

# Digest

## Of Russia's Medical Device Market

August 2015



# Key Industry News

## Market Regulation

### Roszdraznadzor introduced a simplified scheme of registration of medical devices of the first risk group

A simplified scheme of registration of medical devices of the first risk group began to be implemented on 17 July 2015.

Since then, registration of such medical devices has been implemented in one step in case of availability of documents confirming the clinical effectiveness and safety of a medical device.

Order on the simplification of registration procedures of medical devices of the first risk group “On Amendments to the Order of the Ministry of Healthcare of the Russian Federation from 21.12.2012 № 1353n “On approval of the order of organizing and holding the examination of quality, effectiveness and safety of medical devices” was approved by the Ministry of Healthcare in June 2015.

The simplified state registration procedure of first class risk medical devices will be applied for those medical devices, for which the registration applications are submitted to the Federal Service on Surveillance in Healthcare after the enactment of the above-said Order.

### Offshore companies banned from competing for public contracts

The Federation Council approved 44-FZ “On Amendments to the Federal Law “On the contract system in the area of procurement of goods, works and services for state and municipal needs” in terms of banning companies registered in offshore zones from participating in the public procurement.

In particular, the document clarifies the definition of “participant of public procurement” by excluding offshore companies from competing for public contracts.

The Federal Law will come into force 30 days after its official publication.

According to officials, these changes will help prevent the withdrawal of government funds outside Russia and open up new opportunities for economic growth.

# Companies' News

## Smith & Nephew acquired the trauma and orthopaedics business of DEOST

British artificial hip and knee maker Smith & Nephew announced the acquisition of a Russian distribution and manufacturing company DEOST, in line with its strategy of expanding in emerging markets.

Smith & Nephew said it was adding the trauma and orthopaedics unit of DEOST to boost its local presence for an undisclosed sum. The deal involved adding 350 new employees.

DEOST has distributed Smith & Nephew's products in Russia since 2009, the British company said.

"(Its) local capability to manufacture mid-tier trauma products will enable us to reach more customers following recent changes relating to state tenders supporting Russian produced products," Smith & Nephew said in its statement.

## Johnson & Johnson and Pharmstandard agreed on cooperation

An American multinational medical devices, pharmaceutical and consumer packaged goods manufacturer Johnson & Johnson and a Russian pharmaceutical company Pharmstandard have signed an agreement on the production of OneTouch Blood Glucose Monitoring System on the territory of the Russian Federation in the framework of INNOPROM-2015.

According to the press release of Johnson & Johnson, the domestic products Lifescan (part of the Johnson & Johnson group), a manufacturer of OneTouch blood glucose meters and test strips, will be produced at the facilities of Pharmstandard-UfaVita. The first domestic production Lifescan, allowing patients with diabetes to self-manage the disease, will appear in the third quarter of 2015.

## Medsintez will produce insulin pumps

Novouralsk plant "Medsintez" has begun the registration process of an insulin pump, the first samples of which have already passed clinical trials.

The scientists plan to start manufacturing of pumps which will be sold at 20 to 25 percent below the price demanded by foreign companies. The average price for a foreign pump amounts to 120-160 thousand rubles.

"Currently only one percent of patients with diabetes use such devices. It is very expensive. Prices for imported pumps reach 250 thousand rubles. Over time, foreign manufacturers will leave the Russian market. It will be a completely home-grown technology," the chairman of the Supervisory Board of the Ural Biomedical Cluster, a member of the Healthcare Committee of the State Duma Alexander Petrov said.

## JK Medical patented the smallest ECG recorder

JK Medical patented ECG recorder "Elskan", which size does not exceed the size of a USB flash drive.

According to the chief developer Vladimir Zhankov, the created device will be cheaper than its imported counterparts. "It is the smallest ECG recorder in the world. It can monitor cardiovascular activity for seven days, using a small battery weighing 4 grams. The device is made in a cost-effective way. It will be sold at the lowest possible price," Zhankov said.

During examination, patients wear a portable recorder on a lanyard on their neck while electrodes are attached to the chest. The processed data from the electrodes go into the cardio registrar's short-term memory. It records only the data that are abnormal. It takes 15 minutes of doctors' time to view the gathered data.

Developers are going to release the first 100 samples of the device for Russian hospitals after obtaining the registration certificate.

# Science and Technology

## Novosibirsk company developed a heart valve implant which is 4-5 times cheaper than its imported analogues

A resident company of Novosibirsk Academpark with Novosibirsk Research Institute Of Blood Circulation Pathology E.N. Meshalkin and Novosibirsk State University has developed the first Russian endovascular aortic valve implant, which can be installed without incisions. The price of a domestic implant is four to five times lower than the prices of its foreign counterparts.

“Now the market is divided by foreign manufacturers. In Russia there are manufacturers of implants only for open heart surgery. Before the crisis the cost of an imported aortic valve implant was about 1 million rubles. Now it much be more expensive. It is expected that our implant will cost 200-250 thousand rubles,” the head of the company Andrey Kudryashov said. According to him, endovascular cardiac valve replacement is required for patients who cannot have open-heart surgery. Most of them are elderly people. The need for such implants is very high because a few thousands of such operations are performed every year.

Right now the heart valve implant of the Novosibirsk company is in the development stage. Preclinical trials will be conducted over the next 6 months. If the developers satisfied with the results, human trials will be started at the end of the first half of 2016.

## Researchers from Moscow created a capsule to examine the gastrointestinal tract

Scientists from the National Research Nuclear University MEPhI have developed a special capsule to examine the gastrointestinal tract. It is expected that manufacturing of endoscopic complex “Lily” will be started at the end of 2015.

Complex “Lily” for single use is a small capsule with a power source and a camera. In order to proceed with the study, the patient swallows a tiny capsule. A capsule passes naturally through the human digestive system and makes thousands of pictures of its various sites. Using a standard USB cable after 4.5 minutes all images are transferred from the portable reader on the patient’s waist to the doctor’s computer. The software helps the specialist to do an analysis of the images by which he can make a conclusion about the examination. The study lasts about eight hours: during this time a capsule passes the entire gastrointestinal tract.

When clinical trials are over, scientists plan to produce up to 300 thousand capsules a year. According to their calculations, it will fully satisfy the country’s need.

## Izhevsk scientists developed biochips for cell research

Scientists from Izhevsk developed biochips for cell studies. According to the developers, their biochip have several advantages over foreign analogues.

One of the advantages of the biochip is its low price: its cost varies from 5 to 50 rubles, and the market price does not exceed 400 rubles. “In standard laboratory conditions a few tens of antigens can to be determined simultaneously, and the system are extremely cheap”, a representative of the Izhevsk State Medical Academy Alexander Shishkin said.

According to him, comprehensive studies of cells (e.g. detection of certain diseases) can be carried out with the help of the biochip. It is expected that conducting of clinical trials and obtaining of relevant approvals will cost 8-19 million ruble, while setting up of an enterprise for the manufacturing of 350 thousand biochips a year will require 30-40 million rubles annually.

## Scientists from Buryatia developed a test for a stroke

Experts from Buryatia have created a rapid test system that allows to determine whether a patient will face a stroke or not. Just one drop of blood is needed to predict the risk of stroke.

It is planned to provide ambulances and public clinics with the test systems for rapid diagnosis. If you start treatment of stroke prior to the appearance of the first symptoms, you can avoid serious complications of the disease: paralysis, loss of memory, vision and other important functions.

The test is a stripe, the color of which changes depending on the concentration of antibodies, specific to the stroke.

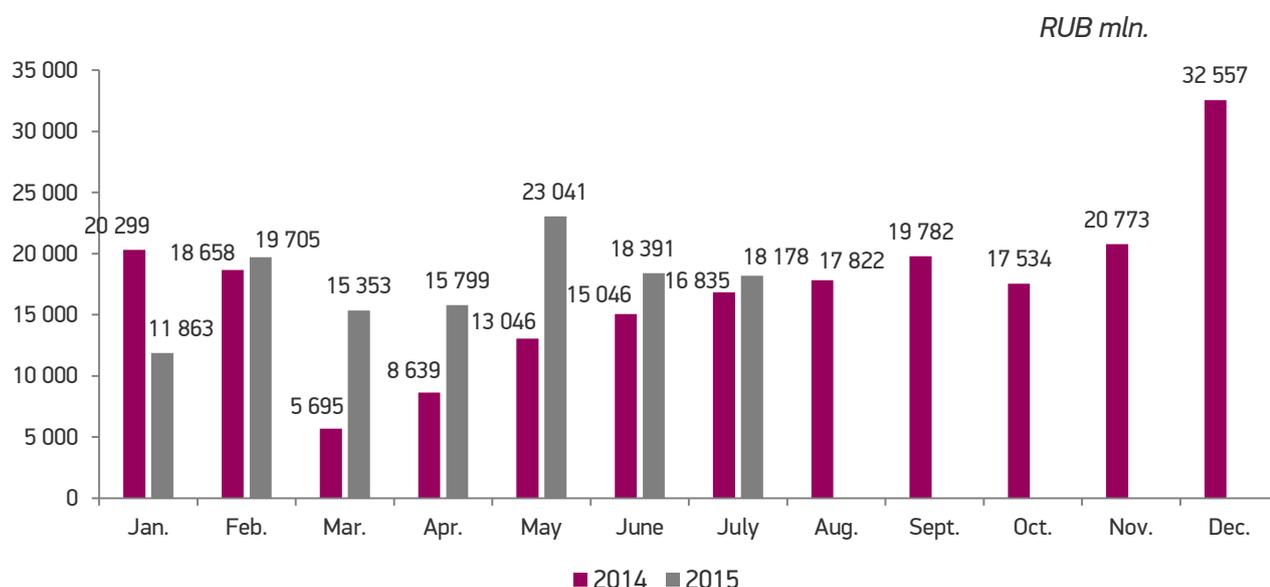
# Market Statistics (July 2015)

Since most of Russian healthcare facilities are state owned, 75% of all medical devices are sold through a public bidding process. Therefore, the dynamics of public procurement of medical devices determines the dynamics of the whole market. It explains the importance of tracking the value of public procurement market on a monthly basis. The analysis of public procurement uses data on tenders for delivery of medical devices posted on the official procurement website [www.zakupki.gov.ru](http://www.zakupki.gov.ru).

Figure 1 shows that the value of public contracts in July 2015 was RUB 18.2 bln., which is 8% higher than July 2014's 16.8 bln.

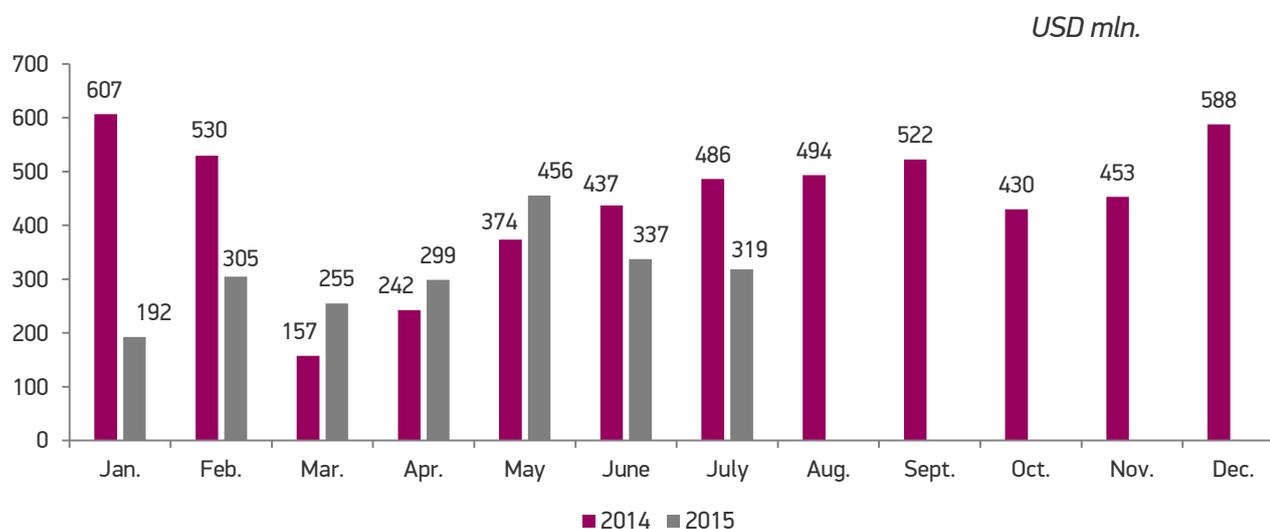
Figure 2 demonstrates that market dynamics in USD is different. It reflects the trend of a strengthening US dollar against ruble.

Figure 1. Dynamics of public procurement in 2014-2015 (RUB mln.)



Source: MDpro

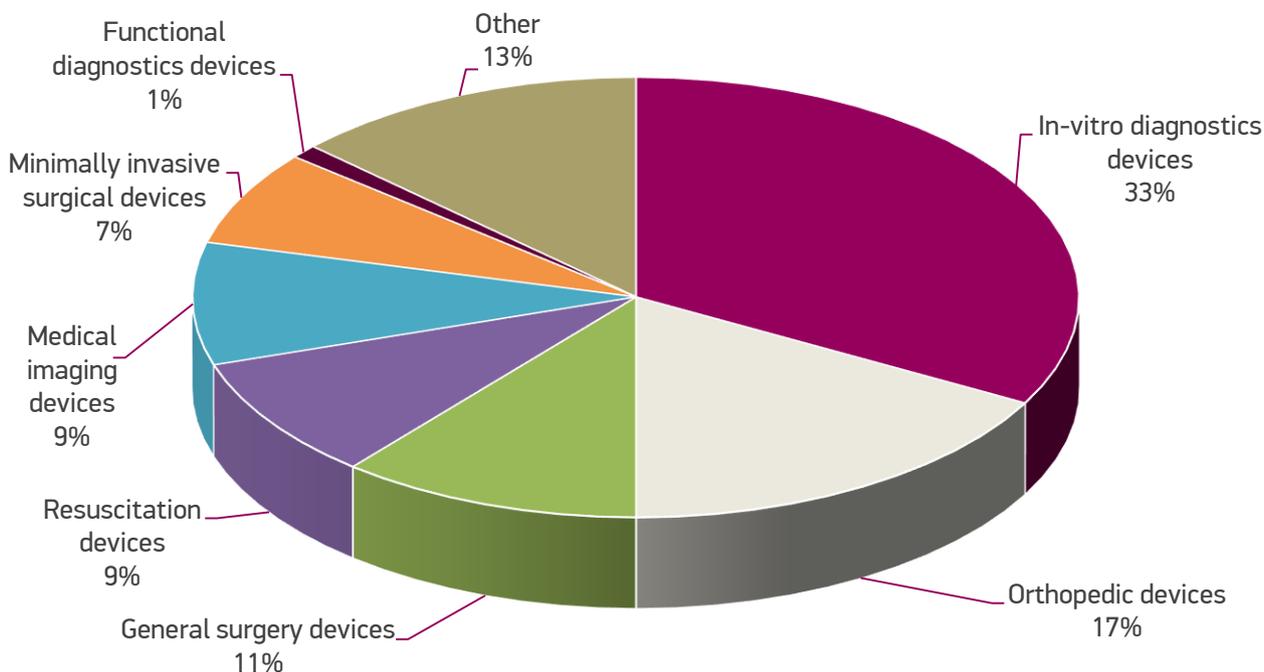
Figure 2. Dynamics of public procurement in 2014-2015 (USD mln.)



Source: MDpro

The largest segments in July 2015 were in-vitro diagnostic devices (33%), orthopedic devices (17%), and general surgery devices (11%).

Figure 3. The structure of public procurement by segments in July 2015



Source: MDpro

For more information about the Russian medical device market, please visit our website at [www.md-pro.ru](http://www.md-pro.ru) or email us at [info@md-pro.ru](mailto:info@md-pro.ru)

Sources of information used in digest' preparation: Pharmvestnik, Medportal, VEDEMECUM, Remedium, RG, TASS, Reuters, Innoprom, Engineering Science Center