federation is elaborating mechanisms for introduction of the medical technology assessment into the Russian healthcare legislation.

The chairman of the Council of Federation has emphasized that the usage of the medical technology assessment may contribute not only to the development of the innovative and effective healthcare treatment methods, but also to effective control of governmental expenses.

Suggested restrictions on sale of certain medicines

The Russian Health Ministry has published the draft order which allows to sell a number of superpotent substances only in the state pharmacies (approximately 10% from all pharmacies) and on the basis of a specific license.

The relevant medicines are aimed at treatment of various diseases (cardiovasculare, oncological, endocrinologic etc.). The draft order lists approximately 94 items. Among them hypnotic drugs, sedating medication, as well as sybutramin (the medicine against obesity which is vitally necessary for patients suffering from diabetes).

Certain experts express concern in relation to the implementation of the above initiative. They believe that a number of patients will not be able to obtain the relevant medicines due to the limited number of pharmacies likely to be allowed to sell the relevant drugs. However, the pharmacies tend to support the draft order in particular due to the fact that the Russian Health Ministry promised not to include into the draft order medicines containing such active substances as valokordin and korvalol.

General Prosecutor's Office has examined the implementation of laws and regulations on provision of vital drugs

General Prosecutor's Office has examined the implementation of the laws and regulations on provision of vital drugs to the patients and revealed that the legal mechanisms for adoption of vital drugs list are far from being perfect, which gives rise to a number of violations of the patients' rights.

Article 60 of the Federal law «On circulation of medicines» sets forth that adoption of vital drugs list is one of the methods of the state control over drug pricing. According to paragraph 4 of the Resolution of the Russian Government «On the state control over prices for drugs which are included into the vital drugs list» the Russian Health Ministry on the annual basis must submit to the Russian Government the draft list of vital drugs (not later than 15 October of the relevant year).

However, the Regulation of the Health Ministry, approved by the Resolution of the Russian Government dated 19 June 2012 No. 608, and other regulatory acts technically do not set forth the procedure for drafting the vital drugs list and the relevant powers of the Health Ministry.

Therefore, in accordance with the Instruction of the Russian Government dated 30 July 2012 No. 1378-r the vital drugs list approved in 2011 must apply in 2013.

As a result during a significant period of time there is no opportunity to include into the vital drugs list innovative and effective drugs, which leads to violation of the patients' rights guaranteed by the state.

The General Prosecutor's Office has submitted to the Russian Government its proposals for improvement of the system of provision of vital medicines.

Governmental Procurement System

On 21 May 2013 Dmitriy Medvedev gave instructions to federal executive authorities to assure the timely implementation of the Federal law «On contractual system in the sphere of state and municipal procurement». In particular, the Health Ministry, Ministry of Industry and Trade and Federal Antimonopoly Service must develop and submit for Government's approval a draft regulation «On approval of the procedure for formation of a list of medicines procured in accordance with their trade names» by October 2013.

These state agencies also must develop and submit to the Russian Government a draft regulation «On approval of the list of medicines procured in accordance with their trade names» by 15 December 2013.

Draft law on circulation of medical devices

At the end of May 2013 the FAS presented a report «Draft law «On circulation of medical devices»: FAS position».

In particular, FAS outlined the main competition issues existing on the MDs market: weak regulatory framework; incorrect interactions between distributors, public procurement authorities and medical community; exclusive vertical agreements between distributors and manufacturers of medical products.

FAS suggested the following ways to resolve the above issues:

(i) introduction of definition and criteria of MD interchangeability and MD accessories;

(ii) introduction of the provisions governing the state registration of MDs into the federal law (in particular the law must reflect the main registration stages, list the requirements for the documents, set forth the maximum period of application review and grounds for refusal to register a medical device, describe clinical trials procedure);

(iii) specific restrictions on interactions between MD manufacturers and HCPs;

(iv) introduction of direct regulations on the reasons for cancelation of MDs registration and withdrawal of MDs from circulation;

(v) enhancement of state control over MDs circulation.

Interchangeable MDs, according to the FAS suggestions, are MDs which can be compared in their functional purpose, usage, quality and technical characteristics so that it is possible to substitute one medical product for another.

MD accessory means that a product does not amount to an independent device, but is specially aimed to be used together with a specific medical equipment.

In connection with the introduction of a separate category of MD accessories the FAS also suggests to ban:

(i) the usage of technical tools (e.g. chips, smart-cards, bar-codes, etc.) to restrict the application of alternative accessories/consumables;

(ii) guidelines in the operation manual which directly limit the usage of alternative accessories/consumables for certain types of MDs;

(iii) requirements to use only original accessories/consumables as a warranty condition.

ANTIMONOPOLY CONTROL

Russia and Italy will create a unified data base for monitoring of drug pricing

The negotiations between Italian antimonopoly service and the FAS have resulted in agreement on creation of a unified data base designed to reveal overpricing on drugs. The same negotiations are being held on CIS level. The FAS also hopes that the antimonopoly bodies of European Union will support the above initiative. The FAS emphasized that in case of discovery of different drug prices the FAS may conduct an investigation which may result in antimonopoly proceedings.

Court practice

On 30 April 2013 the Moscow Arbitration Court annulled the decision of the Federal Antimonopoly Service dated 21 December 2012 that revealed concerted practices of two Russian companies during state auctions for drug supply with overall value of RUB 3.4 billion.

This decision of the court is an important precedent where the court did not support the standard of proof suggested by the Federal Antimonopoly Service in concerted practices cases related to the price setting during state auctions.

However, the Federal Antimonopoly Service strongly supports its position that written evidence is not necessary to prove cartels. The FAS suggests to apply the program of liability mitigation and release from criminal liability the natural persons who voluntarily revealed their participation in cartel. However the FAS also emphasized that prison sentence for cartel participants must be the most effective sanction in cartel cases. The Russian Government has already introduced to the State Duma the relevant draft law.

Antitrust proceedings

On 28 May 2013 the Federal Antimonopoly Service has started the antimonopoly proceedings against the Government of the Republic of Sakha (Yakutia), Ministry of Health of the Republic of Sakha (Yakutia), budgetary enterprise «Republic hospital No. 2 – Center of urgent medical help», and the group of companies supplying the medical equipment.

The antimonopoly proceedings were commenced on the basis of materials submitted to the Federal Antimonopoly Service by the Russian Investigation Committee. The FAS claims that the state authorities of the Republic of Sakha (Yakutia) and a number of companies (including foreign MD producers) have entered into an anticompetitive agreement during state procurement of medical equipment which violated the provisions of Competition Law.

It is the first antimonopoly case where the proceedings in the field of antitrust collusion were initiated against foreign legal entities registered and residing abroad.

CONTACT INFORMATION:

JULIA
TORMAGOVA

Head
of Commercial Group

Tormagova@vegaslex.ru

MARIA
BORZOVA

Senior associate
Commercial group

Borzova@vegaslex.ru

Additional information about the products and services of VEGAS LEX can be found at www.vegaslex.ru.

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RECOMMENDATIONS & RECOGNITION:

- European Legal Experts 2012
- Best Lawyers 2012
- International Financial Law Review 2012
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  - Corporate and M&A
  - Project finance
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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