Interview with Gennady Shirshov, Executive Director, Union of Professional Pharmaceutical Organizations (SPFO)

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Last time Focus Reports met with you in 2006, the Russian pharmaceutical industry had enjoyed five straight years of growth. This growth has since continued through 2011. Can you provide some insight on what has happened in the industry since 2006, and how the market has been able to maintain its upward thrust?

Let us backtrack a bit, to 2004 or 2005. At that time, Russia had reaped the benefits of oil prices, and, all of a sudden, the government was sitting on a lot of money in its budget. There was a surplus. The situation was reviewed, and the government held a three-day brainstorming session organized by one of Russia's development institutions, the Academy of the National Economy. A decision was made to address social issues and the authorities began to implement various initiatives over time.

One of the outcomes was a reinvigorated focus on healthcare, on a number of fronts. First, the government intensified programs for three major concerns of national health—namely cancer, cardiovascular diseases, and noncommunicable diseases (NCDs). A decision was made to inject quite a bit of money, relative to the general budget, into the medicinal supply chain.

More money was also allocated to the so-called 'National Healthcare Project.' The goal here was to furnish healthcare facilities with new, sophisticated equipment, to build some dozen high-

technology centers (tertiary healthcare facilities), and to retrain doctors in order to strengthen the primary healthcare sector. Outpatient clinics and first-aid stations were improved, new vehicles were provided, and doctors' salaries were increased—this resulted in the outflow of doctors and nurses from hospitals to outpatient clinics, because of the more lucrative opportunities there. Then the government established a sort of 'Medicaid' program addressing the needs of disabled persons, pensioners, and people who needed specialized medicines. It was called the Additional Medicine Supply Program, with the acronym DLO. All in all, the Ministry of Health and Social Development calculated that there would be about 15 million such people, and the state allocated 2Bn USD annually to the program. But what happened was that there was a drive towards making people choose whether they needed free medicines, or just money. A law was adopted that stated that people within this target group could make such a choice. At that time, half of the people opted for money and the principal of consolidated funding was disrupted. So from the very beginning, the system stumbled and within the next 24 months faced logistical as well as financial difficulties.

Despite these difficulties, the potential of this scheme attracted a lot of interest from both domestic and multinational companies (especially R&D-driven multinationals). I remember that the managers of the system had some difficulty in putting together a list of medicines to be procured —because the funds were given all of a sudden and they needed to be disbursed without delay. At the time, more than 3000 medicinal products were placed on the list.

I am not going to get into the specifics of why the initial model failed, because the true reason is this: people walked away from the system. They wanted money instead—especially those living in the countryside.

But the best thing that happened to the people of Russia—that did not opt for the money—was that, because of this system, many of them, for the first time in their lives, received innovative products—which improved their health and lifestyle. And when I say lifestyle, I do not mean it in any complex sense: I mean that people used to simply be sick, and all of a sudden they started receiving good treatment. When the program started having its problems, there was one very strong message from them: do not stop the supply!

The program also generated a lot of good for the industry. Because domestic companies saw that they could produce more effective drugs, and be included into this program, and, as such, they could be confident about their production future—should they choose to capitalize on the opportunity (and, unfortunately, many have not chosen to do so). Because the program is still there! Except instead of 15 million, it now serves some four million—and these people are those

who really need drugs.

Another good thing that happened as a result of this program was that when the government reviewed the outcomes and results, they noted a small but significant need group that must have drugs for very difficult and expensive diseases, and they decided to segregate this segment of people under the general umbrella of the ‘Seven Nosologies,’ or seven diseases. The weight of this program was even heavier than the DLO program as it was. I will give you two figures from this year: the Seven Nosologies program is worth about 43Bn RUB, and the remaining portion of the DLO program—now named the ONLS—is worth 28Bn RUB. We see that despite the global financial crises, and budgetary difficulties, the government still maintains both of these programs—and this is good.

The Seven Nosologies program has saved many, many lives—most of them children’s. The president has recently said that they are thinking of expanding it. I cannot say whether he means money-wise, or in terms of the list of reimbursable drugs—but, regardless, he mentioned prospective expansion.

I see this program as a trigger for market development. Let us imagine something. Suppose a company decided to introduce innovative drugs into this marketplace—to introduce them into this program. Drugs that have never been in Russia before. There are several questions to consider: do doctors know how to use these drugs? Is the regulator aware of the value of these drugs? What will happen if the drug supply stops for a time—will the drugs disappear? A sensible risk-management technique, in this case, is to make sure that the product is visible, that doctors are trained, and that the pipeline is not dry. So most companies have decided to actually double their supply: they sent their products into the program, and they decided to also retail them. This is why the market started growing very fast.

There is, of course, another factor of market growth: inflation. We had the 2009 global crisis, when prices skyrocketed, because the government decided to inflate the local currency. Around the same time, in Europe, many companies decided to switch from dollar prices to Euros. This was a huge factor! When you look at the market cost structure, you would see a different figure if you start calculating by units, rather than by money. Yes, there is growth—according to analytical studies, the market grew quite well. But when you look at units, you will see that this growth is, in fact, a bit less than one might think. Still, I will stress that unit-wise, there was a huge leap, initially, because of the implementation of these programs.

When the global crises struck, the government launched monthly social surveys, and one of the key outcries of the people was that there were exorbitant prices for drugs. So the government decided to act. One of their first decisions was to curb prices by introducing a mandatory price registration system for ‘essential medicines.’ But what actually happened was, though the prices were frozen to some extent, it did not affect the marketplace that much—because to cover margin loss, companies increased their supply, trying to sell as much as possible before the ‘curfew hour.’

In parallel with price regulation, the government decided that, for a country as big as Russia, having no national industry is not good! A localization program was discussed and introduced. But if you look at the current structure of domestic manufacturing facilities, you would see that there is an over-abundance of capacity for solid forms of drugs: such as tablets, capsules, and etc. All in all, as far as generics are concerned, everything is ok in Russia.

However, let me give you two figures that are self-explanatory. Everyone, including government officials, keep on stating that about 75% of the market share is dominated by foreign manufacturers. That is true—but these are in monetary terms. In unit terms, it is the domestic companies that dominate the marketplace: they account for about 60% of the market share. But when you analyze what they sell, the picture is totally different. In quite a lot of cases it is not a medicines in the modern sense of this word—these are herbs, concoctions; things like that. So the challenge is to turn the local industry into a quality- and value-based industry, rather than just to build manufacturing facilities.

The strange thing that happened with the DLO program was that local industry started out providing 25% of its drugs, but currently their share is about 7%. When looking at the principles of any localization program, you might say that demand should trigger localization, rather than direct orders or threats from the government (i.e. increased tariff penalties for those who fail to localize). But though demand was generated from the DLO Program, and despite the fact that, as I mentioned, the industry became more confident about increasing their share of value-based products when they saw they could be included in this program, it has not been enough to change the fundamentals.

What is good about message voiced by the Prime Minister, Mr. Putin, is that he understands localization is not going to happen tomorrow, or the day after tomorrow. It is a long way off. You need research capacity; you need specialists such as chemists; you need young idealists to stay in the country instead of traveling West; and many other things.

There is another factor, actually: quality. The domestic industry is not GMP-based. And, strategically-minded multinationals have, many times, canvassed the entire spectrum of domestic companies—trying to find a partner to localize: to contract manufacture, to license out; etc. They have very rarely found a partner! GMP is a prerequisite in the global industry. If a multinational contracts out manufacturing to a local company, and is not confident about the quality, then it is a health risk.

GMP is a key factor that hinders local development. But happily, the government is trying to move ahead in introducing it into the legal framework. We are helping them a lot, because there is a huge communication gap regarding what GMP exactly means!

So this is where we stand. We somehow have made it past the global crisis, and most of the actors are still there. Margins are much narrower, to be frank with you; but I do not know a single company leaving the marketplace.

Portfolio-wise, Russia is huge. We have over 19,000 medicinal products registered—which is a lot. We have 2,500 molecules registered, compared to 3,500 across the world. So we are doing ok there, more or less. And the new process of marketing authorization, though slow, but is going quite well: every day, new products are added to the registry.

You mention the lack of GMP. How do you explain that? It seems that with a relatively small investment in quality, companies here could become attractive partners, exporters, and good choices for the home market. Why has the industry not yet implemented these standards, and where is the starting point?

It is a matter of political will. Until about five years ago, we had only one regulator—the Ministry of Health. And historically, the market was small. No one cared! A more comprehensive insight into what GMP really is, and why it is so important, came with the localization drive.
The first time the bell rang, actually, was when the financial crisis struck, and the government saw the importance of medicines for the population. A decision was made to pay more attention to the sustainability of the sector, and to oversight. Things like GMP introduction, and data exclusivity, became topics of high-profile meetings in the government—even to the extent, for example, of one of the deputy prime ministers inviting several big players in the industry to discuss what GMP upgrade would entail. This is what I mean by political will. There is now an intention to really develop the industry.

Another key turning point was the international conference that was organized by SPFO and a number of other companies, which we called “GMP: Blessing or Burden?” We invited renowned

international figures to speak with us. The Minister of Health herself came to open up the session, and proclaimed that we would have GMP rules that are not Russian, but rather are harmonized with Europe. That was a trigger that started things rolling.

GMP was included in the new law on Circulation of Medicines, and each company should be up to standard by 2014. But it is not simple! There is a lot of work ahead. It is not just about machines or equipment—it is about fostering a quality development culture within the industry. This is something we lack. Plus, the government must develop and approve about 30 regulations, and make sure that they are embraced by the international community.

Again, there is a huge communication gap. To prepare regulations is easy—no problem. You can borrow them; you can translate them. The difficulty is in understanding which way you need to go. You can easily say that in order to meet a given set of standards, you need to do this, this and this. But you need a government inspectorate to really control quality issues and production; you need a sufficient amount of oversight; and you need to have integrity throughout the entire system. Regarding these points, we had a discussion recently, in an industry-wide expert council. We discussed the fact that we need to move forward. We need to establish basics. And we need to be very good communicators. Because otherwise, everything will go down the drain.

Having said that, it is not only about the government controlling what is going on. It is about the general public knowing which products to buy from whom. My point of view is this: we need new technical barriers. For example, if you are not GMP-based, you should not be allowed to sell to government procurement systems; you should not be allowed to market your products.

If you want to export nowadays, even countries like Vietnam demand a GMP certificate; and not a simple GMP certificate, but one that meets European standards. That means to me, and to many other people, that GMP is more than a government tool, and more than a regulation tool—it is a tool for market access! So the market will eventually decide who will move forward. These are the finer points upon which we communicate the message to the government.

Considering the poor track record that Russia has on matters of integrity; and considering the poor track record that the government has regarding conflicts of interest, with government officials having interests in private organizations—do you see things changing?

Yes, I do. I will share an anecdote with you: I am often part of radio and television shows. On the latest talk show that I was on, this issue came up. You might know that many television programs are strictly controlled by the government. And all of a sudden, in the middle of the session—and it was live!—they started asking these ugly questions about integrity: about why a government

official would promote a specific drug, and things of that nature. I could not believe it! And the fact that it was being spoken about, live, on a government-controlled program, is a great sign of where we are heading.

I will be frank with you. I keep telling members of our association that we have been in this market for 19 years, and Russia was always a mostly unregulated market—laxly regulated, we might say. Companies did what they wanted to do, within certain limitations. Now, regulation becomes stronger everyday; we have stronger laws. We are still not that strong on following those laws, but we are improving. My latest session with government officials was rather curious in terms of outcome: it was said that within 18 months, there will be a dramatic improvement in terms of integrity, and things like that. There will be a 'cleansing of the stables.' The industry received a clear message: "you behave." And that concerns government officials, as well.

Officials come and go; business, industry and business will stay. And it will keep on developing. Things like some officials flagrantly supporting individual companies—this will end sooner or later. In the end, it is bad for business.

If GMP regulations are implemented, this opens the door for things like contract manufacturing, out-licensing, and other collaborations. Do you believe there is a future there for the Russian industry?

There is an opportunity, but not for everyone. It is a matter of trust. Suppose that you are a major innovator that does not have that much share in the Russian marketplace; economically it makes no sense building anything in Russia. So you want to outsource your manufacturing. Who would you contract out to? An unknown domestic facility sitting somewhere in Novgorod? Or to a well-known international player localizing in Russia? Such an international player is called a 'local' producer and will enjoy all the privileges.

What about moving beyond manufacturing? Very few countries in the world now conduct R&D. Fewer countries still create R&D where there was none or little before—because the cost and complexity is very high. Do you see Russia adopting any meaningful R&D infrastructure?

There will be many changes in the marketplace. It is not only about building facilities. I remember a business breakfast with Viktor Khristenko, the Minister of Industry, in June of last year, when he said that, "When we say localize, we do not mean build. We mean create." It is more about establishing R&D infrastructure, and supporting it, rather than just constructing buildings.

All the steps you see the government taking are actually focused on establishing this infrastructure. First of all, the government generated a list of 57 strategic medicines that it wishes to produce locally—drugs that are high-tech, and very expensive, especially to import. They are for difficult diseases, like AIDS and cancer. Because of the level of complexity, they are very difficult to localize. Still, to support the drive to produce them here, the government decided to inject about 8Bn USD, over a period of 10 years, to assist R&D.

The questions that we have been asking the owners of such innovative products—multinationals—draw smiles from some of them. They say that domestic companies will not be able to produce anything on the complexity level of these medicines, because of the high-technology focus; because of the cost. But the process is already under way.

R&D is expensive in the West. But some officials and domestic companies maintain openly that R&D in Russia will cost peanuts compared to the West.

The question you may be asking yourself is, “Will Russia succeed or not?” We will see. It is important to take the first step. I do believe that, two or three years from now, there will be a better understanding on the part of the government regarding whether the drive is succeeding or not.

In mature pharma markets around the world, many have gone beyond thinking about pharmaceuticals. They think in terms of healthcare, and consider the global value chain, and the technological chain—because treatments are not just limited to pills anymore. A lot more is involved: therapy plans, complex systems of illness identification, etc. Do you see Russia thinking this way?

That is exactly what we have been telling our companies—it is not about pills! The board of directors of our association is crystal clear about which way to go to develop this industry. It is more than pills; and there is no profit in pills anymore, anyway. You need to introduce new treatment technologies.

Much depends on the attitude of administrations: healthcare facility administrations, and regional administrations. A lot might be said about the environment people live in. You can treat people in a hospital, but the moment they are out of the hospital, what happens to them? So it is about a new way of thinking; about ensuring that your patient is your patient—even when he is healthy.

So yes, I support this approach. In the meantime, let me quickly list what changes we have in terms of regulation in Russia. The first change—which we have touched on a bit already—was a

resolution by the government regarding the mandatory registration of maximum drug prices, and the establishment of the EDL: the Essential Drugs List. This was supported at a later stage by the new law on Circulation of Medicines, and the matter is actually about marketing authorization, besides price control. It faces some difficulties now, because it is still raw. The new unit of the Ministry of Health had to screen over 14,000 trade names when taking over from Roszdravnadzor. Believe me, from May until now, almost every company in the industry had to deal with that! Because if you failed to cope with the issue, it would spell the end of your business.

The second important event—although it is not particularly important yet—was the establishment of the so-called 'Customs Union.' Eventually, we will see the establishment of a single economic environment, much like an EU.

Then, after a lot of arguing, a law on Mandatory Medical Insurance was adopted, which is about a one-channel financing of healthcare system. The idea is for businesses to pay more than they pay now into the social funds. This financing is not meant to come from the people, but from businesses.

Now, the so-called 'Fundamentals of Law on Public Healthcare In Russia' is going to be adopted. As far as pharmaceuticals are concerned, this act will affect the regulation of relations between pharma and doctors; it will also affect standards. There is an interesting thing there: impending equality of healthcare facilities of different property status. That, to me, means that, perhaps in 2013, privatization of the system will start. An indirect indication that there are steps in this direction is the adoption of a so-called two-year modernization program, wherein almost 400Bn RUB was allocated: half will go to the refurbishment of facilities, and the other half will go into buying more medical devices, establishing IT systems, and improving standards.

Soon, there will be a law on the civil liability of healthcare facilities. It will also be adopted this year, and with its adoption, patients will be protected—to some extent—from bad outcomes, errors, and things like that. In 2014, the civil liability law of healthcare facilities will evolve into a law on the civil liability of physicians. This is because in 2014, we will move from a system of licensing healthcare facilities, to a system of licensing doctors—like in Switzerland.

Also, there is a lot of discussion now about the law on procurement. There was a message from the office of the president that the government should start buying directly from manufacturers, rather than from anyone else. But it is not that simple.

There are other changes in the market place, as well. If five years ago, one of the largest risks to public health was the high incidence of counterfeit drugs, today it is quite low. We have won that

war for now—although it is a never-ending process. We are always monitoring, evaluating, cooperating and, of course, acting.

For the part of the SPFO, what is at the top of your agenda for the coming time?

We have several priorities. Priority 1 is building partnerships and that means communication, communication, communication. Partnerships between all stakeholders. You might ask what tools we are using to do that. I will give you an example: in April 2012, the SPFO is arranging its first annual international forum and exhibition, under the title of “Innovative Technologies for Healthcare.” We will be bringing the innovative world to Russia. We will bring together Russian and international R&D people, organizations, and innovative promoting systems; and provide opportunity to share and to see what others are doing internationally.

The second priority for us is to harmonize legislation. This is huge! It is a never-ending task, but our current focus is on making improvements over the next four years.

The third priority is reimbursement. In this area, we intend to take practical steps. There is a committee on reimbursement, and we selected four initial Russian regions, where we have a good understanding of the basic components of the potential reimbursement system, to start our discussions.

Our fourth priority is, of course, GMP and other components of international quality standards. This is our main priority now. Russia must become part of the international quality community—without this, there will be no market development.

The fifth priority is proactive participation in building, or identifying, the role of the pharma industry in the so-called ‘single economic space.’ Sooner or later, countries of the former USSR will have harmonized regulation systems, and this is where there are both risks and potential for growth.

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