

## **Overview of the Federal Law “On circulation of medicines”**

On March 24<sup>th</sup> the RF State Duma (lower chamber of the Russian parliament) adopted the draft law “On circulation of medicines” (hereinafter “the Law”), which was then approved by the Federation Council (upper chamber of the Russian parliament). The Law has been signed by the Russian president on April 12.

### **Background**

At the present time the circulation of medicines in the Russian Federation is regulated by the Federal Law that was adopted in 1998. After that time a lot of complementary acts were adopted by state bodies (bylaws), which made the process of registration and circulation of medicines rather complicated. The draft of the adopted document was first prepared several years ago by the Ministry of health and social development; however for several reasons the document could not be approved by other respective ministries.

In 2009 a drastic price increase on medicines was detected by the Supervisory bodies, which led to a more thorough attention of the Government to this sphere and initiated a more vigorous discussion of the Law. The RF Government has approved the compromised version and submitted it to the State Duma on December 26<sup>th</sup>, 2009. It was immediately put on the priority list of the draft laws to be considered by parliamentarians.

### **Registration**

The section of the Law devoted to the registration is construed according to the sequence of the stages of the registration. Respective articles in a detailed manner describe the process of registration. The general provisions of the Law read that the registration of medicines shall apply to:

- original medicines;
- generics;
- new combinations of the previously registered medicines;
- medicines previously registered but produced in different formulations and dosages

The state registration of a medicine is conducted based on the results of the expertise of the medicines and the ethic expertise aiming to determine whether clinical trials may be conducted for the medical purposes. The state registration will be conducted by the state authorized body. One of the positive novelties of the Law is that the time needed for the registration is strictly fixed and should not in any case exceed 210 days starting from the submission date of official application and all necessary documents (dossier) by the applicant. This set time includes the time needed to conduct all necessary expertise.

The registration should not apply to the medicines imported by private persons for their own usage, for medicines that will be exported and a number of other cases. The expertise of medicines that are submitted for the registration shall be conducted by a federal state institution affiliated with the authorized body conducting registration of medicines. The recent amendments to the Russian Tax Code transform the payments for the expertise procedures (that a registrant had to pay in order to get his medicine registered) into a state due. The state dues rates vary from 30 thousands RUR for the expertise of a medicine that was on a market for over 20 years) to 225 thousands RUR (for expertise of a newly introduced medicine and its suitability for medical purposes). All in all the registration should not amount to more than 300 thousand RUR. That is another good RF

Government's initiative which makes the process of registration more transparent and less costly.

The Law also stipulates a "compact procedure" for generics, which should be conducted upon the decision of the authorized body and in any case should not exceed 60 days. The compact procedure does not imply lower requirements with regard to security and efficiency of a medicine.

The registration is over when an applicant receives their "registration certificate", which is valid for an unlimited period of time, however, medicines that are registered in the Russian Federation for the first time will receive registration only for 5 years, after which they are eligible for the unlimited registration.

One of the main novelties of the Law is that foreign pharmaceutical companies will now have to conduct clinical trial on the Russian territory in order to have their medicines registered. Such clinical trials may be conducted upon prior approval by the Ethic Committee (which should not include more than 50% of medical representatives) in the certain institutions accredited in the authorized body.

The registration of a medicine may be revoked based on several grounds, among others including;

- the conclusion of the authorized body upon its usual assessment that a registered medicine is harmful for human health;
- a request of the producer or its authorized person to revoke registration of its medicine;
- in case of the registration of a homogenous medicines under different trade names;
- in case there is a court ruling establishing a violation of the IP rights of a right holder.

## **Circulation**

The Law allows the circulation only of the registered medicines; however, unregistered ones may be brought into Russia only for personal consumption.

The most significant change in the sphere of the medicines circulation is the transformation of the provisions of the Government Resolution (from August 9, 2009, N 654) into the law. These new provisions govern price control of the medicines sold in the Russian Federation.

The new rules set that pharmaceutical producers should register release prices (sale prices) on the medicines included into the list of Vital and most essential drugs (ЖНВЛС) at the authorized body, which should administer a special register of such prices. This list of medicines includes more than 5500 items, which overall constitutes more than 30% of the Russian pharmaceutical market. The price claimed by a pharma producer may not be registered by an authorized body in case if it does not correspond to the price set by this body. The maximum sale prices of the foreign pharmaceutical producer are calculated based on the special Methodology, which prescribes to fix such prices based on the referent prices (prices set in the state where such medicine was produced). This approach indeed is very contentious as some states provide very significant financial support (in a direct or indirect form) to its pharmaceutical producers, and referring to those national prices would be at least not fair and logical. Hence, such methodology may potentially provoke foreign producers not to import certain goods, as the official maximum prices will not cover the expenses of putting it into free circulation on the Russian market.

Russian regions will have a right to set wholesale and retail “mark-ups” for the prices of the producers (which in turn should not exceed the maximum registered price). The information already available shows that both mark-ups are fixed based on the prices of the medicines (less than 50 rubles, 50-500 and more than 500 rubles) and the average mark-ups for wholesale and retail are 20% and 25% accordingly.

### **Miscellaneous**

Numerous drafts of the Law that were available for public discussion did not contain a provision securing Data Protection. The Association of European Businesses together with other business associations had addressed all respective ministries with a request to include such a provision in the Law. Nevertheless, the abovementioned provision was not included into the final text of the Law. Though the document has direct reference to the civil legislation (art. 10) as the possible means of the producer to protect its rights, the data submitted to the authorized body does not enjoy any specifics. The fact that numerous letters and requests to the stake holders of the Law to include the “data protection” provision were ignored presents some serious concerns for the business community in Russia.

It should also be noted that the final provisions of the Law set a transitional period till 2014 for Russian pharma companies to switch to the Good Manufacturing Principles. The earlier dates of such transfer were rejected by Tatiana Golikova, RF Minister of health and social development as the Russian companies need prolonged time in order to implement new requirements. All other provisions of the Law will enter into force on September 1<sup>st</sup> 2010.

#### **Note:**

The Russian Government plans to adopt certain legislative acts that would govern the circulation of Biologically active supplements, as these goods were not effected by the abovementioned Law and their circulation is not anyhow regulated at present. Upon the preliminary information available at present, the circulation of biologically active supplements may be regulated through the adoption of technical regulation on food security. However, there is also an alternative draft law that suggests banning all sales of biologically active supplements through pharmacies.