



Newsletter

Pharmacy and Pharmaceuticals Market Regulation News

September 2014

NEWS BRIEF

Most Clinical Trials in Russia Are Not Compliant

This conclusion has been made by Roszdravnadzor after summing up the research on control over clinical and pre-clinical studies of medical products.¹ The non-compliances identified include those with the regulations for storage of drugs, as well as documentation errors. As stated by Head of Control over Clinical Trials of the Directorate for State Control of Medical Products Quality at Roszdravnadzor Evgeny Rogov at a conference on clinical and pre-clinical trials held this June in St. Petersburg, when exercising its control duties, Roszdravnadzor faces the problem of no liability for the said non-compliances provided for by the law. Roszdravnadzor representative also mentioned another problem: no assessment of clinical trials results.

To see the report delivered by Roszdravnadzor at the conference click [here](#).

Common Drugs Market within the Eurasian Economic Union to Operate from 2016

At the Supreme Eurasian Economic Council meeting in late May 2014 the Presidents of Russia, Kazakhstan and Byelorussia signed the Treaty on the Eurasian Economic Union. The Treaty provides for phasing of establishment of free movement regime for goods, capital, labor, and services, as well as equal access to transport and energy infrastructure and the general customs regulation rules. It is also planned to create the common drugs market that would comply with the Good Pharmacy Practice (GPP) standards. The novelties will include:

- adoption of the common regulations for circulation of drugs;
- harmonization and unification of the drugs circulation legislation.

The common drugs market is to be established by 2016.

For more details please click [here](#).

¹ <http://www.pharmvestnik.ru/publs/lenta/v-rossii/roszdravnadzor-pochti-vse-klinicheskie-issledovaniya-v-strane-proxodjat-s-narushenijami.html>



Share of Domestic Goods Purchased for State Needs Is to Be Increased Up to 80%

In order to limit state procurement of imported goods the Ministry of Industry and Trade has started drafting the list of goods for state needs that will be ideally purchased from the domestic manufacturers or the Customs Union manufacturers. The relevant departments and state companies are to develop the schedules of transition to the new procurement regime until 2017. The project has initially provided for a full ban to purchase the goods belonging to the said list from foreign manufacturers, but then the ban was replaced with restrictions. The new wording of the draft decree provided for admission to tendering of requests for foreign goods in the following cases: where a tender raises no interest at all or where only one bidder from the Customs Union countries, i.e. Russia, Belorussia or Kazakhstan, is interested in the tender.

For more details please click [here](#).

Healthcare Development State Program Implementation Plan Approved

Russian Prime Minister Dmitry Medvedev has signed relevant Russian Governmental [decree](#) No. 1727-p dd. September 4, 2014.

The [Program](#)² implementation plan contains a list of moves of particular importance for its implementation. The plan also specifies the timelines and the federal executive bodies in charge.

Thus, the plan provides for the following moves and the timelines for their performance:

- drafting of the list of drugs that are to be purchased by their trade names before June 1, 2015;
- drafting of the list of VED by December 30, 2014, 2015, 2016;
- ensuring of the state regulation of the drug prices before September 30, 2015.

Medical Equipment Manufacturing to Be Controlled by the Russian Ministry of Health

According to [RIA Novosti](#), manufacturing of most advanced medical equipment at the Zelenograd facilities is to be particularly controlled by the Russian Ministry of Health. According to Veronika Skvortsova, the Head of the Ministry, medical equipment manufacturing support will be provided under the federal target-oriented program for development of pharmaceutical and medical industry. Mrs. Skvortsova also reminded that the first list of medical equipment Russia will no longer purchase from abroad had been drafted a few months ago and emphasized the need for medical equipment development and manufacturing in Russia.

The FAS of Russia Clarifies the Issues Related to Establishing the Validity of Drugs

Setting requirements to the validity periods in percentages may result in unequal terms for drug manufacturers, as well as in limitation of the competition and reduction of the numbers of parties to the procurement process. In this regard, the FAS of Russia in its [Letter](#) ref. No. AK/34487/14 dd. August 26, 2014 explains that the validity of drugs specified in the documents for procurement by the state and municipal customers shall be well-grounded and specified in form of a period (e.g. in years, months, days) within which period drugs shall remain valid, or a specific date before which drugs shall remain valid for intended use.

Withdrawn Drugs May Be Searched for Online

² Healthcare Development State Program has been established by the Russian Governmental Decree dd. April 15, 2014 No. 294.



The relevant [service](#) is now available at Roszdravnadzor site. According to Mikhail Murashko, the Acting Head of the Federal Service, a similar service for control over the drugs quality is currently under development.

Expert Board for Improvement of the Contract System Regulatory Support Established

The [Expert Board](#) has been established at the Russian Ministry of Economic Development. The Board shall consist of 14 experts and is headed by Sergey Kalashnikov, Deputy Russian Minister of Health. Sergey Kraevoy has been appointed his deputy.

The Board activities shall be mainly focused on the following:

- expert review of the draft regulations developed as part of the contractual relationships being established and developed;
- review of notices from individuals and public institutions on the need to improve the procurement efficiency and the Russian law in the field;
- drafting of proposals to improve the transparency and the availability of information under contractual relationships, including those related to development and improvement of the common data system in the procurement sphere.

State Committee Against Illicit Trafficking, Manufacturing and Circulation of Counterfeit Goods

Its purpose is to coordinate the activities of the federal executive bodies, the state executive bodies of the Russian subjects, as well as the local authorities to prevent illicit trafficking, manufacturing and circulation of industrial and counterfeit goods. The Russian Presidential [Order](#) to establish the State Committee provides for establishing of commissions to coordinate the activities of territorial bodies to prevent illicit circulation of industrial goods and to assess the situation in the field in the Russian subjects. The Order is being currently reviewed.

LEGISLATIVE AMENDMENTS

AMENDMENTS IN THE RUSSIAN CIVIL CODE

On September 1 the amendments to the Russian [Civil Code](#) of particular importance for the Russian companies' operation entered into force.

These are particularly the following ones:

1. **New Classification of Legal Entities** (Art. 65.1)

The lawmakers have abandoned division of joint-stock companies into open and closed ones, now the Russian legal entities will be either corporate or unitary.

As per the amendments entered in force, those legal entities whose founders (participants) have a right of participation (membership) in them and establish their supreme body shall be corporate entities, while the founders of unitary entities shall not become their participants and shall not have a right of membership therein.

However, the existing CJSC and OJSC shall be entitled to specify the new name at the next amending of the Charter.

2. **Amendments to the Provisions on Legal Entity's Bodies** (Art. 53)

Legal entities shall now be entitled to appoint two or more people that shall be entitled to act on behalf of such legal entity jointly or individually, which shall be provided for in the constituent documents.



Actual compliance with the regulation is challenging, since no form to amend the Russian Unified State Register of Legal Entities accordingly is currently available.

3. **Amended Rules for Holding of General Meetings** (Art.67.1)

Joint-stock companies shall have their participants' resolutions acknowledged by a registrar or a notary. Holding of a general meeting of LLC's participants shall be acknowledged by a notary, unless the Charter of such Company has been amended as appropriate or it has been unanimously resolved that no notarization is needed prior to voting on the agenda items. No notarization had been required before.

4. **Amended Procedure for Payment of the Authorized Capital** (Art. 66.2)

When establishing an LLC, the founders shall pay at least $\frac{3}{4}$ (formerly at least $\frac{1}{2}$) prior to its state registration, and the rest within the first year of the company's operation.

5. **Provisions on the Liability of a Person Authorized to Act on Behalf of a Legal Entity, of the Members of a Legal Entity's Boards and Persons Defining Legal Entities Actions** (Art. 53.1)

- the amendment shall introduce liability of a person acting on behalf of a legal entity (including the members of a legal entity's boards, except for those having voted against the decision resulting in the legal entity suffering losses, or those having acted in good faith and not having voted) that shall be obliged to compensate for legal entity's losses resulting from their fault, as requested by the legal entity, or its founders (participants) acting for the benefit of such legal entity;
- however, a person authorized to act on behalf of a legal entity shall be liable if it is proven that when exercising their rights and fulfilling their duties they acted in bad faith or in unreasonable manner, particularly if their actions (omission to act) have not been compliant with the standard terms of civil business practices or a standard entrepreneurial risk;
- joint liability of a person in case of joint damages to a legal entity is introduced.

6. **Notion of a Corporate Agreement Introduced** (Art. 67.2)

As per the Civil Code, a corporate agreement shall be an agreement on exercising of corporate (member's) rights by business entity's members. Business entity members having entered into a corporate agreement shall be obliged to notify the company on entering into a corporate agreement; however, there are no obligations to disclose its contents.

Non-compliance with such corporate agreement may constitute a ground for invalidating of a resolution made by the business entity's board in a claim filed by a party to such agreement. This shall become possible where all the participants to a business entity were the parties to a corporate agreement at the moment a relevant resolution was made by the business entity's board.

7. **Notion of Affiliation Introduced** (Art. 53.2)

Affiliation shall be defined as association relationship between persons.

AMENDMENTS IN STATE PROCUREMENT

Russian President Vladimir Putin Signs the Federal Law Amending the Law on the Contract System in State Procurement

The documents provides mainly for the following amendments and developments:



- the conceptual framework shall be expanded: a concept of *aggregate annual procurement volume* shall be introduced, procedures for application of the methods to justify contract prices and to purchase from SME and socially oriented non-commercial organizations be made more specific;
- the procedure for purchasing to support the activities to customers in foreign countries shall be specified;
- the number of purchases from a single supplier (contractor, provider) shall be increased and the procedure thereof shall be simplified: a possibility of purchasing whose amount does not exceed RUB 2 million or 5 % of the aggregate annual volume (but not exceeding RUB 50 million) from a single purchaser;
- purchasing through limited-bidding tenders shall be provided for.

The full wording of the Federal Law “On Amending of the Federal Law “On the Contract System in Procurement of Goods, Works and Services to Meet the State and Municipal Needs” may be found [here](#).

Russia's Treasury Agencies to Register the State Procurement Participants

The Russian Ministry of Justice has registered [Order of the Russian Treasury No. 4н dd. March 25, 2014](#), pursuant to which the Treasury Agencies shall register the state procurement participants and deliver digital signature verification keys to the state procurement participants. To get registered at the official site an entity shall submit to the Federal Treasury Agency at its location the information on such entity provided for by the Order. The scope of information shall depend on particular state procurement participants. The said regulations shall apply to customers and those persons covered by [Federal Law](#) dd. April 5, 2013 No. 44-FZ “On the Contract System in Procurement of Goods, Works and Services to Meet the State and Municipal Needs”, except for suppliers (contractors, providers).

Regulations for the Russian Ministry of Health's Exercising Departmental Control in Procurement to Meet the Federal Needs Approved

The relevant [Order of the Ministry of Health No. 293н dd. June 19, 2014](#) was published on August 15 in *Rossiyskaya Gazeta*.

Its main provisions include the following:

- departmental control shall be exercised by the departmental control commission approved by the Russian Minister of Health. The commission shall comprise the ministerial officials as suggested by the relevant ministerial departments, as well as customers' experts authorized to exercise departmental control by the customer's head;
- departmental control shall be exercised through desk and field reviews;
- the timeline for a departmental control reviews shall not exceed 15 calendar days and may only be extended once for at most 15 calendar days upon decision of the Minister or the Deputy Minister authorized by him;
- should the checks identify actions suggesting an administrative offence, the check materials shall be submitted to the relevant federal executive agency authorized to exercise control in procurement of goods to meet the state and municipal needs, and should the check identify actions suggesting a criminal offence, to the law enforcement bodies.

AMENDMENTS IN THE PHARMACEUTICAL INDUSTRY

The Law Amending Article 101 of the Federal Law “On Fundamentals of the Public Health Protection in the Russian Federation” Enters in Force



The amendments relate to the date of entering into force of certain provisions of the said Federal Law stipulation for transfer of authorities with regard to provision of medicines to people having rare diseases as per the list approved by the Russian Government and drafted in accordance with the procedure established by it to the state authorities of the Russian subjects. Transfer of duties related to provision of medicines to treat costly diseases put on the 7 Nosologies Program at the level of Russian subjects has been postponed from January 1, 2015 to January 1, 2018.

According to State Duma deputy Olga Borzova, the initial deadline, i.e. January 1, 2015, does not meet the public interests with regard to provision of medicines and will only lead to inefficient budget spending.³ It has also been noted that numerous regional tenders will lead to a reduced number of direct manufacturer offering substantial discounts and an increased number of intermediaries setting highest premiums.⁴

The amendments entered into force appear to be likely to positively affect the pharmaceutical companies activities, since the said companies will be able to expand their activities in various regions of Russia and will be able to get prepared to the Russian subject-level tenders.

The legislative draft may be found [here](#).

Procedure for Holding of the Register of Delivered Medical Device Clinical Trial Permits Approved

The relevant [Order of Roszdravnadzor No. 2525 dd. April 14, 2014](#) was published on August 27 in *Rossiyskaya Gazeta*. The document contains provisions on what a register entry shall specify, as well as on the timelines for making entries to the Register. The Register shall be kept electronically. The document has become valid on this September 7.

Lists of Codes of the Drugs and Medical Devices VAT Taxable at 10% for Sale and Import Adjusted

[The Russian Governmental Decree No. 870 dd. August 28, 2014](#) "On Amending of the Russian Governmental Decree dd. September 15, 2008 No. 688" has been published. The amendments shall expand the scope of the Decree. The relevant adjustments can be seen from the Section names: Section *Drugs, Including Those Compounded in Pharmacies* has been renamed in *Drugs, Including Pharmaceutical Substances, and Medical Products Compounded by Pharmacy Entities*, while *Healthcare Products* will be called *Medical Products*.

The document has entered into force on this September 9.

Procedure for Drug Registration and Expert Review Amended

The relevant [Order of the Russian Ministry of Health No. 152H dd. April 3, 2014](#) "On Amending Certain Orders of the Ministry of Health and Social Development of the Russian Federation and the Ministry of Health of the Russian Federation". Particularly, the following documents shall be amended:

Order of the Ministry of Health and Social Development No. 750H dd. August 26, 2010 has been particularly amended so that no materials required for an expert review may be demanded from the applicant when making an expert review of medicines. Should the materials provided to the expert for delivering their opinion be not enough, the expert shall apply for materials required to the management of their expert institution, and the management shall file a relevant application to the Ministry.

³ <http://www.pharmvestnik.ru/publs/lenta/v-rossii/sovets-federatsii-vnes-izmeneniya-v-zakon-ob-osnovax-oxrany-zdorovija-grazhdan.html>

⁴ *Ibidem*.



The administrative regulations of the Russian Ministry of Health for provision of state registration of drugs provides for more specific timelines and procedure for review of documents.

Lists of Narcotic Drugs and Psychotropic Substances Manufactured, Stored and Imported (Exported) Under the State Quotas Extended

The relevant Russian Governmental Decree No. 513 dd. June 4, 2014 "On Amending of the Appendix to the Russian Governmental Decree dd. June 22, 2009 No. 508" was signed by Prime Minister Dmitry Medvedev.

LEGISLATIVE DRAFTS

The State Duma Adopts Amendments to the Law "On Advertising" As Relates to Advertising of Medical Services

Article 24 of the Law "On Advertising" has been amended to conciliate differences between Parts 7 and 8 thereof. Part 7 provides for certain requirement to the advertising content, including the need to accompany the advertisements of medical services, of which prevention, diagnostics, treatment and medical rehabilitation methods with a warning on contraindications to their use and application, and on the need to consult the leaflet or a specialist, except where such advertisements are placed at the venues of medical and pharmaceutical fairs, seminars, conferences and such other events, as well as in specialized publications for medical and pharmaceutical workers, as well as where only medical and pharmaceutical workers act as consumers for such advertisements. Whereas, according to Part 8, advertising of medical services, of which prevention, diagnostics, treatment and medical rehabilitation methods may only be placed in specialized medical and pharmaceutical media. As of now, the difference has been conciliated, since advertising of medical services has been removed from the scope of Part 8.

The Russian Ministry of Health Drafts a List of OTC Drugs for Sale in Grocery Store Chains

The document has been drafted as instructed by First Deputy Prime Minister Igor Shuvalov at the meeting of the Governmental Commission for Competition and SME Development this June 17. The List contains seven treatment groups: throat antiseptics (washes, pastilles and sprays), iron preparations, sea water and sodium chlorine based drugs for cold and rheum, activated carbon, antiviral and anti-allergic ointments and creams.

The Draft List is available at Pharmvestnik's [website](#).

Regulations for Provision of State Licensing Service for Narcotic Drugs Circulation Activities Developed

The Draft Order of the Ministry of Health "On Approval of the Administrative Regulations for Provision of State Licensing Service for Narcotic Drugs and Psychotropic Substances by Executive Bodies of the Russian Federation Subjects (Except For Activities Performed by Drug Wholesalers and Pharmacy Entities Subordinate to the Federal Executive Bodies and the State Academies of Sciences)" will make the procedure for provision of the state service more concise and clear. The Regulations provide for a standard procedure and standards for licensing, which is supposed to substantially facilitate the process of applying to the executive bodies of the Russian Federation subjects.

The Russian Government Develops the Draft Decree "On Approval of the Procedure for Establishing the Lists of Drugs Provided for by the Russian Law"

The Draft is meant to clarify the process of establishing the following lists:

- the list of vital and essential drugs – the VED List;



- the list of drugs for people having hemophilia, mucoviscidosis, pituitary dwarfism, Gaucher disease, malignancies of lymphoid, hematopoietic and related tissues, multiple sclerosis and people undergoing organ and (or) tissue transplant surgery purchased using the federal budget funds;
- the list of drugs for medical use, including those prescribed by the medical panels of medical institutions.

Moreover, the draft also provides for establishing of the minimum range of drugs for medical use required for medical assistance. The minimum range shall be established for various types of pharmacy entities by international non-proprietary names (by generic or chemical names if no INN available) out of drugs for medical use. Amending of the VED List, whose current version has not been amended since 2012, is being planned now.

Administrative Liability Suggested for Doctors Not Complying with the Procedure for Drug Prescription

A relevant draft federal law has been submitted by the Ministry of Health for public debates that is supposed to have lasted until this September 20. The draft provides for imposing of a fine amounting to RUB 2000 or 3000 thousand on doctors failing to comply with the procedure for medical-use drugs prescription. Roszdravnadzor would be vested with the powers to consider cases involving relevant administrative offenses. If approved, the document shall enter into force from January 1, 2015.

Draft Law on the International Medical Cluster Submitted to the State Duma

The draft law has been submitted by Edinaya Rossiya Deputy Nikolay Gonchar. As per the draft, domestic and foreign legal entities may join the cluster and act as its residents for up to 10 years. A specific legal regime providing for simplified terms of the residents' operation is expected to be applied within the cluster. Thus, documents on establishing of a foreign legal entity are expected to be accepted *pari passu* with the Russian ones.

The draft law will be currently considered in the first reading.

JUDICIAL PRACTICE

The Union of Arbitration Tribunals Applies to the Russian Constitutional Court to Have Article 9(8) State Contract of Federal Law No. 94 "On Placing of Orders for Delivery of Goods, Performance of Works and Provision of Services for State and Municipal Needs" Checked Against the Constitution

The application relates to Ruling of the Supreme Arbitrazh Court of the Russian Federation on non-arbitrability of state procurement disputes (Ruling of the Presidium of the Supreme Arbitrazh Court of the Russian Federation dd. January 28, 2014 No. 11535/13). According to President of the Union of Arbitration Tribunals Alexey Kravtsov, it is still unclear, for what reason the Supreme Arbitrazh Court of the Russian Federation decided to alter the practice, for 9 years of the Law existence, there had been no doubts about the competence of arbitration tribunals in state procurement.

Background of the case: Following a tender, a state public health institution had entered into a contract for fire safety works with ArbatStory LLC. The contract contained an arbitration clause, therefore the parties submitted their dispute to the arbitration tribunal that ruled in favor of the institution. ArbatStory LLC then appealed from the decision, however, the appellate and cassation courts upheld the decision of the arbitration tribunal. The contractor appealed from the decision at the Supreme Arbitrazh Court of the Russian Federation.

Decision of the Supreme Arbitrazh Court of the Russian Federation: the defeated party's representatives claimed that the contract entered into following the tender is in fact an adhesion contract, which prevents the successful bidder from amending of its terms unilaterally. The Supreme Arbitrazh Court of the Russian Federation accepted the argument and stated that state procurement disputes may not be treated as private disputes between private parties, and therefore are not arbitrable.

For more details please click [here](#).



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