

Interview with Arkady Nekrasov, General Manager, Petrovax Pharm

27.07.2011

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Petrovax has always been an innovative company, making it quite unique in Russia where the domestic industry is predominantly comprised of generics manufacturers. How would you describe the positioning of this organization, as the Pharma 2020 initiatives set clear industry targets in terms of a greater proliferation of locally-made, innovative medicine?

First of all, it is important to qualify what "innovation" means to our company. The fact is that in Russia, innovation is not formally defined in the lexicon. For Petrovax, innovation is first of all the creation of novel molecules, which have no analogue in the world. It is the patenting of these molecules, substances, and compounds. It is the development of these molecules, and their formulation into finished medicinal products. These products, patented in Russia and abroad, are then commercialized and it is up to our sales and marketing staff to derive an economic effect from such innovations.

Hence, our definition of innovation is analogous to the internationally understood definition of the term, used by the large research-based pharmaceutical enterprises. In Russia, too often, domestic genericization of known molecules, and even novel packaging techniques, are termed innovation. Our company's understanding does not recognize such efforts as truly innovative, and the class of compounds that we have developed here are original and protected by patents. We personally underwent the basic and applied research phases of their development. We sell our products in Russia, and are beginning to successfully distribute them abroad.

With the government announcement of the Pharma 2020 strategy toward domestic innovation, we find ourselves fully aligned with national goals. However, we have worked for over 30 years in this direction long before the 2020 initiative.

We have also long preempted the government drive toward high technology, high research standards, high manufacturing standards, and international collaboration. This fact is well exemplified by our partnership with Abbott, (formerly Solvay Pharmaceuticals) with whom we have been collaborating for approximately 10 years.

A final portion of the authorities' strategy is to increase the export efforts of Russia's pharmaceutical companies. As I have mentioned, this is again a direction that we are working in. Our high standards, meeting international requirements, allow us to compete abroad. While Russia is our main focus, we are actively expanding our horizons.

An especially difficult factor in all of this is personnel, because new technologies require a new level of professionalism in an organization's staff. Following the collapse of the Soviet Union, many of the professionals in the pharmaceutical sector left the country and not enough emphasis was placed on developing the next generation of leaders and specialists that would drive the Russian pharmaceutical market forward. Petrovax has worked extremely hard to assemble a team of high-quality specialists that are able to manage the challenges of high technology assimilation—something we owe in part to our alliance with experienced foreign companies, who shared their expertise with our company in many areas. Both of our key existing partners, Abbott and Pfizer, have transferred technology and know-how to Petrovax and have assisted our company in its development. Our partners appreciate the competence of our staff, and are interested in conducting international business with us.

Pharma 2020, therefore, perfectly characterizes our own vision, and our own operational direction.

The role of the government in our business is paramount. For example, we manufacture Russia's principal flu vaccine—it has 80-85% market penetration, and is mostly sold via the state purchase sector. Moreover, we are now entering the national immunological calendar as producers. Therefore, the extent of the government's involvement with our company will have a strong effect on our future. Our accordance with their goals and strategies is highly beneficial for our internal development.

Your partnership with Pfizer, the largest pharmaceutical company in the world, was a landmark deal, and only the beginning. Do you believe that foreign confidence in Russian companies is increasing?

I believe that the fact that partnerships are being secured in Russia is in itself a clear sign that indeed, investor confidence is on the rise!

Our partnership with Abbott was an example of such confidence. It was an extremely ambitious project involving new influenza vaccine development that would consist of Abbott's antigen technology and Petrovax's adjuvant-based method for reducing the antigen load and improving the safety of vaccines. In connection with this project, Abbott also helped us build a modern manufacturing facility in accordance with European GMP standards. This was an unprecedented example for the Russian market of such a deep and large scale technological collaboration between a local company and one of the world's leading biotech players. This again speaks to the confidence of foreign parties in Russian innovation. It also demonstrates how Petrovax has leveraged our international collaborations—in this case, with Abbott—as a springboard for more collaborations with other leading pharma and biotech companies.

We are now working with some of our foreign partners to penetrate Western markets. We believe that our best source of entry into these markets is with the strategic aid of a strong international company.

However, as I have mentioned, our greatest focus is the local Russian market and I would like to elaborate on our deal with Pfizer. It was our first collaboration where we did not use our own technology, but rather pursued a localization of a leading product from our partner—a pneumococcal vaccine. Pneumococcal infection is one of the leading causes of death amongst infants worldwide, and the Russian government wanted this vaccine localized.

This is a new direction for our company: the localization of other companies' medicines with the full transfer of technology and production cycle.

In Russia, there are a number of academic institutes working toward the same goal of developing local analogues of vaccines. However, this process unfortunately takes too long to realize, because

there is no strong connection between academic science and commercial enterprise. That is why the Pharma 2020 strategy is wholly correct in advising that private companies should integrate and develop partnerships with foreign companies to localize the most essential medicines. This is the best way to ensure that their manufacturing realistically takes place. Of course, the other way that we could potentially localize the production of strategic medicines is to invite foreign players to build their own facilities in Russia. But if they can instead partner with local companies that own GMP quality infrastructure and operate at international standards, this option provides for a quicker and more efficient way for achieving the objectives of the Russian government's strategy.

The reality is that there is only a handful of local partners for foreign companies to choose from that meet big pharma's criteria for high standards of research, production, and marketing. So, returning to our conversation about foreign confidence, it is rising but selectively. Petrovax, however, is one such company that has been able to successfully execute partnership with the world's leading pharmaceutical companies. In fact, everyday we improve, because many noted foreign specialists from our partner companies contribute to our evolution.

Localizing production of strategic medicines is a strong growth driver for our business. To us, localization can not be just about packaging of finished product; it has to involve a transfer of technology, methods and processes to enable full cycle formulation, filling and packaging of drugs and vaccines. These are the types of localization projects we were working on with our foreign partners.

But we do not want to be just contract manufacturers for our partners. We want to also engage in licensing deals: for example, wherein a foreign partner licenses a product to us, and we develop the product full-cycle going forward. And ultimately, as an innovative company, we are most interested in joint development projects, using our adjuvant platform technology for vaccines and the protein conjugation technology to develop next generation biologics. We have strong experience in this regard, and this strategic model is highly regarded by the local market as a successful path for the advancement of domestic industry.

As innovators, can Russian companies truly compete with Western players?

It depends. In Russian and CIS, we compete quite successfully. I have already mentioned that our original flu vaccine is the leading product in its class in Russia. It leads in both commercial and state purchase sectors.

In the West, we can too compete, but we have a long path ahead of us. We are on our way, because we have very strong patented technology that has great potential not just in Russia but in the rest of the world. Going forward, we will work with our foreign partners to carry out preclinical and clinical studies within the framework of international standards and, with our partners' help, commercialize our compounds in global markets.

Again, we view partnerships as a key instrument to the success abroad—especially if we are to accelerate our entry. The parameters could be based around the joint marketing of Petrovax original products or around the joint development of original products. Our experience with Abbott showed us that collaboration proves to be an extremely fast business development tool for us.

We believe our company is an excellent example that high quality products, with proven efficacy, produced in modern GMP facilities, do indeed exist in Russia. Moreover, innovative ideas that lead the market also can be found in Russia. For example, our adjuvant-based vaccine was developed and successfully commercialized 15 years ago. Over this period, it has proven to be safe and effective and has captured leading market positions. Today, the WHO recommends similar technology for flu vaccines—a global pandemic caused the organization to consider how to

optimize limited antigen samples, and adjuvant technology came to the forefront. Novartis, GSK, and others now use this approach—however, we can claim that we developed and successfully commercialized this technology before all of the world’s largest vaccine companies.

What is the future of this company?

We see a very bright future. If we speak of internal product development, we are currently developing approximately 10 novel products. If we speak of collaborations, we are actively working with a number of foreign players in ventures that are designed to battle the most difficult diseases. In terms of foreign market penetration, we already work in the CIS, Slovakia, and Venezuela and expect to significantly increase our geographical penetration in the coming years.

There are several Russian players selling generics in the E.U., or contract manufacturing on Russian soil to export products to Europe. However, from the point of view of entirely original products, it is quite likely that we are the only Russian company selling internally-developed, innovative medicines in the E.U .

This is only the beginning! It is important to lay a foundation; with time, we will expand yet further using our existing achievements as a catalyst. For example, we worked successfully with Abbott, and we became visible to the world’s pharmaceutical community. Now, through our collaboration with Pfizer, we are yet more visible! Other multinationals are interested in collaborating with us.

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

Do not be afraid of the Russian market and do not be afraid of Russian innovative science. There are excellent opportunities and development projects ongoing here.

Petrovax is a truly innovative company with a strong product portfolio and a history of successful collaborations with world’s leading pharmaceutical companies. We welcome the prospect of further international collaboration and invite foreign players to become our partners.

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