Interview with Victor Dmitriev, General Director, Association of the Russian Pharmaceutical Manufacturers (ARPM)

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If ARPM was founded in 20[illegible], and you were its director from 2002-2004, before leaving for a post at the Roszdravnadzor. You've since rejoined as director since 2007. The organization was originally founded as a unifying force amongst Russian national manufacturers, and has now grown to encompass several foreign members. How have you seen your industry evolve over the years?

This year marks nine years of our existence, and we have seen many changes in the economy—in the micro economy, the macro economy; the local economy, the global economy. We entered and left the financial crisis. The crisis in particular left an interesting legacy, because despite its difficulties, it helped to develop our industry: during the crisis, it became very apparent that not everybody was able to pay for expensive, imported drugs. They needed their medicine to be much cheaper, so many sought to buy locally manufactured products.

Cheaper, but of inferior quality?

I would not say that the quality is inferior. If you look at our industry today, you will see that it is very diverse. On one hand, we have ageing Soviet manufacturers who have long histories, and good backgrounds, but today cannot work within a modern framework—they cannot work within GMP standards. They have no money for reconstruction, or for revising their operations. On the other hand, we have some other Soviet manufacturers, who have, over the years, found an opportunity

to attract investment and change their situation. Today, they work under new standards.

For example, Akrikhin has an old factory that was built about 70 years ago. Today, Akrikhin has updated that facility and it operates as a subsidiary of Polpharma (a joint venture between Hungary and Poland). The same can be said of Nizhpharm, which today operates as part of the German Stada holding group. When you look at Nizhpharm's operations, they manufacture at a plant in Obninsk, Russia, and they sell their products to Germany! This says a lot about the quality of these medicines and it says a lot about the status of our entire industry, as manufacturers.

We also have new plants and new factories, that were built seven, five, even three years ago. For example, Polysan and Sotex have such recently-built factories, and they have advanced European certificates for GMP. They produce not only their own medicines, but they are also contract manufacturers. Sotex works with Nycomed, for example. Another company, Zio Zddorovie, is today a subsidiary of Actavis, and they produce products for companies such as Boehringer Ingelheim, Berlin Chemiee, and Sanofi-Aventis. Petrovax, only last week, signed an agreement with Pfizer to produce new vaccines. These are all good examples of companies with absolutely new plants and absolutely modern capabilities.

Another segment worth examining is that of small research companies that were organized from what we used to call "cooperatives." These companies are usually research centers or research institutes. They have not-so-big portfolios—maybe two or three medicines, or sometimes even one, and not more than five—and they do not have good manufacturing plants. But at the same time, they have a patent for these medicines, and many of the medicines are very popular in given nosologies. For example, there is a company called Pulmomed, which produces medicines for pulmonary applications—asthma, etc.

This is why I say that our industry is very diverse. It is very colorful: different qualities, different situations, and different products. When we discuss local manufacturers, we should note their diversity.

Our association's biggest drive and principle is for our members to work in GMP standards. Today, the key criteria for membership is not a matter of nationality—whether the company is Russian, or foreign, or whether it is a joint venture—it is that the company should have a manufacturing plant in Russia, it should provide jobs to Russians, it should pay a fee to the state; and finally, as I mentioned, it is imperative that it manufactures under high quality standards. Today, our association has the 20 biggest manufacturers in Russia as members and we produce about 85% of the locally-made medicines in the country.

Some of our members, as I have mentioned, are also exporting: for example, Polysan exports as much as 50% of its products. We were actually just discussing Polysan today—they are currently looking to build another plant and then to build a research center. Polysan has actually innovated

novel medicines in the past, which are used for anti-viral applications. Their products are very popular in the South Asian region—Mongolia, Vietnam, Malaysia, Singapore, etc. With the development of the research center, they are looking to come out with additional innovator drugs.

The industry is indeed becoming more colorful. But some things have not changed since Focus Reports' last Russian report in 2006. There is still a too-heavy reliance on imports and even the government-reimbursed DLO program drugs are 90% imported. Furthermore, the Russian public still does not trust its own "made in Russia" brands and although some companies have adopted advanced European quality standards, many have not. What is being done to move things forward?

Each company has its own strategy for development. If you look at the Stada-held Nizhpharm, they have a large OTC portfolio—they are not thinking about innovation. A company like Polysan, or Pharmsintenz, may not have a large portfolio, but their medicines are innovator drugs. Other companies, like Actavis' Zio Zdorovie, do not think about their own products, but work in the contract manufacturing sphere. You see that there are different situations in different companies, and each company has their own ideas about promotion and their own ideas about working with brands, with generics, with innovation, etc.

At the same time, in the last four years, our government began to think, more and more, about the local pharmaceutical industry. Throughout this push, our association has tried to demonstrate that the local industry not only contributes to social welfare, but is, in the end, a strategic aspect of state security. For example, during the Beijing Olympic Games the Chinese closed all of the chemical manufacturers within approximately 200 kilometers of Peking. During this time, it became very apparent that we have a big problem with APIs, since we buy them from China and had trouble getting them as the games proceeded. This was a good lesson for our government and today they are encouraging the growth of the local industry.

A few years ago, they adopted a strategy called Pharma 2020. This strategy has three steps: the first is generic import substitution; the second is the localization of foreign companies in Russia—and when we say localization, it is not only to build new plants, but to contract manufacture, to buy already-existing plants, and etc. The third step is the development of R&D projects in Russia. I can say that today, we are on our way to realizing all three of these steps.

The first step is more active, because even when it had not yet been formally strategized by the government, local producers were aiming toward import substitution. In terms of localization of multinationals, I can give a few examples: Nycomed, which is our member, plans to build a new plant; Sanofi-Aventis just bought a big plant in the Oryol region, and they plan to produce insulin there; Boehringer-Ingelheim want to build a plant in the Kaluga region; Novo Nordisk also; Teva plans to build a plant; etc., etc. The process is well under way.

We also see the first drops of R&D. Roche, for example, has a joint project with a Russian company to develop new molecules.

We try to study foreign experience. We see that the generic market has become bigger and bigger throughout the world—including in the U.S., in Europe, in Japan. This development is supported by the WHO. At the same time, we understand that without innovation, without research, we cannot have generics. That is why there must be a balance.

Further, it is not only our forecast, but also the forecast of foreign experts, that 10-15 years in the future, we will not see any principal new medicines come out of chemical synthesis. The discoveries will come from biotech. That is why a few of the newer Russian companies are working in this sphere—and they have had fair results. In Russia, these companies are competing well with multinationals.

This summer, our government adopted a special list of 57 high-tech medicines—the strategic medicines list—that are in our market, but are not produced locally. The main idea is to localize them so that we can reduce their cost. Some of them are under patent—we want to either produce generic versions or secure a license agreement with their owners.

Regarding the people's state of mind about our brands, you are quite right that among Russians, there is an idea that local medicines are somehow substandard. We are working in a few directions on this. First of all, we work with doctors. We try to show them the results of our clinical trials, in different regions; we try to compare the clinical results from local medicines versus imported medicines. At the same time, multinational companies like Nycomed, KRKA, Servier—they are local producers themselves.

I cannot speak for the whole industry; I can only speak for our members. There are 450 companies with licenses to manufacture in Russia, but our association numbers only 20. On the part of our members, we try to work with the government reimbursement programs. We try to work with different regional authorities; there are 83 regions, and each has a disparate situation. Each must balance their financial limitations and the health demands of their people. In our discussions, we try to find an optimal solution.

The government plans to institute full harmonization with European GMP standards among local manufacturers by 2014. What is the status of this drive?

This is an interesting question, because it seems to me that approximately 50% of all Russian manufacturers should be shut down. They have no opportunity—financial or otherwise—to upgrade to these kinds of standards. It is cheaper, in fact, to simply destroy their facilities and build anew, rather than try to upgrade.

But when I speak about the closing of these manufacturers, it should be understood that there would be a number of outcomes—not all beneficial. These manufacturers provide jobs and if we are to close them we must think of people's livelihoods. There are sometimes small townships for which these factories are the central hub, down to the provision of heating and water systems. If we close given factories, we should prepare new jobs, and new municipal organization.

This would be an immense project. Is it really possible to close 50% of these factories, build something new, find new employment for the surrounding populace, etc.?

But we should do it; we should do it. As I have mentioned, Russia has around 450 manufacturers, but our 20 member companies produce more than 85% of the locally manufactured drugs on the market. These statistics do not correspond. The extraneous manufacturers are a problem for the market and they are a problem for the patient.

This is why it seems to me that this datum—2014—should be strongly enforced. Our members support this idea, and they will all meet the date. Several of them, as I have mentioned, are already producing for, or directly exporting to, highly regulated markets—and they successfully passed strong international audits. I think that after this datum is reached, manufacturers who have not improved their standards should not have an opportunity to renew their license. Furthermore, I think that locally produced drugs should be in the budget sphere.

We have seen the experience of Baltic countries. When they became members of the E.U., they closed their market to all medicines that were not produced under GMP standards. This was a big problem for older people, because they had gotten used to using traditional medicines that perhaps were not very effective in reality, but nonetheless seemed to have a strong placebo effect. So the Baltic governments changed the situation: they broadened their own market again, but did not export, to other parts of Europe, those medicines that did not meet GMP. It was an easy process to cleanse this market. I feel that we could follow their example.

Russia is currently the largest world market that is not yet a member of the WTO and there are a few lingering complications to joining, including Georgia's approval—but assuming the hurdles are surpassed, what will Russia's entrance into this organization mean for the local manufacturers?

To tell you the truth, I am not wild about this idea. For Russian pharmaceutical manufacturers, I see more minuses than pluses. We see the example of Ukraine, whose local industry suffered when they became members.

There are two factors. How fast, and under which conditions, we enter the WTO. We see the examples of, say, Brazil, China, or India, which had a transition period before entrance, and were able to work out their adoption of things like the TRIPS intellectual property clause under their own

terms.

Today, our patent legislation corresponds with WTO standards—as the WTO's own experts have asserted. But international companies are taking a very strong position, saying that Russia should adopt data exclusivity. International companies do not want Russian generics players to use their data and instead want to delay generics products by forcing these companies to conduct new clinical work. They also do not want Russians to have the Bolar Expemption, which, in many parts of the world, allows generics companies to conduct the full range of preparatory work before the expiration of patent on a novel drug—allowing them to bring it to market as soon as the patent expires. For example, there was a judiciary hearing when Novartis refused to allow a generics company to conduct this pre-registration work on one of its products. A high court allowed the generics company to conduct this work, and this kind of legislation is, as I said, typical around the world. Why should Russia not be allowed the Bolar Exemption? I do not think this is right for the industry, or for the patient. Data exclusivity, and the lack of the Bolar Exemption, all drives up the price of brining a generic drug to market—and that cost then trickles down to our patients.

If we were to directly and blindly accept all the demands of the WTO, it would not be beneficial for the pharmaceutical industry, nor for many other industries. Therefore, this process must be gradual and based on earnest negotiations. If you look at the E.U., despite the fact that trade barriers are limited, and each country is a WTO member—in Austria, you will not be able to buy nasal drops drop Denmark; and vice verse. In other words, they have retained mechanisms that protect their home markets. If we are able to implement these mechanisms, then yes, we should join as well. Otherwise, there are specific threats to our industries that we see.

Let's look toward the future. You said that the three parts of 2020 were localization first, import substitution second, and, finally, the drive toward research, innovation, and new sciences like biotech. What role will these latter directives play in the future of the Russian market?

This question must be looked at in relation to the whole system of healthcare and in relation to the economic situation. Look at the last ten years. Our market grew much quicker than the world market and the reasons for this growth were varied and intermingled with the economy at large: high oil prices helped us grow; the macroeconomic situation, and the growth of Russia's general economy; the development of the local pharma industry; and etc. Further development will also depend on various factors, both macroeconomic and microeconomic.

But regardless, it seems to me that we will grow. We will grow and we will change the structure of using medicine. For example, today, we use many medicines not for prevention, but for treatment. Whereas, say, in the E.U., many people over the age of 40 use Statins to prevent the future development of hypertension, our people only use medicine when they are already sick. We should

change this.

We can also look at the reimbursement system. We think that Russians pay too much from their own pocket for drugs. There will be a new system—maybe privatized reimbursement companies, maybe a more universal state reimbursement system—we will discuss this. There are different situation in each region, and it is a financial issue, as well. But I can say that without a new system of reimbursement, and of insurance for each Russian, it will be very difficult to develop.

And, again, our growth will depend on the broader situation in the country, and, indeed, in the world. I am sure that we will grow, but how quick, and in which direction, we will see.

You have worked both for the industry, and for the regulatory authority. What synergies and conflicts do you see?

I have gone from the state to private business, back to the state, and then back to private business! I find this movement to be a good experience, because I see the situation from both sides. I can see the mistakes and problems arising in each sector. It is very easy to criticize, but it is very difficult to wok towards the good. When I worked in the state system, sometimes there were problems that I recognized, but I could not change them, because I worked under the umbrella of legislation. It is very difficult to change legislation from one day to the next—there are, of course, several levels: federal, regional, etc. Sometimes you can try for five years to change a law, and get no results. That is why I understand the staff that work in the Ministry of Health. I understand the difficulties with which they are met everyday. At the same time, I understand that the industry should criticize, because without criticism there is no progress. But criticism should be constructive: you should not say this and that is bad, but rather suggest how to do it differently. And these suggestions should be realistic.

In Russia, we have two problems. The first is legislation and the second the implementation of this legislation. It seems to me that—and this is not only Russia, but throughout the world—each person can have a different interpretation of the same law. And after interpreting the law, each person my implement it differently. I know this from experience. From my work with the authorities, I know how to help my industry to prepare legislation, to work with the Duma, to work with regulators, etc.

What does the industry want from the government?

First of all, we want the freedom to conduct our business. But also, we want to work more closely with the authorities. This is key. The goals of the state should not be placed above those of business, nor should the goals of business be placed above those of the state. These goals should be complementary. There should be discussion, and there should be balance.

It is very difficult to make ideal laws. Each law is a compromise amongst different parties. And it is maybe a crazy idea, but I want to have minimum problems in this process!

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