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Amendments in the Federal Law on circulation of drugs

On 25 December 2012 Federal Law No.262-FZ "On amendments to the Federal Law on circulation of drugs" (hereinafter – the "**Law**") was signed by the President of Russia.

The Law is aimed at prevention of non-medical use of drugs by persons abusing narcotic and psychotropic substances.

This Law has governed at statutory level the order of dispensing and inventory of drugs for medical use that are not treated as narcotic or psychotropic substances – *drugs inventory accounting*. Before the similar order was stipulated in regulations– Ministry of Health and Social Development Decree dated 14 December 2005 No. 785 "On order of dispensing the drugs" (hereinafter – the "**Decree No. 785**").

Under the Decree No 785 the duty to maintain drugs inventory accounting was established only for pharmacies, drug wholesale companies, medical institutions and private practitioners.

According to the Law the list of subjects being under this duty has been expanded. Now the following subjects are also obliged to maintain drugs inventory accounting:

- drug producers;
- individual entrepreneurs holding a license for pharmaceutical or medical activities;
- medical organizations.

The order of including the drugs to the list of drugs subject to inventory accounting shall be established by Russian Ministry of Health upon approval of Federal Drug Control Service of Russia.

During drugs inventory accounting the entities engaged in the circulation of drugs are obliged to place in the special registration books the data about all changes in quantity and (or) conditions of drugs subject to inventory accounting.

The list of drugs subject to accounting, rules of registration of operations connected with circulation of drugs, rules of maintaining the special registration books shall be approved by the Russian Ministry of Health.

At present time Decree No. 785 containing the list of drugs subject to inventory accounting is effective and, possibly, upon enforcement of the Law it will be cancelled due to adoption of new regulations.

Control over compliance with the Law shall be exercized in frames of licensing control by authorized federal executive bodies (Russian Ministry of Industry and Commerce, Russian Federal Service for Supervision in the Sphere of Health Care, Russian Federal Service for Supervision in Agriculture) and executive bodies of constituent units of the Russian Federation that are licensing drug production, pharmaceutical and medical activities.

The Law was published in Rossiyskaya Gazeta on 28 December 2012. Enforcement of the Law shall be upon expiry of 180 day period as of date of official publication. Before enforcement of the Law several regulations, defining the implementation of the Law provisions and being directly referenced to by the Law, should be elaborated and adopted. Currently, the adoption of these acts is being expected.

Medical device safety monitoring

On 14 September 2012 Russian Ministry of Health adopted the Decree No. 175n "On approval of medical device safety monitoring" (hereinafter – the "**Decree**"). This Decree has been elaborated to implement

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provisions of articles 95 and 96 of the Federal Law dated 21 November 2011 No. 323-FZ "On fundamental healthcare principles of the Russian Federation" establishing medical device safety monitoring as one of measures of state control over circulation of medical devices.

The aims of medical device safety monitoring (hereinafter – the "**monitoring**") is to detect and prevent side effects not indicated in the user's manual for medical device, adverse reactions in course of its use, peculiarities of intercourse between medical devices, facts and circumstances posing a threat to life and health of citizens and medical professionals in course of use and exploitation of medical devices.

The monitoring includes collection, processing, registration and analysis of information about side effects not indicated in the user's manual, adverse reactions in course of its use, peculiarities of intercourse between medical devices, facts and circumstances posing a threat to life and health of citizens and medical professionals in course of use and exploitation of registered medical devices (hereinafter – the "**Information**").

The monitoring is carried out by the Russian Federal Service for Supervision in the Sphere of Health Care (hereinafter – the "**Rozdravnadzor**") and it territorial bodies (hereinafter – the **"Divisions of Rozdravnadzor in constituent units of the Russian Federation**") on the basis of:

1. Statements containing the Information received from natural persons, including patients, individual entrepreneurs and legal entities, being subjects engaged in circulation of medical devices, producers of medical devices or producers' authorized representatives (hereinafter – the "**statements**') in accordance with the Order approved by Russian Ministry of Health Decree dated 20 June 2012 No. 12n.
2. Information received during the state control over circulation of medical devices (the relevant procedure is established by Regulations on state control over circulation of medical devices approved by Russian Federation Government Decree dated 25 September 2012 No. 970).

Upon receipt of statements Roszdravnadzor shall register them within 1 working day and notify the producer of medical device (its authorized representative) on necessity to acknowledge or to deny the data in statements and to provide additional information regarding the facts containing in the statement within 3 business days.

Based on received statements Roszdravnadzor also makes a decision to suspend the use of medical device for the period not exceeding 20 business days and conducts the check of received information in the order prescribed by the law.

The following decisions shall be made on the basis of check's results:

1. on withdrawal of medical device from circulation in case the information in the statement is confirmed;
2. restoration of the use and circulation of medical device in case the information is not confirmed.

Based on monitoring's results Roszdravnadzor (Divisions of Rozdravnadzor in constituent units of the Russian Federation) notifies the subject engaged in the circulation of medical devices on decisions made within 3 business days.

Rozdravnadzor places the information relating to the monitoring on its official website in the Internet. The list of such informarion is established by Decree.

On 25 December 2012 the Decree was registered by Russian Ministry of Justice. The Decree comes into effect upon expiry of 10 days as of the date of its official publication (the publication is expected in the nearest future).