

Digest

Of Russia's Medical Device Market

July 2015



Key Industry News

Market Regulation

Minpromtorg is adjusting the program for Pharmaceutical and Medical Industry Development for 2013–2020

The Ministry of Industry and Trade of the Russian Federation (Minpromtorg) put forward for public discussion the Russian Government Decree “On Amending of State Program of the Russian Federation “Development of the Pharmaceutical and Medical Industry for 2013-2020”. Public discussion of the document took place from 3 till 18 June 2015.

According to the Explanatory Note, attached to the document, the draft Resolution specified the amount of funding of the State Program. It is proposed to reduce the funding from 99.4 billion rubles, provided by the previous document version, to 75.9 billion rubles (by 24%).

Besides, the Resolution provides financial support for Russian manufacturers of medical devices and medicines to support high-priority areas.

According to the document, Russian manufacturers of medical devices will have the right to receive subsidies from the Federal budget for the partial compensation of expenditures on the implementation of projects, involving manufacturing of medical devices or conducting clinical trials of implantable medical devices.

Investors may be allowed to participate in public procurement under special conditions

The draft Federal Law N 821579-6 “On Amending the Federal Law “On the contract system in the procurement of goods, works and services for state and municipal needs” was developed recently.

The document proposes providing a purchaser with a possibility to buy products from a single supplier on condition that these products are manufactured in Russia under the rules established by the Government of the Russian Federation.

According to the draft, investors taking part in manufacturing of products in the territory of the Russian Federation in accordance with special investment contracts (pursuant to the Federal Law “On industrial policy in the Russian Federation”) may be determined as the only suppliers of the produced products in Russia. It means that purchasers, willing to buy these products, will be allowed to enter into contacts only with the investors.

This act will apply only to industrial products, which have no Russia-made counterparts (in accordance with the Federal Law “On Industrial Policy of the Russian Federation”).

Sales of any glasses and contact lenses will be released from VAT

The Russian government introduced to the State Duma the draft law Decree “On amendments to paragraph 2 to article 149 of the Tax Code of the Russian Federation” in terms of improving the existing system of medical products taxation.

The document was developed in order to clarify the legal provision concerning taxation of glasses, contact lenses and eyeglass frames. According to the document, sellers of these products will not pay value added tax (VAT).

According to the current legislation, sales of these products (besides from those protecting from the sunlight) are already VAT exempt. What is proposed now is to exempt all sales of glasses and contact lenses from VAT, regardless of whether they are sun-protective or not.

Companies' News

United Instrument Manufacturing Corporation is planning to develop over 30 new types of medical devices by 2020

United Instrument Manufacturing Corporation will develop over 30 new types of medical equipment by 2020. Medical devices, produced within the import replacement program of the Ministry of Industry and Trade, are intended to replace imported peers in such areas as cardiology, traumatology, neurology, brain surgery, transfusiology, hematology, and laboratory diagnostics. "As early as in 3-5 years we expect to put serious pressure on foreign medical equipment, which covers 80% of the Russian market at the moment", says the Head of Association of Defense Industry Manufacturers of Medical Equipment Alexander Kulish.

One of the key priorities of the corporation is to develop a range of import substitution equipment for blood banking, where the share of foreign hardware and consumables is especially large. One of the latest developments in this area is thrombocyte incubator "Thrombocyte", which has no equivalents on the Russian market. The incubator has a microprocessor control system capable of high precision temperature control in the chamber, self-testing and troubleshooting; it is also protected against unauthorized access. Blood transfusion stations, polyclinics and research institutes need such equipment for intensive care, treatment of tumors and blood diseases requiring thrombocyte deficit replacement transfusion therapy, as well as for heart surgery and other types of surgeries.

Concern Vega, which is the key unit of UIMC responsible for medical equipment, will complete the development of the whole range of sophisticated products during the two years to come. Some of them are: neurostimulator for treating neurological and mental diseases, magnetic stimulator for investigating and treating cases with central nervous system disorders, surgery navigation station which shows the surgeon a 3D picture of patient's organism during the surgery, as well as portable instant diagnostics system called Reader, which identifies pathogenic microorganisms and their sensitivity to germicides. Development of Autoplan, a device for automated planning and control over the results of surgical treatment, and Maloinvasia, a device for minimally invasive tumor treatment, is at the final stage.

GE Healthcare will be engaged in localization of medical devices in Moscow Region

GE Healthcare and the government of the Moscow Region have reached an agreement on the location of GE Healthcare manufacturing plants in the Moscow region. The agreement was concluded during the 19th St. Petersburg International Economic Forum.

They formalized an agreement, which they reached in December 2013. It is aimed at improving the delivery of health services and creation of necessary infrastructure facilities in the region.

GE in partnership with ZAO "Medical Technologies LTD" plans to focus primarily on manufacturing of high-tech medical equipment for perinatal centers, including resuscitation system for premature babies, bedside monitors, CT scanners and ultrasound equipment.

In partnership with the Moscow region, GE also plans to hold educational programs for health professionals and to develop programs of medical devices maintenance.

Industry Initiatives

All OMS tariffs will be revised in 2015

All tariffs for medical services provided under obligatory medical insurance (OMS) system will be revised in 2015. This was announced by the Minister of Health, Veronika Skvortsova.

“By the end of the year, we will review all tariffs for medical services”, Skvortsova said during the 19th St. Petersburg International Economic Forum. She noticed that the total amount of funding for health care has increased by 265 billion rubles in 2015.

For her part, Russian Deputy Prime Minister Olga Golodets noted that Russia’ health care system is working in a context of very constrained resources, which make up 3.7% of GDP of the country. “This is much less than in most countries of the world”, she said.

Russian Finance Minister does not exclude the possibility of increasing public expenditures on health

Finance Minister Anton Siluanov said that public expenditures on health care may increase in 2015. According to him, this will be possible if the government has necessary resources.

“I think that health care has always been a priority for us, an area, on which we allocate resources first”, he said. At the same time, according to Siluanov, the government is unlikely to make new changes to the budget until the autumn of 2015.

Siluanov also stressed that the volume of public expenditures on health care has increased this year. “Since more resources of Federal Compulsory Medical Insurance Fund are deployed, health care costs, even as a percentage of GDP, are growing”, the Minister said.

Science and Technology

Rostec is developing biodegradable materials for strategic industries

Holding “PT Himkompozit”, which is a part of Rostec, signed an agreement with the “Federal Research Centre “Fundamentals of Biotechnology” to develop a line of biodegradable materials and products for strategic industries of the Russian Federation.

An engineering center, within “PT Himkompozit” will serve as a basis for creating of production chains: from the initial plant biomass producing, processing with the use of alcohols and carboxylic acids to manufacturing output of ready materials and products for major industries. Produced items will be used for the needs of medicine, aviation, agriculture, construction, oil production and even 3D printing.

“It will be bioresorbable surgical sutures, biocompatible implants and prosthesis, antifreeze and de-icing fluid, oil industry reagents and reinforcing materials, 3D model and raw materials for 3D printing”, the chairman of the Board of Directors of the Holding “PT Himkompozit” Alexey Kuzmitsky explained.

The first surgery using Russia-made nanoceramic hip joint prosthesis performed in Novosibirsk

The first surgical operation using a Russian nanoceramic hip joint prosthesis made at the Novosibirsk plant ZAO NEVZ-CERAMICS, was performed in June in the Novosibirsk Scientific and Research Institute of Traumatology and Orthopedics. A Russia-made nanoceramic endoprosthesis was implanted for a patient for free, under the system of government guarantees.

The development of the endoprosthesis has taken more than 4-years efforts of a joint team of specialists from the Novosibirsk Scientific and Research Institute of Traumatology and Orthopedics (NSRITO), the Medical and Technological Innovation Center “Medical Technopark”, the Novosibirsk State Technical University, the Institute of Solid State Chemistry and Mechanochemistry of the Siberian Branch of Russian Academy of Science, and the nanoceramics producer, a portfolio company ZAO NEVZ-CERAMICS of the State Corporation “Russian Corporation of Nanotechnologies” (RUSNANO). The ceramic endoprosthesis meets the top-of-the-line international and Russian standards.

The first patient to be implanted a Russia-made ceramic-head hip joint endoprosthesis was a 53-years-old man, a resident of Birobidzhan, from the Jewish Autonomous Oblast, Russia. The surgery was successful, and currently specialists are looking closely at the first Russian endoprosthesis implantation experience with a view to promote it for other clinics and regions. At the moment, 34 surgical operations using the new endoprostheses have been performed in NSRITO.

“Coxofemoral implants are made from high-quality nanosize ceramics, they are known for high bio-inertness and mechanical integrity, along with the best durability rates”, says Anatoly Aronov, ZAO NEVZ-CERAMICS chief executive in bioceramics. Specialists note that such prosthesis has a lifespan of more than 20 years.

Nanoceramic prostheses manufacture launched in Novosibirsk will be the world’s second in the scale of production, after CeramTec company (Germany), which currently holds about 93% of the global implant market. “For the first months, we are planning to produce about 500 units per month, but by 2016, we will reach the point of 20,000 endoprostheses, which will meet about a half of Russian market demand”, says Anatoly Aronov. The only difference between Russian products and their foreign counterparts is the price – about 60 thousand rubles against 2-2.5 thousand euros for German products.

Significant results

Manufacturing of medical devices in Russia increased by 18.7%

Russian Federal State Statistics Service (Rosstat) calculated the value of medical devices (including surgical equipment, orthopedic appliances and their components), produced by Russian companies in January-May 2015.

According to the report of Rosstat, the total value of produced medical devices in January-May 2015 amounted to 11 billion rubles, which is 12.3% more than in the same period in 2014. In May 2015 production value increased by 18.7% as compared with the previous month. The value of manufactured medical devices was 2.2 billion rubles.

It is proposed that Russian companies producing certain types of medical devices focus on national standards. In early June the first drafts of standards for neurostimulators, equipment for lithotripsy, telemedicine conferencing systems, digital X-ray machines and other medical devices were released. Development of these documents was commissioned by Federal Agency on Technical Regulation and Metrology (Rosstandart).

The number of rejected registrations of medical devices is on decline

In 2013 about 47% of refusals to register medical devices was recorded. In 2014 this figure reduced to 30%. This was announced by the Acting Head of Roszdravnadzor Mikhail Murashko during the 7th All-Russian Congress of Pharmaceutical and Medical Industry Workers.

“The first quarter of 2015 showed a significant decline in the number of refusals – they accounted for 3-5%”, Mikhail Murashko said.

According to him, 1500 medical devices are currently under consideration.

“The main problem faced by the experts is badly prepared documentation. We have lost engineers who knew how to prepare it properly”, Mikhail Murashko added.

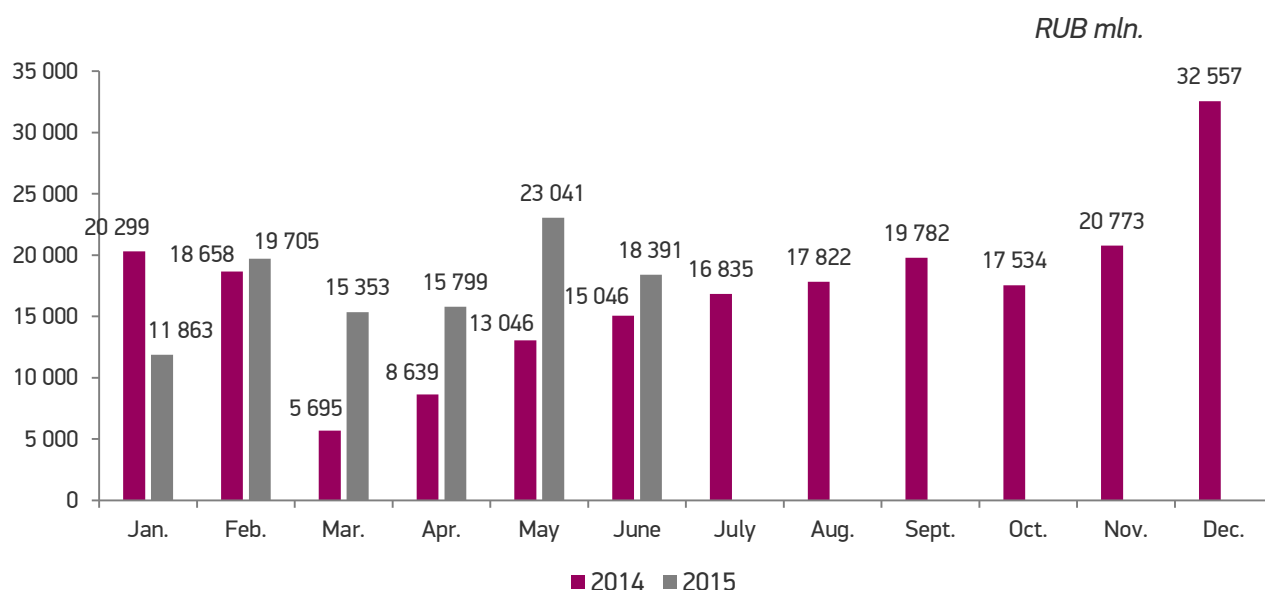
Market Statistics (June 2015)

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.

Figure 1 shows that the value of public contracts in June 2015 was RUB 18.4 bln., which is more than 23% higher than June 2014's 15 bln.

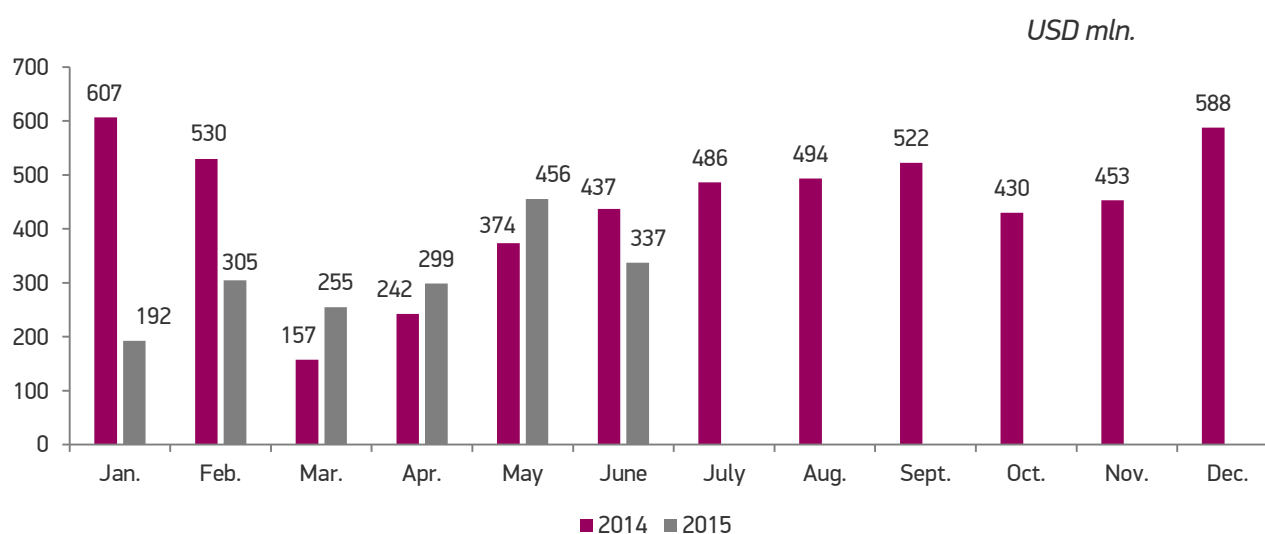
Figure 2 demonstrates that market dynamics in USD is different. It reflects the trend of a strengthening US dollar against ruble.

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



Source: MDpro

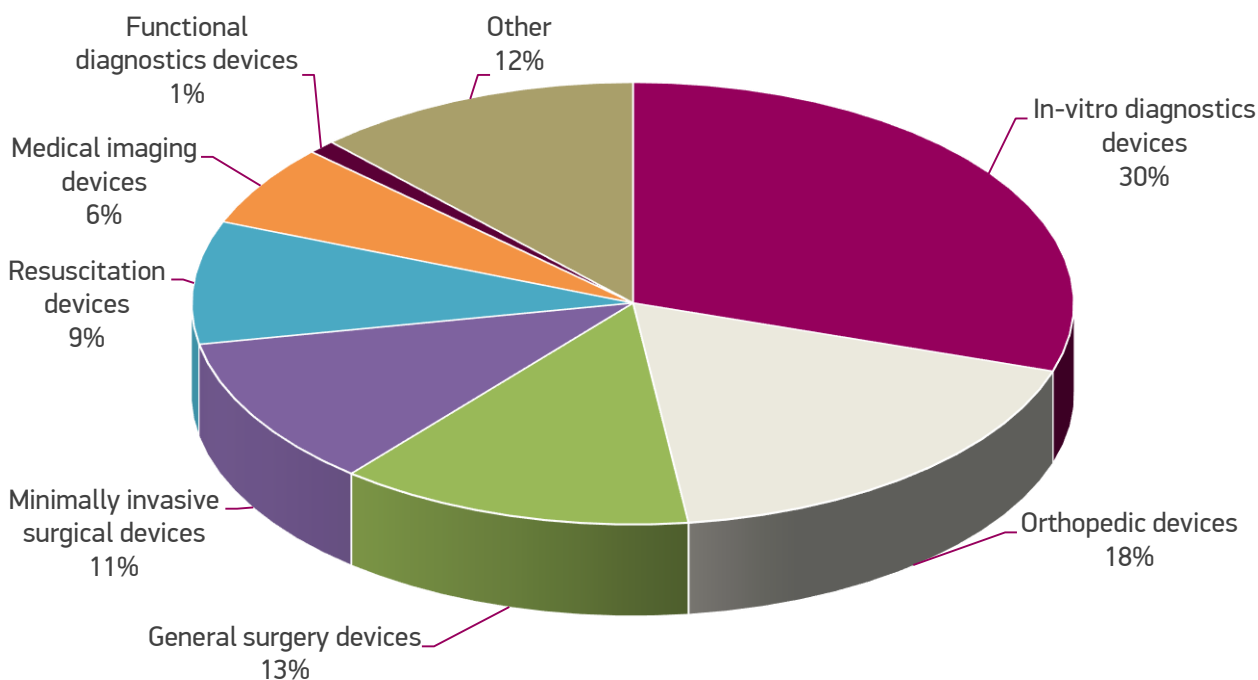
Figure 2. Dynamics of public procurement in 2014-2015 (USD mln.)



Source: MDpro

The largest segments in June 2015 were in-vitro diagnostic devices (30%), orthopedic devices (18%), and general surgery devices (13%).

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



Source: MDpro

For more information about the Russian medical device market, please visit our website at www.md-pro.ru or email us at info@md-pro.ru

Sources of information used in digest' preparation: Pharmvestnik, Medportal, RIA AMI, Rostec, Sygma