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PHARMA AND MDS. LEGISLATIVE REVIEW. LATEST DEVELOPMENTS

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LEGISLATIVE INITIATIVES

PPP in healthcare

It is expected that by the end of 2013 the general PPP Law may be enacted by the Russian federal authorities. Within the framework of this law the Russian Health Ministry plans to adopt a number of legislative acts, governing PPPs in healthcare.

To develop cooperation between the private investors and state authorities in healthcare sector a specific Coordination Council must be created by the Russian Health Ministry. This Coordination Council must comprise representatives of the federal and regional authorities, pharmaceutical companies, investors, patients, law and economic experts.

Draft resolution «On procedure for determining the content of the federal drug lists»

The Russian Health Ministry has elaborated the draft resolution «On procedure for determining the content of the federal drug lists». At the moment the procedure for determining content of most of the federal lists of drugs (usually used for state procurement purposes or for the purposes of pricing regulations) remains non transparent.

The relevant document inter a*lia* provides for:

- criteria for inclusion of the drugs into the federal lists and exclusion of the drugs from such lists;
- requirements to the information and documents in relation to drugs, which must be assessed;
- requirements towards expertise of the relevant information and documents.

It is planned that the very determining and review of the federal drug lists will be coordinated by the interdepartmental commission of the Russian Health Ministry.

Federal program of state guarantees in healthcare

On 18 October 2013 the Russian Government has considered the draft federal program of state guarantees in healthcare for 2014 and planned 2015-2016 period (the Program).

The Program sets forth the types of medical services, provided free of charge; conditions for provision of such medical services; the list of diseases during which the medical services are provided free of charge; tariff rates for medical services and the relevant payment options; as well as requirements to regional programs of state guarantees in healthcare (the Regional Programs).

The Program expands specific medical treatment options for day hospitals (provided within obligatory medical insurance system), including chemotherapy options for the patients suffering from cancer.

The Program also increases the value of the Regional Programs in 2014 on 15.3% as compared with 2013.

Russian Government approved draft law introducing administrative liability for violations of the Law No. 223-FZ

On 10 October 2013 the Russian Government approved the draft law «On amendments to the Russian Administrative Code» (the Draft Law) introducing administrative liability for violations of the Federal law dated 18 July 2011 No. 223-FZ «On procurement of goods, works and services by certain types of legal entities» (the Law No. 223-FZ).

The Law No. 223-FZ is in force since 1 January 2012, however the exact sanctions for violations of its provisions have not yet been introduced.

The Draft Law suggests introducing administrative liability (in the form of fines) for:

- violation of the deadlines for publication of information regarding procurement of goods, works and services as well as refusal to publish the relevant information;
- approval of tender documentation which does not satisfy requirements of the Law No. 223-FZ;
- rejection of a bid on the basis of requirements which were not included into tender documentation as well as usage of a non transparent assessment system not indicated in the tender documentation.

REGULATORY CHANGES

Restrictions on auction lot structure during state procurement of drugs

On 17 October 2013 the Russian Government adopted the Resolution No. 929 (the Resolution No. 929) which establishes restrictions on auction lot structure during state procurement of drugs. The document will enter into force on 1 January 2014 and will replace the existing Resolution of the Russian Government dated 6 April 2013 No. 301 (the Resolution No. 301).

The Resolution No. 929 prohibits to include into the mixed auction lots INN of unique drugs, as well as narcotic, psychoactive, radiopharmaceutical drugs, if the price of such lots exceeds certain thresholds. The principal difference between the Resolution No. 929 and existing Resolution No. 301 is that thresholds for a maximum price of a mixed lot range from RUR 1 million and RUR 5 million depending upon annual purchase volumes of the relevant buyer.

The Plan for implementation of the state program for development of healthcare sector

The Russian Government approved the Plan for implementation of the state program for development of healthcare sector in 2013 and planned 2014-2015 periods (the Plan). The Plan includes 11 subprograms.

In particular the Plan provides for the following steps:

- by 30 November 2013 – settlement of the legislative gaps in relation to the procedure for determining the content of the federal drug lists;
- by 30 November 2013 – elaboration of the procedure for determining the content of the federal drug lists;
- by 1 June 2015 – approval of the list of drugs which must be procured in accordance with their INN;
- by 1 June 2015 – approval of the procedure for state registration of orphan drugs;
- by 1 December 2014 – implementation of referent pricing system;
- by 1 August 2014 – enhancing state control over drugs' safety and effectiveness;
- by 1 January 2015 – putting into operation the information system for HCPs;
- by 1 June 2015 – introduction of the public control system over medical prescriptions and drugs quality;
- by 1 June 2015 – enhancing the state standards relating to various aspects of drugs circulation.

Liability for violations of drug and MDs advertising regulations

On 22 October 2013 the Federal law dated 23 July 2013 No. 200 amending the Advertising Law and the Russian Administrative Code (the Law No. 200) has entered into force.

The Law No. 200 identifies the violations of drugs and MDs advertising regulations as specific category of administrative violations and establishes the fine for legal entities for such violations in the amount of RUR 200,000-500,000.

PRACTICE

FAS intervenes in the list of state procured drugs

On 14 October 2013 the FAS discovered that the Russian Health Ministry ignored the application of an insulin glulisine producer for extension of the List of drugs procured by the state, approved by the Order of the Russian Health Ministry dated 18 September 2006 No. 665 (the List of State Procured Drugs).

The List of State Procured Drugs provides a minimum basis for state procurement of drugs for disabled people. The List of State Procured Drugs went through numerous amendments, however insulin glulisine has not been included into this list, notwithstanding the fact that its producer submitted the relevant applications several times.

Today insulin glulisine is included into medical treatment standards, which means that healthcare providers must prescribe the relevant drug to the patients provided that certain therapeutic indications are met. However, formally the patients are not able to receive insulin glulisine free of charge, as far as it is not included into the List of State Procured Drugs.

The FAS believes that the Health Ministry created discrimination for the insulin glulisine producer. Therefore, the FAS intends to issue an order for the Health Ministry to cure this inconsistency.

FAS supports position of pharmaceutical distributors

The FAS has issued several warnings to major pharmaceutical companies for unreasonable refusals to enter into supply agreements with pharmaceutical distributors.

In one case the FAS justified its position through unique character of the drug and the actual inability of the distributor to enter the relevant market without supply of such drug.

In the other case the FAS argued that the pharmaceutical company forced its distributor to enter into supply agreement on unfavorable terms and unreasonably avoided conclusion of the agreement.

Several years ago the FAS would have initiated the antimonopoly proceedings for such alleged violations of the Completion Law, which might have resulted in turnover fines. However, today the companies have an opportunity to cure such violations upon receipt of the FAS warning (without opening of the FAS investigation). At the same time the companies have an opportunity to adopt their commercial policies to justify refusals to enter into supply agreement before the FAS.

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VEGAS LEX

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RECOMMENDATIONS & RECOGNITION:

- European Legal Experts 2013
- Best Lawyers 2012
- International Financial Law Review 2013
  - Restructuring and insolvency
  - Corporate and M&A
  - Project finance
- Chambers Europe 2013
  - PPP
  - Competition/Antitrust
  - Dispute Resolution
- PLC which lawyer? 2012
  - Competition/Antitrust
  - Insurance
- The Legal 500 EMEA 2013
  - Dispute Resolution
  - Real Estate
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  - Energy & Natural Resources
- Pravo.ru-300 2012
  - Competiton/Antitrust
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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.

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