Regulatory developments in pharmaceutical sector in Russia: December 2014 – January 2015

VEGASLEX.RU

VEGAS LEX

ФЕВРАЛЬ 2015

CONTENT

1. TERMS AND DEFINITIONS

7 Nosologies means the Resolution of the Russian Government dated 26 December 2011 No. 1155 «On Procurement of Drugs for the Treatment of Patients with Malignant Neoplasms of Lymphoid, Haematopoietic and Related Tissues, Hemophilia, Cystic Fibrosis, Pituitary Dwarfism, Gaucher's Disease, Multiple Sclerosis, as well as after Organ and (or) Tissue Transplantation».

Competition Law means the Federal Law «On Protection of Competition» dated 26 July 2006 No. 135-FZ (as amended).

EDL means the List of Vital and Essential Medicines approved by the Russian Government.

FAS means the Federal Antimonopoly Service.

Federal Law «On Drug Circulation» means the Federal Law dated 12 April 2010, No. 61-FZ «On Drug Circulation» (as amended).

Federal Law «On Health Protection» means the Federal Law dated 21 November 2011, No. 323-FZ «On Protection of Health of Citizens in Russia».

FST means the Russian Federal Service on Tariffs.

HCP means a healthcare professional.

MoED means the Russian Ministry of Economic Development.

MoF means the Russian Ministry of Finance.

MoH means the Russian Ministry of Health.

MoIT means the Russian Ministry of Industry and Trade.

Russian Administrative Code means the Code on Sanctions for Administrative Violations of the Russian Federation.

Russian Criminal Code means the Criminal Code of the Russian Federation.

2. REGULATORY CHANGES

Amendments to the Federal Law «On Drug Circulation» were signed into law

On 22 December 2014, the long discussed amendments to the Federal Law «On Drug Circulation» were enacted. The amendments concern a wide range of issues, inter alia:

(a) key terminology;

(b) IP and data exclusivity protection;

(c) criteria for interchangeability of chemical and biologic drugs;

(d) registration procedure and requirements for registration documents;

(e) separation of registration and clinical trials procedure;

(f) GMP compliance, etc.

Most of the amendments must enter into force from 1 July 2015. However, certain amendments will enter into force later on, in 2016 and 2017.

Russia signed the agreement on a common market for medicines within the EEU

On 23 December 2014, the member states of the Eurasian Economic Union (EEU) signed an international agreement establishing common principles and rules of functioning of the market for medicines within the EEU. The agreement should enter into force starting on 1 January 2016.[1]

The MoH believes that creation of a single pharmaceutical market will simplify the drug turnover and market access for drug manufacturers from different EEU member states.[2] According to the agreement, the market authorization for a particular medicine received in one EEU member state, will be valid on the whole EEU territory. For these purposes, the member states are working on the necessary regulatory framework. In 2015, it is planned to sign 25 acts governing various stages of drugs circulation. Most of these acts are under discussion within the Eurasian Economic Commission.

The MoH also affirms that the enacted amendments to the Federal Law «On Drug Circulation», are to the maximum possible extent harmonized with the discussed EEU legislation.[3]

The Russian Government approved drugs lists for 2015

The Decree of the Russian Government dated 30 December 2014 No. 2782-r approved the new contents of the following drugs lists:

(a) the EDL;

(b) the list of drugs for 7 Nosologies;

(c) the list of drugs for provision to specific groups of citizens;

(d) the minimal assortment of drugs required for medical aid.

These lists will enter into force starting on 1 March 2015. Until this date, the Decree of Russian Government dated 7 December 2011 No. 2199 (governing the EDL approved for 2012 and prolonged further) shall apply.

Based on the formal grounds, it is not entirely clear from the Decree of the Russian Government dated 30 December 2014 No. 2782-r how other new drugs lists will apply before 1 March 2015. However, due to the complex construction of the current procurement regulations, it follows that new drugs lists may not be applicable until the Decree of the Russian Government dated 30 December 2014 No. 2782-r fully enters into force.

The law against counterfeit drugs was enacted

On 31 December 2014, Vladimir Putin signed the Federal Law No. 532-FZ «On Amendments to Certain Federal Laws against the Circulation of Falsified and Counterfeit, Poor-Quality and Non-Registered Drugs, Medical Devices and Falsified Food Supplements» (The Law No. 532-FZ). The Law No. 532-FZ comes into force starting on 23 January 2015.

The Law No. 532-FZ inter alia amends the Russian Criminal Code and Russian Administrative Code. Particularly, the Law No. 532-FZ establishes liabilities for: (i) production of drugs and medical devices without special authorization; and (ii) production, import and turnover of counterfeit drugs, medical devices and food supplements.

[1] See at: http://www.rg.ru/2014/12/23/lekarst-site.html

[2] See at: http://www.pharmvestnik.ru/publs/lenta/v-rossii/podpisano-soglashenie-o-edinyx-printsipax-i-pravilax-obraschenija-lekarstv-v-ramkax-eaes.html#.VNMcjkv8OB4

[3] See at: http://www.pharmvestnik.ru/publs/lenta/v-rossii/podpisano-soglashenie-o-edinyx-printsipax-i-pravilax-obraschenija-lekarstv-v-ramkax-eaes.html#.VNMcjkv8OB4

Such amendments are made to bring Russian laws into compliance with the «Council of Europe Convention against the Circulation of Counterfeit Medical Products and Similar Crimes Creating Threats to Public Health» signed by the Russian Federation.

3. DRAFT REGULATIONS AND LEGISLATIVE INITIATIVES

The MoIT intends to elaborate additional preferences for deep localization stages of drug production

By 1 June 2015, the MoIT intends to elaborate a document describing the manufacturing stages of different types of drugs.[4] Based on this document, a preference is anticipated to be established for drug manufacturers investing into deep localization in Russia.[5] The MoIT created a specific working group involving industry representatives, in order to prepare a list of localization criteria, which may differ for various types of drugs.

Furthermore, additional preferences would be available for patented innovative drug manufacturers who will sign long-term contracts involving localization of production.[6] The mentioned acts could be drafted in 2015.

Compulsory licensing: new developments

At the end of December 2014, Sergey Kalashnikov, Chairman of the State Duma Committee for Health Protection, sent to Dmitri Medvedev an official letter concerning the necessity to introduce compulsory licensing in the pharmaceutical sector in Russia.[7] The letter states that certain countries, such as India and Thailand, have already used this mechanism, and therefore Russia should also consider the possibility to adopt the relevant regulations. The letter, however, does not describe the full picture and consequences for the economies of the countries, which used compulsory licenses for medicines.

Furthermore, in February 2015, several governmental discussions are being held in relation to the usage of compulsory licenses and possible scope of application of the relevant instrument.

The MoH is working on developing a long-term strategy of healthcare development

On 19 December 2014, the MoH published a draft of the «Strategy for the Healthcare Sector's Long-Term Development» (further the "Draft Strategy").[8]

This document sets forth the main priorities of the national healthcare policy, such as improvement of medical treatment quality, increase of accessibility to medical assistance and life expectancy, as well as a decrease in death rate.

According to the Draft Strategy, the main development areas will be:

(a) improvement of the program of healthcare guarantees;

(b) development of compulsory and voluntary medical insurance systems;

(c) PPP development;

---

4 See at: http://minpromtorg.gov.ru/press-centre/all/#!minpromtorg_podderzhit_proizvoditeley_lekarstv_polnogo_cikla

5 See at: http://minpromtorg.gov.ru/press-centre/all/#!minpromtorg_podderzhit_proizvoditeley_lekarstv_polnogo_cikla

6 See at: http://minpromtorg.gov.ru/press-centre/all/#!minpromtorg_podderzhit_proizvoditeley_lekarstv_polnogo_cikla

7 See at: http://www.pharmvestnik.ru/publs/lenta/v-rossii/primenenie-prinuditeljnogo-litsenzirovanija-v-otnoshenii-nekotoryx-lekarstv-mozhet-statj-glavnoj.html#.VNN34Uv8OB4

8 See at: http://www.pharmvestnik.ru/publs/lenta/v-rossii/minzdrav-rossii-razrabotal-proekt-strategii-razvitija-rossijskogo-zdravooxranenija.html#.VNOhxEv8OB5

(d) development of public medical organizations;

(e) mandatory HCP accreditation;

(f) development of IP solutions in healthcare system;

(g) enhancement of vertical control and supervision system;

(h) accelerated innovative healthcare development, based on biomedical and pharmacology researches; etc.

The Draft Strategy implementation shall contribute to the achievement of macroeconomic key performance indicators set forth in the Concept of Long-Term Economic Development and the Concept of Demographic Policy.

The MoH intends to eliminate unreasonable administrative barriers for price registration

On 30 December 2014, the MoH publicly notified market participants about the preparation of the draft Resolution of the Russian Government «On Amendments to the Resolution of the Russian Government dated 29 October 2010 No. 865» (further the «Draft Resolution»).[9] The Draft Resolution is expected to come into force starting on 1 May 2015.

Amendments will be aimed at the elimination of the necessity to go through the full procedure of price registration, if a manufacturer of essential drugs applies for the introduction of minor changes to the register of maximum prices. The MoH believes that the document will improve the registration timelines and make the administrative procedures easier.

The MoH intends to elaborate interchangeability guidelines

On 22 January 2015, the MoH publicly notified market participants on the preparation of the draft Resolution of the Russian Government on the procedure for interchangeability determination.[10]

At the end of December 2014, the interchangeability criteria were introduced into the Federal Law «On Drug Circulation». However, the procedure for implementation of the interchangeability criteria must be further developed and approved by the Russian Government. The public discussion of the relevant notification continues until 6 February 2015.

Restrictions on access of foreign drugs to state procurement may be introduced in the mid-February

The Russian Government approved the Plan of high-priority measures for sustainable economic and social stability development in 2015 (further the «Plan»). The Plan was signed by the Russian Prime Minister Dmitry Medvedev on 27 January 2015 No. 98-r.

The key areas outlined in the Plan are:

(a) import substitution support;

(b) assistance in development of small and middle-sized business;

(c) creating favourable conditions for investments in top-priority economic sectors;

(d) lowering the level of stress on the labour market;

(e) optimization of budget costs and reduction of inefficient expenses; and

(f) improvement of banking system stability.

9 See at: http://regulation.gov.ru/project/22069.html?point=view_project&stage=1&stage_id=7420

10 See at: http://regulation.gov.ru/project/22466.html?point=view_project&stage=1&stage_id=7557

Particularly, in the public healthcare area, the following measures are expected to be implemented:

(a) by 2 February 2015, the MoH, FST and MoED must amend the Federal Law «On Drug Circulation» to provide the possibility of one-time indexation of prices for low-cost essential drugs;

(b) by 27 February 2015, the MoF, MoH and MoED must suggest improvements of public drugs supply; and

(c) by 15 February 2015, the MoIT must provide restrictions on access of foreign drugs to state procurement tenders, if two or more locally manufactured drugs participate in the relevant tender.

However, the Russian Government also informed that the high-priority measures list is not complete yet, and will be expanded with new anti-crisis measures.

Additional measures were proposed by the FAS for IP protection against unfair competition

The FAS has prepared further additions to the «fourth antimonopoly package» of amendments to the Competition Law.[11] Inter alia, such additions are aimed at the enhancement of IP protection against unfair competition.

In particular, the FAS believes that the law should directly prohibit:

(a) unfair usage of established goodwill of a company by competitors;

(b) unfair usage of company's know-how and trade secrets by competitors;

(c) unfair usage of brands, if such brands are highly similar to the brand names of other companies (such as in the Konstantin Vacheron case); and

(d) unfair registration of a trademark, which may damage the established brands of competitors (such as in the AntiGrippin case).

Such measures may be particularly important for the pharmaceutical sector, where the protection of goodwill and know-how plays an extremely important role for companies.

4. REGULATORY PRACTICE

A pharmaceutical manufacturer appeals against FAS ruling

On 25 September 2014, the Moscow Arbitration Court confirmed the legitimacy of the decision of the FAS against a Russian subsidiary of a foreign drug manufacturer for violating the antimonopoly law. According to the FAS the company unreasonably refused to enter into an agreement with a local company for the supply of unique medicine for treating renal deficiency by peritoneal dialysis.[12] The local company provided integrated medical services for organizing and rendering outpatient peritoneal dialysis in the Samara Region.

The court of first instance confirmed the legitimacy of FAS actions. However, the company filed an appellation complaint, which was accepted by the court for consideration in January 2015.[13] Therefore, it is necessary to monitor further development of this case as it may play an important part in the development of regulatory practice on abuse of dominance.[14]

[11] See at: http://fas.gov.ru/fas-in-press/fas-in-press_40101.html

[12] Based on the analysis of the market, the FAS has included the company in the Register of Dominant Entities. This usually means that any behaviour of the company may be at risk, due to the fact that the FAS will not be obliged to prove its market dominance, as soon as the relevant information already is present in the Register of Dominant Entities.

[13] See at: http://kad.arbitr.ru/Card/b174dc66-75a8-4ab6-b23b-5b9e61231516

[14] See at: http://www.pharmvestnik.ru/publs/lenta/v-rossii/bakster-nameren-obzhalovatj-reshenie-fas-rossii.html#.VNIvEp2sUqE

Contacts

ALEXANDER SITNIKOV
Managing partner

sitnikov@vegaslex.ru

MARIA BORZOVA
Manager of Life Sciences Projects

borzova@vegaslex.ru

For further information on the services of VEGAS LEX, please, visit our website www.vegaslex.ru