Interview with Alexandra Mikhailovna Tretiakova, Executive Director, IMEDA

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IMEDA was founded in 2005, and today counts amongst its members 28 leading international companies in the Russian medical technology sector. What are the main goals of the association today, and what battles is it fighting for its members?

The main goal of our association is to represent the international medical device industry in Russia, to bring together the experiences and potential of our members in order to build a healthy, transparent, and modern environment in our sector, and to ensure that patients have access to innovative technologies.

2010 has truly been a turning point for our industry in Russia, and it has been a turning point for our association. For many years, medical devices and medical technologies were very much overlooked at the government level. There was a big focus on pharma, and on financing of the healthcare system. Medical technologies were not on the agenda.

Last year, the government reached the conclusion that pharmaceutical products are only one piece of the iceberg—they must look into healthcare technologies as well, if they mean to modernize healthcare as a whole. Of course, here, we see many opportunities for the association to be a partner: to consolidate the voice of the industry, and to utilize our experience and our vision in helping the authorities to address the challenges in our field.

Our companies, in large part, have been established in Russia for 10-15 years. They have been through various periods. Many of these companies are both pharma and medical device players. Therefore, they can benchmark and compare their experiences, and propose efficient ways to introduce new changes. I think this is the greatest value of our association: to, again, consolidate; and to streamline the views of all of the key stakeholders.

It seems that the main priority of the government in the medical technologies sector is to modernize the equipment in use, and to broaden the proliferation of modern equipment across the country. This takes two things: money and training. We have heard varying accounts of how much capital will be injected to this end, and whether it will be up to the government or multinational manufacturers to provide the necessary training. What is your understanding of this scenario?

There are several undertakings on the government's agenda. One project is the Healthcare Modernization Project, which will run throughout 2011 and 2012. The total amount of money dedicated to this initiative is 460Bn RUB, of which 100Bn RUB goes to medical technologies and medical equipment. The Modernization project is already underway, but is perhaps not yet at full speed, because it is to be carried out on a regional basis. Each of our 88 regions must present its individual modernization plan, and justify to the federal government what resources it needs to make it happen.

This is a complex situation, because these 88 regions have diverse needs, and differing levels of technological advancement and practitioner expertise. There is much planning to be done. There are regions that are quite remote, but nonetheless very well equipped: in the oil and gas extraction areas up north, for example, they do not need new infrastructure—they need patients! Areas like Moscow are very different, and complex in their own way, because they have both top-class clinics and quite basic clinics. There are very under-developed regions in central Russia, which are relatively close to educational centers, but due to a lack of finances, are poorly equipped. It is truly a different world in each region, and it will take much effort from officials at every level to implement this project correctly.

We see other projects on the horizon, as well. The new legislation on healthcare financing will be enforced two years from now, and will introduce a new insurance-based financing system. It will require a new level of regional legislation, and an absolutely new supply-chain system from medical device manufacturers to healthcare providers. This is something the remains under development, and our members have many questions—I think that all industry stakeholders have many questions.

Of course, there will be more money directed towards the modernization of the national healthcare system through this insurance-based scheme. But we do not know yet how much, because in part, it will depend on the results of this initial phase—this 2011-2012 regional modernization project.

The future legislation will also depend on the success, as you mentioned, of educational efforts. Simply placing high-quality and sophisticated equipment in hospitals does not help doctors to learn how to use it. Here, we again have many questions, but we also see many opportunities, because Western companies, and global companies in general, have much experience in establishing continuous medical education projects. Many of our member companies have offered such programs in Russia for years.

The education provided by private companies must be married somehow with Russia's own system of medical post-graduate education. It is unproductive to look at these two things separately. Our members believe that this can be a great opportunity for partnership between companies and the state—a partnership that will reduce cost and increase efficiency.

As Johnson & Johnson is doing with its public-private partnership for medical equipment training in Tatarstan.

Absolutely.

How high of a correlation do you see between government announcements, and implementation?

As usual, in Russia, announcements do not always lead to the kind of change that we anticipate or would hope for. There are several reasons for this. First of all, the healthcare system is truly in poor shape. This is one of the last pieces of the Soviet Union that has not been modernized over the last 20 years—and there are reasons for that, as well. We understand that it is not an easy job for anyone to turn an established system into something else, especially when you do not know which model to follow—because there are few good healthcare models in the world today. Coupled with this, as I mentioned, the regions are at very different levels of development. As we say in Russia, you cannot measure the average temperature; rather, each individual piece has its own temperature. I believe it is very difficult for the government, at the federal level, to develop a unified design.

Secondly, we must consider that Russia has a rather tough demographic situation. The Russian population is diminishing, it is getting older; and of course, the more elderly people you have, the more medical effort is required. If the number of people that remain diminishes, there are less and less taxpayers to support this effort. And the overall health of our society is in poor shape!

Everyone knows this well. I think that we have an extremely difficult task set before us, and the best thing that we all can do in this situation is to focus on the key factors that may prevent demographic collapse. Indeed, this is the main target for the government, and I understand them. They cannot satisfy all needs at once: they must first satisfy the urgent need to maintain our very population, and ensure that there are people who can work, can support their children, can support the growth of the middle class, and support the elderly demographic that is growing and growing.

At the same time, we understand that the experience that people have here in Russia is very much a crisis management experience. For 20 years, everyone underwent some crisis almost daily! Any day, whether you worked for a private organization or for the government, someone could come to you at 9 o'clock and say, "we have a disaster!" Thankfully, now times are changing. Now there is time to sit down, develop a strategy, and follow up. Experience with this kind of non-crisis strategizing is limited—for government officials, for managers, for doctors, etc.—and we are in the midst of a learning curve. How do we develop a strategy, implement a strategy, and monitor its success? People are learning this now.

Last year, as I mentioned, the government finally looked at the medical technology sector, and realized that there is no legislation, and there are many difficulties coming with the Customs Union. Import taxes are low for the moment: 5.15%. But the VAT rates are different: it goes from 0 to 10 to 18, and it is a bit of a mess. If you import something that is registered as medical equipment, you pay 0, but if you import spare parts, you pay 18. Again, because there is no legislation in place.

Now, there is a decision on the part of the government to include medical technologies under the auspices of the technical regulation law. There is a task to marry the expectations of the three customs involved in the Customs Union. It is extremely difficult!

In addition to the current lack of legislation, and lack of transparency at the Customs Union level, there is much discussion about what the healthcare system needs, and how to satisfy these needs. The Russian government is very eager to support Russian manufacturers, and there is a special federal target program to develop the local pharmaceutical and medical device and technology industry.

All of this is going on now, for the last 12 months. We are in a busy year! We have not had a busy year like this for the last two decades.

Is it clear who is in charge of all this? There has recently been a reshuffling of government roles, amongst agencies such as the Ministry of Health, the Ministry of Industry and Trade, the Roszdravnadzor, and etc. How has this affected the medical device and technology sector?

We are still waiting for clarifications!

We began to speak about localization of manufacturing. There has never been much of a medical equipment manufacturing tradition in Russia, but nonetheless Prime Minister Putin has said that just as with pharmaceuticals, he would like for multinational medical device and technology manufacturers to engage in production here in Russia. Is this realistic, and do we see steps in this direction?

Our position is the following. We think that localization of medical devices and technologies can be done, and should be done, in Russia—but we must consider different phases of the product life cycle. Manufacturing of medical technologies is no longer a central part of this process. Because in many cases, when you think of complex medical equipment, it is probably assembled, finally, by the customer. Why have a manufacturing site to assemble 5, 6, 10, 15 pieces that are being brought in from different countries? This is the scenario today.

On the other hand, there are very critical steps in the development of medical device products, which can be localized depending on the level of development of the market. We can start from market research, and the needs of patients and doctors. There are clinical studies, and technical studies. There are R&D efforts, and computer modeling. Further down the line, there is education, and service, and follow-up; fine-tuning and re-working.

We can take any part of this process, and localize it. This is what many of our companies are doing already. Because manufacturing in of itself is not particularly important. Many of our members have manufacturing sites that employ perhaps 10 or 15 people, and everything is automated. What is to be gained by simply putting this in Russia? There are also many medical technologies that are now customized to doctors—this is a general trend we are seeing. We are not talking about massive production! We are talking about bespoke customization that is done either where the customer is, or at one central manufacturing site, because this site allows us to combine all the parts together.

Russia is a good place for localization of several, or many, of the development cycle steps. It will all depend on market development, the legislative environment, the ease of carrying out complex projects involving multiple institutions, etc. We should not be talking simply about building a factory—even less so than with pharma!

Mr. Voskertchyan at JNJ mentioned the same concept: the value-creation chain inherent in medical technology development. Perhaps, with projects like the Skolkovo Technopark, Russia may become increasingly attractive for the R&D phase of this chain. In your view, how attractive is Russia, then,

for R&D, rather than manufacturing?

Russian doctors are extremely creative. I can tell you with certainty that Russian doctors, as the source of innovation for any medical technology company, are a very good option. We know that, unlike pharma, innovation in our field does not come from the top; all around the world, it comes from the customer. If you open the catalogue of any medical technology company, you will see the names of doctors next to each instrument.

Not only are Russian doctors creative, they are very receptive and open, and they are very easy to talk to. I think there are many opportunities—if our members choose to overcome the language barrier and establish close relationships with physicians and surgeons—to implement their ideas.

We have heard that in Russia, there is a problem of development: of going from idea to commercialization. What role can your members have in making doctors' ideas a reality?

We are talking about two different issues here. If we consider ideas in the sense of pure, new ideas for novel devices which have never before existed, it is true that an individual doctor, engineer, etc. will have difficulty in finding the venture capital needed to commercialize it in Russia. But if we are talking about modification, or a new idea that follows existing technology trends, it is much easier. Because then, if you are close enough to your customer as a corporation, you can make agreements to ensure that trial and development happens. In a small Russian company, if someone comes out and tries to develop something novel, it is hard to attract capital, and it is not the role of international companies to invest in this. We think that there, the government can be a pivotal player, because they have the resources and motivation to invest in high technologies in healthcare. The corporations come at a later stage: once the idea has a tested prototype. If it works, then corporations can pick it up for mass production.

Taking a broader view, let us consider the market itself. Statistics are hard to come by in the Russian medical technology segment. Can you provide some of your own ideas on how this market is growing?

Indeed, there are no good official statistics. Some of the latest numbers from 2010 tell us that the total market, including the private segment, is worth about 110-120Bn RUB. If we have 100Bn RUB invested over two years from the Modernization program, it will approximately double the current market.

For the past, we cannot really say. In 2007-2009, we had the National Healthcare Project, and that provided an injection of finances and products into the system. But we know relatively little: we

cannot pool the data from different sources and confirm our figures. Unfortunately, there are no international research companies in the guise of the IMS that are producing credible reports on our industry here. This is still an unfilled niche. Some Russian companies that produced data for the Ministry of Industry and Trade, for instance, have provided some idea, but this is only for one year.

We only know for sure that with all the prospective investment, the market will grow.

What do you see as the main opportunities for your members in the years ahead?

First, a market that is growing 50% per year is already a big opportunity—this is clear. We also understand that Russia is a large country, with a large population, and the population wants quality healthcare resources. People who were born in the 70s and 80s are usually the most successful portion of our population, and they know exactly what they want. They will push the public healthcare system from one side, and the private system from the other side, to make sure that they have access to adequate services.

So opportunities are abundant! Because patient demand is on the rise, the government is investing, and our members are investing in education.

But how do these companies read the market, if there is no available telling them which segments are attractive? How do they know what to bring to Russia?

This is one of the biggest problems, but I think that the best thing to do is simply to have an office here, and people dedicated to reading local opportunities. As I have said, there is some data available: the Russian government produces statistics as of late, and companies can also look at the tenders. There are some efforts to produce data by international companies, but you had better benchmark them against reality.

IMEDA is now thinking of producing a market report ourselves, to help guide our members. This report will be organized in terms of the largest segments.

What is your final message on behalf of IMEDA to the international readers of Pharmaceutical Executive?

Russia is a country of opportunities, but you must be present in the country to realize them. You have to be patient, and trust your local office to overcome the challenge of establishing your business here. You can then enjoy the fast growth that this market will offer. You need people who are prepared to learn, and want to introduce and implement the best technologies in Russia.

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