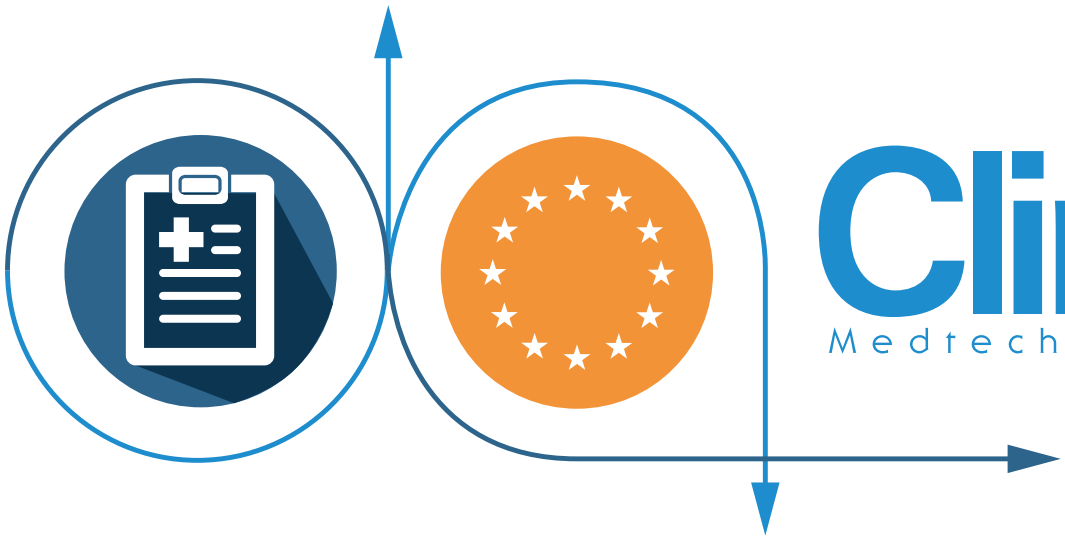

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Russian Move To Limit Medtech Imports Could Harm Domestic Innovation

By Ashley Yeo, 21 January 2016

IMPORT SUBSTITUTION AND TENDERING PRACTICES that put non-Russian/EAEU-based medtech manufacturers at a disadvantage were introduced under Russian Resolution 102 in February 2015. *Clinica* asked executives from IMEDA, Russia's International Medical Device Manufacturers Association, what effect this will have on market supply, patient care and innovation

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Almost a year ago, the Russian government introduced measures aimed at ensuring that domestic producers (and those in the four other Eurasian Economic Union states) are given preference in supplying local medical device market needs.

The measures were introduced by Resolution 102 (dated February 5 2015), " Establishing Market Entry Restrictions for Individual Types of Medical Devices Originating from Foreign Countries in the Context of Procurement for State and Municipal Needs. "The document was signed by Russian Prime Minister Dmitry Medvedev.

Resolution 102 lists the individual types of medical devices originating from foreign countries that are subject to import restrictions in Russia. It also lists the basis for exceptions to this rule, and further states that non-Russian/EAEU companies are excluded from public tenders if two local suppliers apply under a call for procurement tenders. The notice finally refers back to a five-year old CIS instrument (Rules for Determining the Country of Origin of Goods in the Commonwealth of Independent States, of November 20 2009) as the basis for the current procurement restrictions.

he move, which is not just a reaction to the sanctions being imposed on Russia, has destabilized the supplier base and thrown the market into confusion. Some observers see the "Medvedev law" as harmful to foreign companies and as dissuading potential investment by companies which now find it harder to make a business. An order similar to the medical devices resolution was signed in early December.

IMEDA chief executive Sergey Kolosov admits that the import restrictions, which have accelerated since the introduction of the sanctions against Russia, have created a situation where there is not a single set of criteria applying to the whole medtech industry. Speaking at the European MedTech Forum, in December 2015, he acknowledged that what constitutes a "local manufacturer" is not clear. Is it a secondary packager, or a manufacturer, companies asked. "They are still working on Resolution 102," he told delegates at the meeting, held in Brussels.

Speaking to *Clinica* during the meeting, Kolosov said that restrictive procurement and import substitution measures are not totally new; the Russian government had been talking about implementation of such policies for many years, but the whole issue had come to a head as a result of the current economic and political situation in Russia.

Resolution 102 is part of the Russian government's Crisis Management Plan for 2015, which came into effect under Executive Order No 98-r of January 27 2015, one element of which is to increase dramatically the proportion of locally

manufactured medtech. At present, only 15% of local Russian usage of medical devices is sourced from local manufacturers. By 2020, the government has set an ambitious target of raising procurement of locally-produced medtech to 40% of the total, said Kolosov.

This is open to confusion too, as the ministry of industry and trade has slightly different aims. Further, the 2009 CIS agreement says a product is considered to be locally manufactured if it has not more than 50% of foreign components.

Indeed, IMEDA notes that there has been little coordination between the government departments that oversee Resolution 102. The trade and industry ministry introduced the Resolution without discussing it with patients, healthcare professionals or the industry. In August 2015, the list was augmented by a hundred or so extra products and there are now over 60 categories of products listed. There are constant talks about expanding the list of restricted products, said the IMEDA executive director.

The expansion of the list brought a huge response from clinicians and surgeons who criticized what they see as "unnecessary moves". Domestic producers, on the other hand, have supported the move, of course.

Opportunities To Be Had

But it should not be viewed as a closed door by foreign companies. "Although it is complicated, there are opportunities," said Kolosov, whose industry association counts 40 global manufacturers. "Multinationals are queuing up to find out what is going on," he said, and meanwhile deputy Prime Minister Rogozin seems to be trying keep an open door policy for direct foreign investors

Kolosov said: "As soon as you make yourself 'domestic', you can go for public procurement. The government has decided to promote heavily the idea of direct contracts on both regional and federal levels. It is considering giving privileges and incentives, such as tax holidays, if companies decide to localize production.

What "localized" means has not yet been clarified, but companies going through public tenders need to show that their product is local on a special form (ST-1), issued by the Russian chamber of commerce (under Order No 29 of April 10 2015).

Another alternative is to opt for a special investment contract. This applies to manufacturers that are single suppliers of a certain product and can be used in cases where there is no analog being produced in Russia.

Kolosov's view is that the authorities understand that they need to find a compromise. The feeling among many is that Medvedev does not want to stop channels of trade that enable foreign manufactured products to get into Russia, in spite of Resolution 102.

The authorities also want to be able to deal decisively with counterfeit and unregistered products. On January 23 2015, Federal Law No 532-FZ (December 31 2015) Amending Selected Legislative Acts of the Russian Federation to Counter the Market Circulation of Falsified, Counterfeit, Poor-Quality, and Unregistered Medications, Medical Devices, and Falsified Dietary Supplements, came into force. It promises harsher penalties, but again, what exactly comes under the scope of the law has been open to question.

European MedTech Forum Focus On Russian Issues

Eventually, product quality and the innovation piece will have to come into the equation. At the European Medtech Forum, Kolosov was on a panel session ("Localisation – Russia and beyond") with the European Commission's Wolfgang Igler (DG Trade), Stago senior VP public affairs Christian Parry, J&J's EMEA regional VP diabetes solutions Nadav Tomer, and EDMA director of international affairs Jesús Rueda Rodríguez. Most of the debate centred on Russia, where Kolosov gave his views on what the Russian authorities are seeking.

He said: "The Russian government wants R&D to be brought into Russia and to work with local companies. They have seen some interest registered in this, but no positive impact yet." Kolosov also aired concerns that the current pathway could actually reduce levels of innovation in Russia, as the prioritization of local companies gets underway. This is a risk, he added.

National Regulatory Issues, Agency Update

While work proceeds apace to build the EAEU regulatory system, Russia's national regulatory system is still not complete. An updated draft of the basic medtech document for the Russian Federation, the Federal Law On Market Circulation of Medical Devices, was still in debate in 2015 and was with health ministry in the final months of the year, but was yet to be submitted to the State Duma (the lower house of the Federal Assembly).

The pace of regulatory clearances slowed as Russia changed to a new regulatory system, following implementation of fundamental healthcare law No 323-FZ (on public health protection in the Russian Federation), in November 2011. Relations between the medtech sector and Roszdravnadzor, the federal service on surveillance in healthcare, have often been strained in the wake of slow and low approval rates.

But relations with the regulator are now improving, Kolosov observed, although this has not yet translated into faster registration processes. "It was definitely a big step forward

when we succeeded in meeting with the senior Roszdravnadzor management. Previously, it adopted an authoritarian approach, but now we are at last getting access to the lower-level specialists, access to certain meetings and bimonthly meetings with the agency head."

Roszdravnadzor has also doubled the number of expert staff since last year, and there have indeed been improvements, "but no breakthrough yet". It has agreed to let applicants bring additional documents during the registration procedure – one set of additional documents for each of the two phases of evaluation; that is new. Applicants are also told the reasons for file rejections. But the process is still very long, and unpredictable. Applicants have little idea of when a decision will be made – it could be mere months up to several years.

No Turning Back On Procurement Measures

Kolosov's view is clear. "We are not against rules, we just want them to be set up clearly." That goes for all ongoing government measures related to medtech, including those on procurement and import substitution, which are "firmly on the agenda". On this, he said: "There is no turning back. It's not a fashion trend, and even if there were no sanctions, the government sees itself as being on the right track in its drive to secure a stable economy and political independence."

IMEDA for its part is seeking to become more involved in all processes, to raise the profile of ongoing Russian issues at international events and be a source of expertise and advice for companies seeking to work in what will eventually become a major medtech growth market once more.