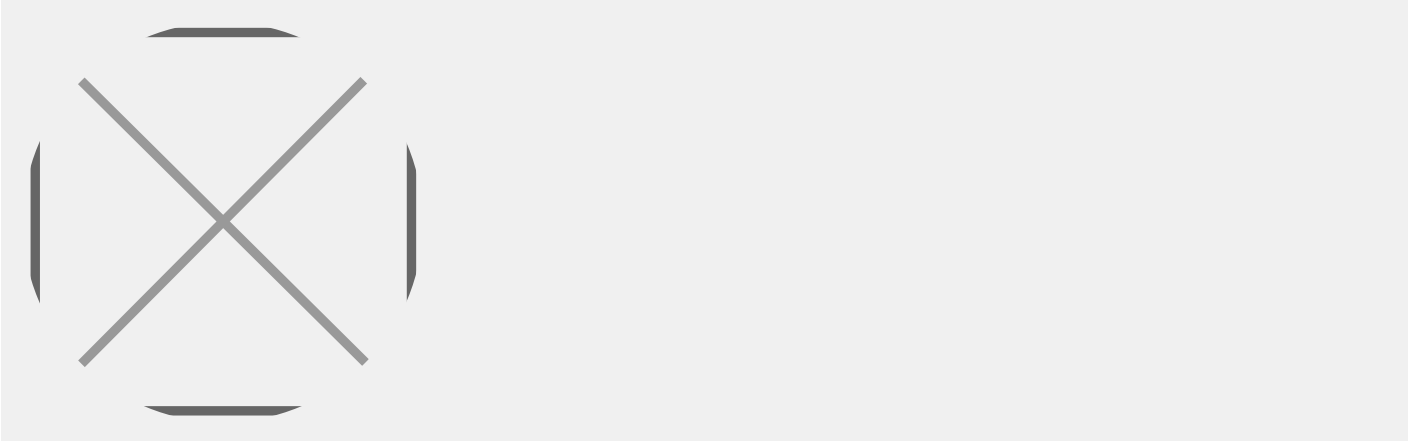
Interview with Victoria Anashkina, General Manager, Amgen Russia



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Since 2006, Russia has witnessed quite a dynamic few years, with sweeping legislative reforms like the Law on Circulation of Medicines and development strategies like Pharma 2020. What have been the specific effects of these and other initiatives on the biopharmaceutical sector and the biopharmaceutical market?

If you look at current statistics, the biotech share of the Russian pharmaceutical market does not reach the proportion we currently see in Europe or the US. I would say that from a strategic point of view, each of the latest governmental initiatives have made it clear that biotech will grow in Russia. Pharma 2020, for example, is focused on innovative medicines, and it is well known that going forward, the major portion of innovative medicines will come from biopharmaceuticals. It is inevitable that biotech as a market will advance in this country.

Though still many pieces of legislation need development and clarification—for example, Russia lacks laws properly defining the legal status of biosimilars—I believe that the direction and the aspirations are clear. Recently, Minister Nabiullina of the Ministry of Economic Development declared that the pharmaceutical market will grow 400% over the next ten years, and I believe that the majority of this growth will be attributed to biotech.

Biotech has an extremely bright future in Russia. The relative question is only when, and how quick this segment can evolve.

Is it a challenge or an advantage to exist as a specialty biopharmaceutical company in the Russian environment today?

I would say it is a challenge, but at the same time, a great advantage!

Any time of change is an opportunity—especially for a leading-edge company like ours. We are quite confident that the prospective outcomes of change will be beneficial. Our focus is on new, first-in-class treatment paradigms, which means we are not afraid of competition and we truly believe in the potential of this market. With the price pressures put on the current round of medicines coming off patent, the market should shift toward the direction of highly innovative treatments.

The growth of the biotech market will also increase Russian citizens' access to biotech products, including targeted therapies.

Amgen founded this affiliate in 2006, and handpicked you to run the company. Over the same five years, how has the Amgen organization developed in Russia?

If you think of this company as a human being, we have since then exited the childhood stage, and now find ourselves in our teen years. This means that not all of our skills and expertise are firmly in place yet; but we have a high level of ambition, and we are maturing quickly.

In terms of achievements over these five years, I would note two principal parts. In R&D we are active players in Russian market clinical research (with our program of 33 trials, involving biotech products). We have a fairly significant presence with all of our new pipeline compounds. Five years ago, we outsourced this segment of our operations, but now we run trials in-house — something we are quite proud of. The second aspect of our activities is of course commercial. Over the last five years, we have successfully registered four Amgen products that are currently on the market in 3 therapeutic areas, and there are two more products under registration. We are quickly catching up to our European counterparts in terms of portfolio, and we are bringing to Russia a number of brand-new treatments.

We have developed a commercial presence in Moscow, St. Petersburg, and several other major cities. Additionally, our products are already used by patients in a number of outlying regional areas. We are in the process of developing a strong trans-regional foundation. For some therapeutic areas (for example, hyperparathyroidism) we are introducing absolutely novel approach to diagnostic and treatment of this severe condition using first in class molecule. In partnership with healthcare community Amgen helps to set diagnostics and to develop treatment standards of this condition in Russia.

The prospective law on Healthcare Protection currently under consideration in the Duma may severely limit the permissible level of interaction between pharmaceutical field forces

and healthcare specialists. Do you believe this could impede your efforts to educate doctors and develop novel treatment areas?

There is a large difference between companies like Amgen and companies that are, say, producers of branded generics. I believe that at the end of the day, the restrictions put in place by the government would still allow room for scientific exchange. It is again and again found in publications on the subject that the pharmaceutical industry is one of the major engines for education of doctors on the subject of scientific achievements in medicine.

Amgen deals with specialists, rather than the mass GP market. Our treatments and approaches attract quite a high level of interest, and whatever time slots are available for interaction with industry, I am sure that in our specialty, we will be a top priority for doctors in terms of time allocation. When Amgen enters the marketplace, we do not bring ‘me-too’ products or products that mimic well-known treatments. We bring something new, which upgrades and contemporizes the skills of doctors and domestic standards of treatment.

As an industry, we are working on adaptation of this legislation to be beneficial to doctors and patients. I understand the government’s thought process: doctors need to treat patients, not just meet with medical representatives. There should be some common sense restrictions, but the law must be written in a fashion that allows pharmaceutical companies to share knowledge with healthcare providers.

Amgen works in the field of severe diseases and its products are generally purchased globally by state reimbursement programs. In Russia, it is often noted that these programs are vastly underfunded, and even high-technology drugs are often privately purchased. How does this affect the company’s marketing operations?

In Russia, despite the fact that reimbursement programs are indeed underfunded, the company operates within this sector just as we do elsewhere. We find that we cannot reliably fund our products from private sources, because the biotech industry—taking into account the high expense of R&D and manufacturing—produces high-cost medicine. This is especially true for grievous illnesses, which treatment is exceedingly complex.

The government should fund these drugs. In Russia, funding starts with those who desperately need the product. These are patients for whom the cost-benefit ratio is highest and it usually starts with regional rather than federal reimbursement. After some time, both doctors and patients have a good experience with these drugs. The difference became apparent even in economical terms, and demand for them grows. When efficacy is strong, as it is with our products, then the authorities take notice.

In general, how receptive do you feel the Russian market is for biologics? Russia is still a developing market for healthcare and its medical framework is only now evolving. Is the understanding of efficacy developed enough for Amgen to explain its added value?

I would say it is in the building stages. Having different regions with disparate levels of wealth complicates matters. The framework is more developed in wealthier regions, where auxiliary equipment like diagnostic systems can be purchased.

When the framework is established the value is obvious, but at the beginning matters are challenging because it takes a certain level of experience to recognize product value. This reality is similar in any new field: a lot of initial effort is necessary to prove the efficacy and benefit of your products, and to help establish a structure that is able to utilize them. But when it is done, the results are tangible and expedient. We are confident enough to engage in these extra steps, because we are confident in our products and what they can bring to patients.

What are your key business drivers?

Geographically, it is no secret that we are starting with more wealthy regions. These are regions that can right away understand and afford Amgen products. I would like to cite the Maslow hierarchy of need: If the basic needs are not fulfilled then it is difficult to pay much notice to quality of life. However, as I mentioned, we are quite actively entering outlying regions, and helping to establish modern treatment structures that can support biopharmaceutical therapies.

In terms of therapeutic areas we have a limited number of core brands, but each brand has the potential to become a blockbuster and each brand carries enormous value for patients. From a purely marketing perspective that is why our major business driver is to educate patients and doctors and let them see how products are working in real life. When this happens, it is a nuclear reaction! It is impossible to stop. Of course, many things depend on reimbursement, status, but there is no substitute for good products and for good results. It becomes only a matter of time.

In researching this company, we came across the fact that the corporate website lists no information about the Russia affiliate. What does this say about the commitment of Amgen to Russia?

This will be changed in the nearest future.

Amgen is consistently committed to this market. International expansion currently is an officially defined corporate goal. The company is determined to expand globally and you can see bits of proof around the world; for example Amgen’s recent acquisition of Bergamo in Brazil. The organization is actively investigating both organic and nonorganic growth opportunities in emerging markets and our corporate structure has been readjusted to reflect this drive. Emerging markets are now on the same level as Europe — despite the fact that revenue-wise, they are still a

‘promise,’ rather than real contributors. But it is a matter of focus and commitment.

So, we are adjusting the business side. The communications side will soon be adequately adjusted to reflect this!

What are your future development targets for this company here, and what is your strategy to attain them?

Our future goal is to become one of the top biotech players on the Russian market. The main strategy to attain this goal is to help government stakeholders to develop the biopharmaceutical industry. I mean development in all aspects—starting from R&D, through production, through necessary legislative and regulatory work, up to sales and marketing. The Russian government has announced biotech as a strategic area for development, and “biotech” is a word that we have often heard recently at different levels. But what we have seen so far is that evolution in this field is an aspirational goal, lacking concrete steps for development. Again, this is an area where an organization like Amgen can collaborate with the authorities.

What will it take, in your opinion, for Russia to gain respect as a biotech player?

I believe that the starting point is intellectual property. IP must be reinforced to support an innovative environment. I believe that currently, the IP protection framework in Russia is actually at a fairly high level. There are still some aspects that must be strengthened, but all in all, the foundation exists.

The second necessary element is a very clear regulatory system. The development of biotech products involves processes that are very expensive, and very lengthy. That is why, if Russia would like to be a part of Big Biotech and especially innovative biotech, there need to be regulatory legislative changes recognizing innovation—which, again, means clearly defining biosimilars, original products, and etc. To attract investment in biotech production and research in Russia, there should be very clear, transparent access for biotech products to the Russian population and the Russian market. This includes both regulatory registration and licensing, and reimbursement. Russia needs to establish clear definitions of when, what, how, and what type of data, because any localization makes sense only when the local market is accessible in a clear, transparent, predictable fashion.

It is also necessary to upgrade standards for manufacturing. Local GMP standards must be fully in line with European and American standards. This may eventually lead to mutual recognition, and may open the whole world to Russia.

There is still much to do, but I am quite confident it can be done. With the goals that the nation has established, there is no other way. The area where I am less confident is theexact time of implementation.

On one hand, one might say that legislation is not sufficient, has defficiencies, and that there is much to criticize. On the other hand, I try to always think of the fact that we completely shifted economic formations 15 years ago. In Russia, we had a whole set of legislation for a socialist formation and now we are operating within a market economy. The legislation for this type of economy is only 15 years old! We need time to harmonize and align our legislation across legal spheres, and that is why at the current level, the environment may not be satisfactory. Everyone would perhaps like for affairs to advance more quickly, but we are moving in the right direction, and considering the relative infancy of our economic structures, it can perhaps be said that we are moving as fast as we can.

What are the greatest motivating factors for you as a manager?

Patients. I am a medical doctor by background, and one of my greatest missions in life is to help people. When I see what our products can do for people, I find it remarkable. Our patients receive real hope—often, in areas where hope previously did not exist at all. This is a great motivator.

The second motivating force for me is building this company. Five years ago, I was the only employee of Amgen in Russia. Now, we have full-scale operations! Looking back at what we have built already, it motivates me to continue to build.

We do not meet many women in top management, and you are the first we have met that has been charged with setting up an affiliate from scratch. How challenging is it to be a woman entrepreneur in this environment?

I believe that overseeing the creation of a start-up is as painful and as rewarding as delivering a baby!

Being a woman, in this country, I believe is not a problem. Since socialist times, Russia has expected women to play their traditional role within the family, but at the same time to be highly educated and to deliver the same kinds of results as a man.

Sometimes, being a woman probably helps. People are human beings, and they are motivated by certain things; I believe that being a woman helps you to be more concentrated on the emotional and personal aspects of business, helping you to understand how to motivate people. I consider it an advantage—especially in a man’s world! Being different is an advantage.

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

Amgen is a great company. It is a living legend in biotech. Russia is going to be one of the biggest biotech markets within the next twenty years. It is inevitable that the two should have a very fruitful relationship.

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