This overview outlines recent trends in the pharmaceutical industry in Russia since we issued a similar newsletter in June 2010.

**Law on Circulation of Medicines**


It replaced Federal Law No. 86-FZ “On Medicines,” dated 22 June 1998, which established the general framework for the development, production, pre-clinical and clinical trials of medicines, as well as their quality control, effectiveness, safety, and trading. For a detailed overview of the Law on Circulation of Medicines please refer to our Special Update issued on 13 April 2010.

**State Support of Russian Manufacturers**

Russian legislation contains certain measures to support Russian manufacturers, in particular, in the sphere of public procurement. Goods of foreign origin are treated equally with Russian goods if the foreign country establishes the same regime with respect to Russian goods.1

However, the state may prioritize the delivery of certain Russian goods over the same kinds of foreign goods. Such a priority regime is currently established for medicines until 31 December 2010. Under this regime, participants of an auction or tender applying for delivery of medicines of Russian origin are subject to certain preferences.2 In the case of a tender, applications for delivery of foreign medicines are evaluated with a 15% increase of the contract price. The winning contract is executed based on the price initially indicated in the tender application. In the case of an auction, the winner's price for delivery of foreign medicines is actually reduced by 15%.3

According to publicly available information, the Association of Russian Manufacturers of Medicine (the “ARMM”) suggested extending the period for the abovementioned regime. This proposal was submitted to the Ministry of Industry and Trade on 1 June 2010.4

**The Concept of Medicine of Russian Origin**

Currently, the Customs Code defines the country of goods’ origin as the country where the goods were either manufactured in full or sufficiently processed.5 The preparation of goods for sale or transportation (e.g., assortment, repacking) is not considered sufficient processing.6 Recent practice shows that medicines originating from foreign countries and packaged in Russia are not considered goods of Russian origin.7 Consequently, a person entering into a state or municipal contract for the delivery of such goods will be subject to the less preferable pricing procedure, as...
compared to a contract for the delivery of Russian goods.

The President requested various state ministries, including the Ministry of Industry and Trade, the Ministry of Economic Development and the Ministry of Healthcare and Social Development, to develop criteria for determining which medicines manufactured with substances of foreign origin can be considered Russian goods.\(^8\)

The ministries have interviewed Russian medicines manufacturers to elicit their understanding of the concept of medicine of Russian origin.\(^9\)

The ARMM suggested its own definition of medicine of Russian origin and circulated it among the relevant ministries for their consideration. According to the ARMM:

“A Russian medicine means goods manufactured from both Russian and imported pharmaceutical substances on the territory of the Russian Federation and released for circulation on the territory of the Russian Federation. If only primary and secondary packaging of such goods is performed on the territory of the Russian Federation, such goods will only enjoy the status of Russian goods until 1 January 2014. As of 1 January 2014, only goods that have undergone all the stages of their manufacturing on the territory of the Russian Federation, irrespective of the country of origin of the pharmaceutical substance, can enjoy the status of Russian goods.”\(^10\)

**The Concept of the “Local Manufacturer”**

In addition to a definition of Russian medicine, the ARMM suggested two options for defining the term “local manufacturer”:

**Option One:** A local manufacturer means a manufacturer of ready-made forms of medicine and/or the packager responsible for the release of a series of medicines for circulation on the territory of the Russian Federation, having presented its certificate of analysis with respect to such medicine and holding a Russian Federation license for the manufacturing of medicines, including holders of licenses for incomplete manufacturing, as well as to certain processes of sorting, packaging and marking.\(^11\)

**Option Two:** A local manufacturer may mean one of two categories of manufacturers. The first category of manufacturers may expect the biggest preferences in the form of tax, customs and other benefits. This category covers companies manufacturing medicines based on their own research and development or patents from other domestic experts or companies. Such medicines should be either absolutely innovative or be analogous to foreign medicines irrespective of the country where they are marketed. The second category covers companies with the same parameters, except with their own research and development. To be in the second category, the companies must, as a minimum, cover all the production cycles at their facility. Such “second raters” may expect favored treatment for the expansion and improvement of production facilities, acquisition of new licenses, creation of new jobs, meeting of the needs of the market for vitally essential and most important medicines and – which is a matter of priority – for their own research and development of unique medicines and technical retooling.\(^12\)
Amendments to the Powers of State Authorities in the Sphere of Pharmaceuticals Circulation


The Resolution extends jurisdiction of the Ministry of Healthcare and Social Development to include the powers previously exercised by the Federal Service for Supervision in the Sphere of Healthcare and Social Development. The new powers include: (i) issuing permits for carrying out the expert review of medicines for medical use and permits for the import of medicines; (ii) performing state registration and maintaining the registers of medicines for medical use and manufacturers’ maximum sale prices for essential and necessary medicines; and (iii) certifying specialists involved in medicines circulation and performing accreditation of medical organizations to carry out clinical trials.

The Ministry of Industry and Trade is now authorized to license the manufacture of medicines for medical use and maintain the register of such licenses (prior to the amendments the Federal Service for Supervision in the Sphere of Healthcare and Social Development was entitled to license the manufacture of medicines).

The Federal Service for Supervision in the Sphere of Healthcare and Social Development is now also entitled to place on its website the information regarding decisions on amending instructions on the use of medicines, the suspension or renewal of the use of medicines, and their withdrawal from circulation.

State Registers in the Pharmaceutical Industry

The Ministry of Health Care and Social Development has created a state portal that provides access to the state register of medicines and the state register of manufacturers’ maximum sale prices of essential and necessary medicines. The register of medicines contains information on registered medicines, including their brand and international unpatented names, storage conditions and shelf life, recommended applications and contraindications, side effects, application technique, the manufacturers’ names and addresses. The register of manufacturers’ maximum sale prices, among other things, contains data on medicines’ maximum sale prices and dates of their state registration, numbers of medicines’ registration certificates and their validity period.

The portal also allows medicines’ manufacturers that applied for the state registration of a medicine to monitor on-line the process of such registration.


Restrictions Applied to Medical and Pharmaceutical Workers

The Draft Law stipulates certain restrictions on (i) medical workers (i.e., employees of medical organizations providing medical aid to patients) and heads of medical organizations as well as (ii) pharmaceutical workers and heads of drug stores in the course of carrying out their professional activities. According to the Prime Minister:

“Over the past few decades, improper practices between the manufacturers of medicines... and part of the medical community have taken shape. Undoubtedly, pharmaceutical companies are entitled to advertise their products. However, they should do it in a civilized manner and in full conformity with generally accepted ethical standards and Russian law.”

According to the Draft Law, medical workers and heads of medical organizations cannot:

- accept presents, money (save for payment under agreements on clinical trials and agreements on educational and/ or scientific activities of the medical worker), payment for entertainment or vacations from organizations carrying out development, manufacturing and/ or realization of medicines and medical products, organizations which have the rights to use brand names of medicines, organizations carrying out wholesale of medicines and drug stores (the “Organizations”);

- take part in entertainment and holiday events financed by the Organizations or any events financed by any Organization (save for events held within clinical trials);

- enter into agreements with the Organizations to prescribe or recommend certain medicines or medical products to patients (save for agreements on clinical trials);

- receive samples of medicines or medical products from the Organizations to be offered to patients, prescribe medicines using blanks with the names of medicines or any information of an advertizing nature, or use any products bearing the Organization’s logo, medicine or medical product’s brand name in the medical organization; and

- meet with the Organizations’ representatives during working hours to discuss issues relating to the circulation of medicines and medical products (save for meetings of the Organizations’ representatives with the administrative staff entitled by the head of the medical organization).

In addition, pharmaceutical workers and heads of drug stores cannot:

- accept presents, money, payment for entertainment and vacation made by the Organizations;

- receive samples of medicines or medical products from the Organizations to be offered to customers;

- enter into agreements with the Organizations (both orally and in writing) to offer customers certain medicines or medical products; and

- conceal information about medicines or medical products available at a lower price from customers.
The Pharmaceutical Industry in Russia: Recent Trends

September 2010

State authorities must be notified of any instances of a medical or pharmaceutical worker receiving a proposal from an Organization to carry out any of the above activities. The Organizations, medical and pharmaceutical workers as well as heads of medical organizations and drug stores violating the above provisions are subject to liability in accordance with Russian legislation (the Draft Law does not establish liability for such violations).

Based on the publicly available information it is expected that the Draft Law will be submitted to the State Duma during its autumn session. If adopted, the Draft Law, excluding some articles listed in article 99(1) thereof, will come into force from 1 January 2011.

**Medical Aid Standards**

The Draft Law introduces compulsory medical aid standards (i.e., unified sets of medical procedures, medicines, medical products and other components used in the course of providing medical aid) for all medical organizations in Russia.

In particular, the medical aid standards establish a procedure for prescribing medicines to patients and may include medicines from the list of essential and necessary medicines. The Draft Law sets out cases when medicines not included in such a list may be prescribed, namely:

- when a patient who pays for medical aid agrees to substitute medicines in the list with other medicines and pays up the price difference, if applicable;
- and
- if a patient is provided with free medical aid and certain medicine which is not on the list must be prescribed to him/her for health reasons (e.g., in the event of the patient’s intolerance to medicine on the list).

**Draft Rules of Wholesale Trade of Pharmaceuticals**

The Ministry of Healthcare and Social Development prepared a Draft Order approving the rules of wholesale trade of medicines for medical use (the “Rules”).

The Rules are compulsory for all organizations carrying out wholesale trade of medicines.

Pursuant to the Rules, wholesalers can sell medicines, provided they have a license for pharmaceutical activity, to other wholesalers, medicines’ manufacturers, pharmacies, scientific and research organizations for the purpose of carrying out scientific and research work, individual entrepreneurs that have a license either for medical or pharmaceutical activity, and medical organizations. Furthermore, the Rules stipulate the requirements for (i) warehousing and administrative premises used by wholesalers (e.g. requirements for equipment, premises’ size and location), and (ii) the delivery of medicines, including the requirements for the documentation accompanying medicines. To ensure the medicines quality, wholesalers must carry out internal audit of their operations.

It should be noted that the Rules will not apply to (i) the distribution of samples of medicines by manufacturers’ agents for the purpose of advertising, (ii) the distribution of state standard samples of medicines, (iii) the circulation of blood and its components used in transfusiology, and (iv) the sale of raw materials of animal origin and non-packaged pharmaceutical plant raw materials subject to further industrial processing for medicines manufacture.


5 See Article 31 of the Customs Code.

6 See Article 32 of the Customs Code.


8 See http://i-russia.ru/sessions/decisions/209.html.


11 *Idem.*

12 *Idem.*

13 The portal is available at http://grls.rosminzdrav.ru/.

14 The text of the draft law is available on the Ministry of Healthcare and Social Development website at http://www.minzdravsoc.ru/docs/mzsr/projects/530/.

15 See Article 70 of the Draft Law.


17 Pursuant to Article 45 of the Draft Law medical products include instruments, devices, materials and other products used separately or in combination with each other or with other accessories, including special software, for prevention, diagnostics and treatment of diseases, etc.


19 See Article 99 of the Draft Law.

20 See Article 38 of the Draft Law.

21 *Idem.*

22 See Article 79 of the Draft Law.

23 The text of the draft order is available on the Ministry of Healthcare and Social Development website at http://www.minzdravsoc.ru/docs/mzsr/projects/609.