

# Digest

## Of Russia's Medical Device Market

September 2015



# Key Industry News

## Market Regulation

### It is planned to extend the list of foreign medical devices restricted from participating in public procurement

In February 2015 the Russian government implemented restrictions on admission of foreign-made medical devices to public tendering. According to this regulation, the tenders for state and municipal procurements got closed for foreign manufacturers if at least two bids with medical devices originating from Russia, Belarus, Kazakhstan or Armenia (i.e. the member states of the Eurasian Economic Union) meet the requirements. The list of medical devices, which are subject to restrictions, contains approximately 50 item names, including certain kinds of cardiac monitors, tomography devices, x-ray diagnostic devices, medical clothing, various types of reagents, etc. In August 2015 the Russian Government came up with an idea to extend the list of foreign medical devices which will be under restrictions. More than a hundred of new positions were offered to add.

The new list, in particular, includes the following types of medical devices: medical dressing, means of rehabilitation for people with disabilities, X-ray machines, sterilizers, defibrillators, infant incubators, and other products, which are, according to the Ministry of Industry and Trade, are produced in Russia in necessary volume.

Public discussion of the document was to be completed on August 17 but it was extended until 1 October 2015. The reason for this was a large number of negative reviews from civil society organizations addressed to the Russian government. They wrote a letter to Prime Minister Dmitry Medvedev in which they asked him to create a working group that would assist in finalizing the draft taking into account patients' needs.

The Ministry of Economic Development and The Federal Antimonopoly service also did not support the initiative. They noted that the proposed amendments had been not agreed with them. The Federal Antimonopoly service sees no justification for the extension, The Ministry of Economic Development recommends to finalize the list of medical devices.

The opinion of the Ministry of Health about the extension of the list was expressed by Victoria Skvortsova, head of Russian Health Ministry, at a press conference on 26 August. "At the moment the possibility of expanding the list of medical devices which are exhibited to import to Russia is considered but this issue has not been discussed with the Ministry of Industry and Trade. As soon as we receive the draft from the federal executive authorities, primarily from the Ministry of Industry and Trade of Russia, we will provide our evaluation of it," the ministry said.

### Government Commission on Import Substitution was established

Prime Minister Dmitry Medvedev signed a decree of the Government of the Russian Federation dated 4 August 2015 №785 "On the establishment of the Government Commission on Import Substitution". Also, Dmitry Medvedev signed an executive order of the Government of the Russian Federation dated 4 August 2015 № 1492-p, which contains a structure of the Commission.

The Commission consists of two sub-commissions: on the civilian economy and on the defense industry.

It is chaired by Prime Minister Dmitry Medvedev. Arkady Dvorkovich and Dmitry Rogozin have been appointed deputy chairmen of the Commission, and chairmen of the civilian economy and the defense industry sub-commissions, respectively.

"Import substitution at the moment is one of the key areas of government activities and it was decided that this work should be more systematic so the separate commission on import substitution should be created," Dmitry Medvedev previously commented on the idea of establishing the commission.

We are not interested just in the replacement of good-quality foreign goods by second-rate Russian goods. The focus should be only on creating competitive products – not only for Russian market, but for the world market as well," the Prime Minister set the task.

# Science and Technology

## Moscow scientists developed new early-stage diagnostics for cancer, HIV and hepatitis

Dmitry Fedyanin and Yuri Stebunov, two young scientists from MIPT (Moscow Institute of Physics and Technology) developed what they call a nanomechanical sensor to identify chemical components of various substances. The device is said to be able to also pinpoint biological objects, such as the markers of viruses which appear as our immunity system responds to diseases like herpes, HIV, or all sorts of hepatitis.

The sensor is believed to be sensitive enough to also identify oncology markers that alert to the development of a malignant tumor in a patient. The developers say it can detect other most acute medical conditions at very early stages. This appears to be a very important move into the future of medical diagnostics.

The device itself is described in detail in the Scientific Reports journal. It looks like an optical chip. Unlike analog solutions, this device has no electrical chains and basically provides two simple parts: one is a photonic (plasma) nanostructured waveguide that controls optical signals, and the other is a nanobeam cantilever placed above the waveguide.

As the process starts, two signals travel along the waveguide; one sets the cantilever in motion, and the other reads out signals that contain information about the movements of the cantilever. By those movements the developers are said to be able to identify the chemical composition of a substance in which the chip is placed. 'Sprinkled' with the antibodies of a certain virus, the cantilever begins to 'fish' virus particles from the substance under study.

Calculations done by the researchers showed that the new sensor will combine high sensitivity with a comparative ease of production and miniature dimensions, allowing it to be used in all portable devices.

## Clinical trials began for Russia's first medical exoskeleton

The exoskeleton, produced by Skolkovo resident ExoAtlet, is being tested by a group of volunteers who are paralyzed from the waist down at the N.I. Pirogov National Medical Surgical Center.

"This is a very important transition for us from lab testing and working with a few pilots to large-scale trials on a broad audience," said Ekaterina Bereziy, a co-founder of ExoAtlet and its development director. "At the clinic there are patients with various characteristics, with different injuries, of differing height, weight, even temperament. Each has his or her own wishes and fears. So here we can see the full range of real-life applications for ExoAtlet. For us this is a very important field study," she added.

ExoAtlet is the first company in Russia to deal with exoskeletons and has patented its technology. Its medical-use model, known as ExoAtlet-Med, is to support movement for people with restricted limb function and rehabilitation for lower-limb trauma victims. It is designed to help overcome paralysis caused by cerebral apoplexy or spinal cord injury. It could also benefit sufferers of cerebral palsy and similar diseases.

Seven hundred people volunteered to try out the ExoAtlet innovation, but doctors whittled the list down to just a few people to undergo two weeks of intensive training, Bereziy said.

It is expected that trials will take at least a year. Developers hope to start selling the exoskeletons for private individuals already this year. When it hits the market, the exoskeleton is expected to retail for about 1.5 million rubles.

## Start-uppers created a ring for identifying sexually transmitted diseases

Three start-uppers from Russia, Kazakhstan and Mexico created a ring called Hoope, which allows to identify such diseases as syphilis, gonorrhea, chlamydia and trichomoniasis. The portable device containing a disposable cartridge with a retractable needle for blood is put on the thumb.

Lab-on-a-chip installed inside the ring, analyzes the samples, then the results are transmitted wirelessly to a smartphone with appropriate software. The whole process takes less than a minute. Lab-on-a-chip allows to carry out analysis due to the four antigens (corresponding to the four diseases), which are contained in a disposable cartridge.

Manufacturing of the rings will be organized in China. It is planned that they will go on sale in January 2016. The cost of the set will be \$50.

## Tomsk scientists developed a self-learning artificial brain

Scientists from the Tomsk State University with colleagues from five countries created an artificial brain with the ability of self-training. It is planned to use it for reconstruction of pathological conditions and treatment of memory disorders.

It is reported that firstly mathematical and computer models of the human brain were developed. After that the scientists designed a radioelectronic device containing perceptrons, which are capable of processing different kinds of information, including video and audio.

At the moment the main system of the robotic system – its intelligent control centre – is being developed. Finally the artificial brain is expected to become an analogue of the biological model. The scientists believe that this device will help physicians in the study and treatment of different types of amnesia, as well as Alzheimer's and Parkinson's diseases.

## Kalugapribor started manufacturing of high-tech medical devices

A Russian company Kalugapribor started producing high-tech radioelectronic medical devices, in particular, a portable ultrasound scanner and a fetal and maternal monitor. Such equipment is currently mainly purchased from South Korea.

Production is carried out within the framework of the import substitution program. The first samples of the medical devices are already being tested and certified.

The portable ultrasound scanner has three diagnostic functions: echogram recording, Doppler ultrasonography and blood speed measurement. It enables remote patient monitoring: scanning probes can be at patients' homes, information is transmitted over the phone line, and then the doctor provides recommendations. Devices of this kind are in demand in all health care centres. It is expected that it will be produced about 200-300 units of the scanners in 2016.

The second device is a fetal and maternal monitor is designed for pregnant women examinations and making cardiograms of a mother and a fetus.

## Tomsk Polytechnic to help develop Nuclear Medicine Center in Siberia

Researchers from the Tomsk Polytechnic University are taking part in a project aimed at creating a Nuclear Medicine Center in Tomsk, in Siberia.

A special Working Group is being formed in the region to help further the effort. In the Group, the TPU scientists will join representatives of the local medical community.

The Tomsk project is expected to become the third in a growing network of federal nuclear medicine centers after one in Dimitrovgrad, in the Ulyanovsk region in the mid-Volga area, and in Obninsk outside Kaluga in Central Russia.

"We see as a priority the development of intraoperative radiation therapy based on betatrons and also neutron therapy, including neutron capture therapy," said Alexander Vagner, the head of TPU's applied physics chair and a member of the Working Group.

According to the Tomsk regional authorities, the local Nuclear Medicine Center will be a private-public partnership (PPP).

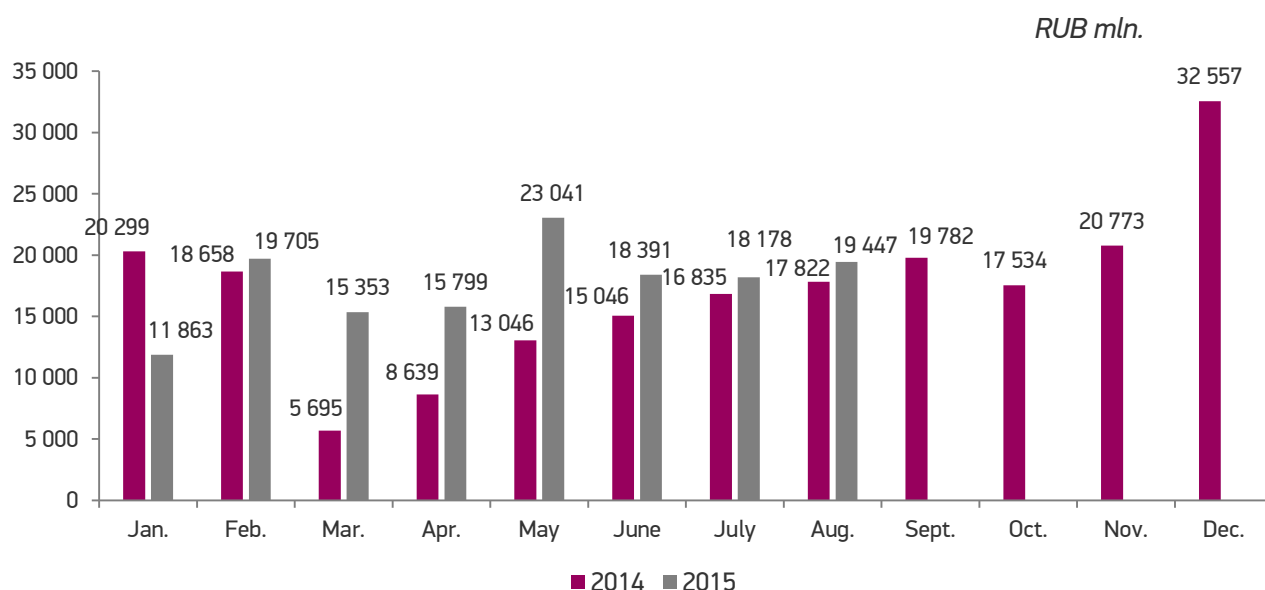
# Market Statistics (August 2015)

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 August 2015 was RUB 19.4 bln., which is 11% higher than August 2014's 17.8 bln.

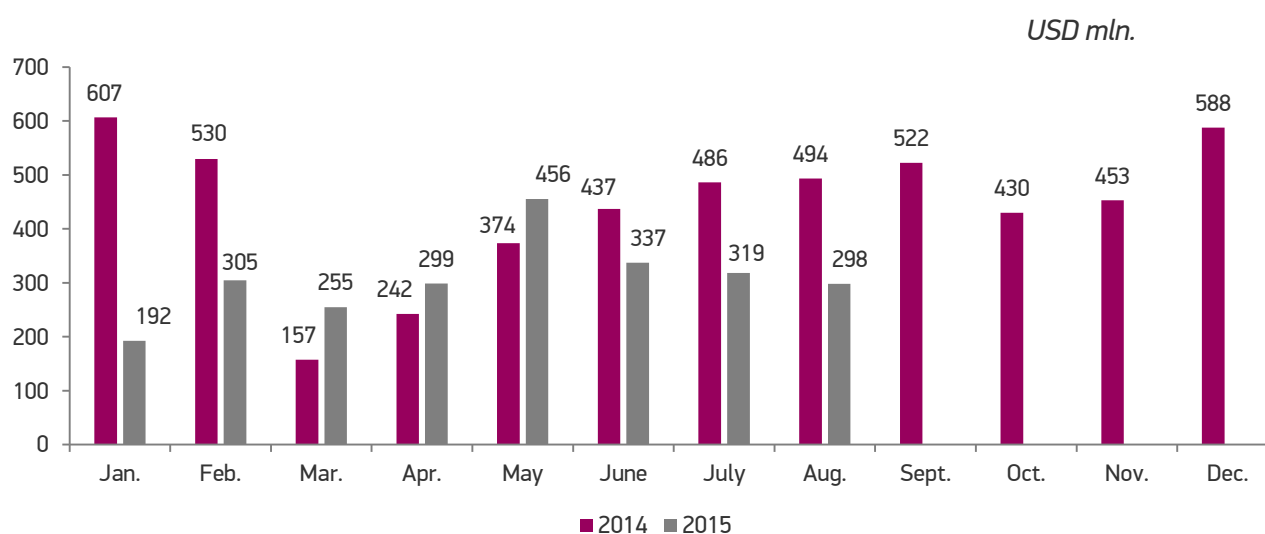
Figure 2 demonstrates that market dynamics in USD is different. It reflects the trend of a strengthening US dollar against ruble.

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



Source: MDpro

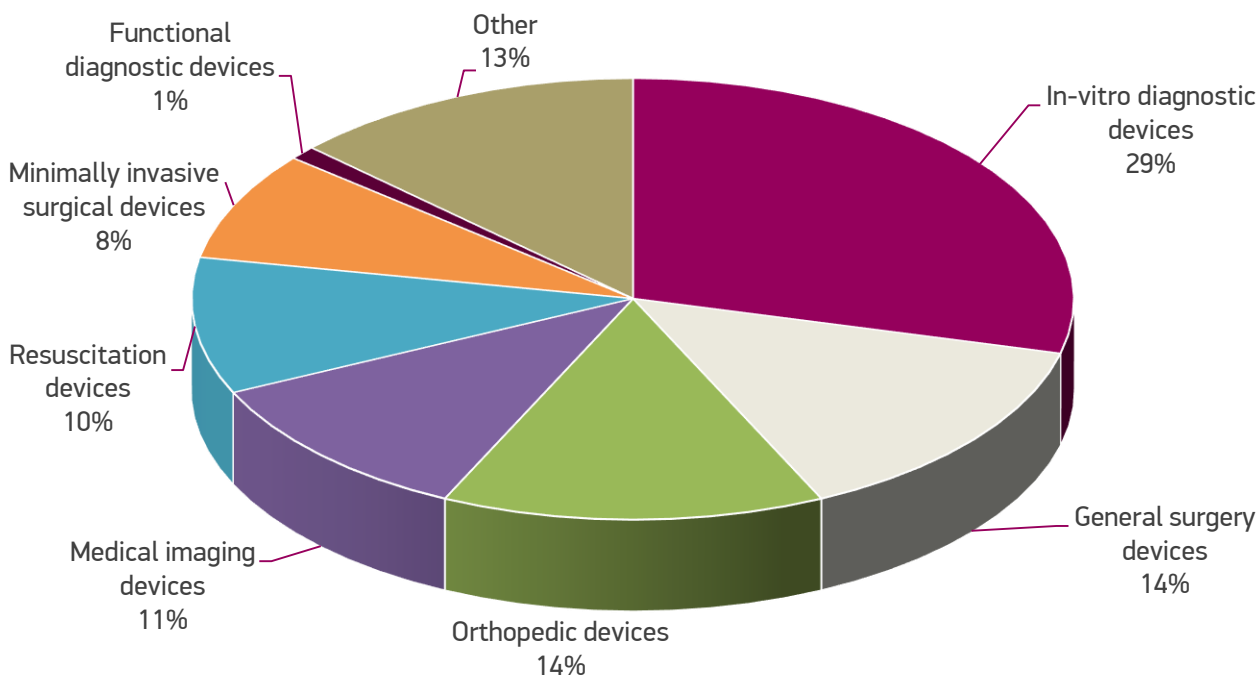
Figure 2. Dynamics of public procurement in 2014-2015 (USD mln.)



Source: MDpro

The largest segments in August 2015 were in-vitro diagnostic devices (29%), general surgery devices (14%), and orthopedic devices (14%).

Figure 3. The structure of public procurement by segments in August 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, VADEMECUM, TASS, lenta.ru, MarchmontNews, Robohub