Interview with Oleg Epstein, General Director, Materia Medica

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Focus Reports first met with Materia Medica in 2006. At the time, the company was enjoying an extremely rapid pace of growth. Looking back over the last years, how has the organization further developed?

We have continued developing quite quicly. In the last few years, the company’s growth was 15–20% per year. Compared to the middle of the 2000s, this is actually not much for us—but rather, it is indicative of a strategic pause that we have intentionally undertaken.

The development of our company is based on original research. We produce and market original drugs that we develop full-cycle, and our products represent the evolution of our scientific expertise.

We started our work 19 years ago, and we were one of the first private companies producing medicines in the new Russia. Initially, we marketed classical homeopathic drugs, being very well acquainted with the technology of production of medicinal products in ultra-high dilutions.

Our first profit in 1995 was invested into the study of ultra-diluted medicines. The first publications on the results of experimental research conducted at a modern scientific level, which proved the biological activity of ultra-diluted medicines, appeared in the 1980s. However, since ultra-diluted substances contain no molecules, and their action contradicts the law of mass action, these data faced skepticism among scientists.

The studies we performed proved that ultralow doses can actually induce molecular and physiological effects in the organism, although their intensity is extremely low. Our most important finding was that ultra-high dilution of any substance possesses chemical, physical and biological properties different from those of the original substance. Studying these properties, we discovered a practically important phenomenon: we found that for any substance, its ultra-diluted solution acts as a catalyst—or, to a wide extent, as a modifier. For example, ultra-dilutions can alter the rate of the chemical reactivity of the initial substance, or its electrical conductivity. Dozens of non-clinical and clinical studies facilitated the creation of our own scientific platform, based on the therapeutic administration of the catalysts (modifiers) of biological molecules—such as erythropoietin, interferon, insulin, etc.—instead of the molecules themselves, in the form of ultra-dilutions. First we used ultra-dilution of a molecule or its receptor as a modifier, but later we switched to use of polyclonal antibodies to biological molecules, since their modifying effect is more pronounced.

Our clinical studies proved the high efficacy and safety of our products. Our experimental and clinical studies demonstrated that they can be used for treatment of severe diseases such as chronic heart failure, stroke, attention deficit disorder, diabetes mellitus types I and II, influenza, AIDS, obesity, and etc.

Our efforts were appreciated by the authorities. Six years ago we were honored with the Russian Federation Government Award for creation of a new class of medicinal drugs. We proved that we are not a homeopathy company, and 1.5 years ago, the Ministry of Public Health decreed that our drugs will no longer be classified as homeopathic.

Thus, we obtained new stimulus for our development, and quite soon created our own department for clinical studies—and in the past half-year, we have become the leading company in Russia in terms of the number of commenced clinical studies.

Beyond a greater understanding of the scientific underpinnings of this therapeutic methodology, what separates your medicines from homeopathic medicines?

The terms “homeopathy” and “ultralow dose” complicate our marketing, since homeopathy provokes skepticism among many physicians. We were the first to draw the line between homeopathy and modern pharmacology. Homeopaths prescribe their drugs individually; every single patient receives his or her own drug. As we have already mentioned, the effects of ultra-diluted drugs are very weak, and homeopaths try to provoke individual hypersensitivity reactions—as they are called in modern medicine—by means of individual prescription, in order to enhance activity of their drugs.

Interestingly, at the outset of homeopathic practice in the XVIII century, its founder used herbs and minerals for treatment—which was absolutely common for that time—but he prescribed them individually, and in order to reduce the degree of hyperergic reactions he diluted medicines.The efficacy of this casuistic, individual method of medicine prescription is impossible to prove statistically. If one hundred patients visit a homeopath he prescribes 100 different medicines. What kind of statistics can we apply here? That is why homeopathy is doomed to have a marginal position in the modern system of therapy, and it cannot be integrated into evidence-based medicine.

The principles we use to study and prove the efficacy of our products are the same as those used for modern pharmacological drugs. We perform all experimental and clinical procedures necessary for marketing authorization of classical medicines. We know which molecular and physiological mechanisms of underly the action of our products. All our drugs have their own targets: i.e., their action is aimed at specific receptors (for example, insulin receptor, cannabinoid receptor or angiotensin II receptor) or at a specific enzyme (endothelial NO-synthase, for instance).As opposed to homeopathy, we increase low activity of high-diluted substances not on the basis of hyperergic reactions and individual prescription for every patient, but on the basis of specific catalyzing (modifying) action against one or another pharmacological target.

As a specialist in the field of molecular biology, I can say that main mechanism of action of our drugs is based on allosteric modulation of a receptor, which intensifies interaction between an endogenous ligand and a target, and activates biological pathway, which involves the ligand. Therefore, our products do not differ from other biological drugs, except for the absence of a dose in the common interpretation. We believe that we created an absolutely new class of donor-acceptor drugs.

In the process of ultra-dilution the initial substance (donor) transfers some activity to the solvent (acceptor); as a result the acceptor acquires new properties and becomes able to modify both the starting substance itself, and its receptor. Before us, no one was acquainted with these molecular processes. It is important to distinguish ultra-dilutions and the simple dilution of a substance in order to obtain 1% solution. From a physical standpoint, they are absolutely different. I compare ultra-dilutions with particle acceleration in the synchrophasotron, where particles acquire new properties in new conditions. The same happens in case of ultra-dilutions when new physical conditions provide solution with new properties, which can successfully be used for production of modern highly effective and safe medicines.

We are practitioners. We have to use the innovation we discovered. It is an impossible task for us to study the fundamental physical basis of ultra-dilution processes. We want to believe that one da,y physicists will take an interest in the physical phenomena, which we discovered and began to use for the production of new medicinal drugs. As you can see now, our work has a historical intrigue in it. Homeopaths believe that homeopathic drugs cannot be used without adherence to the complex principle of individual treatment. Because of the distrust of homeopathy, modern scientists have not studied ultra-diluted solutions, and attribute the effects of homeopathy to the phenomenon of “water memory.’ We were the first to prove on the molecular level that “memory” about a substance can specifically affect the substance itself, and that this phenomenon is reproducible and can be of practical benefit.

The innovation we have brought into pharmacology allows to create really safe and effective medicines, extending the possibilities of pathogenic therapy. For example, we can affect targets, which previously were inaccessible: various receptors, prostate-specific antigen, NO-synthase. We gave a new life to polyclonal antibodies, which are generally used for diagnostics. Our medicines are not drugs of abuse, and thus they can be used for a long-term treatment of chronic diseases and prophylaxis. We can improve living standards of patients with such diseases as diabetes mellitus, heart failure, prostate adenoma, etc. On the other hand, the innovation we have suggested is so uncommon that it prevents us from squeezing into the Procrustean bed of registration processes. For instance, we still do not have any legal name for our class of medicinal products. Secondly, due to absence of the initial substance in the finished drug product, we face bureaucratic difficulties in the chemical part of the dossier. We have to work out some general documents by ourselves. But gradually we have learned how to solve these problems as well. Thus, we not only “visualize” molecular mechanisms of action of our drugs, but we have also developed techniques of semiquantitative and qualitative identification of our drugs.We have learned how to prove that our main pharmaceutical form—the tablet—does indeed contain the claimed activity, which can be expressed in biological or modifying units.

You mentioned that your work has been recognized by the authorities. Can you extrapolate further?

We are very thankful for the way in which regulatory authorities have treated our organization. In one word, I would call it tolerance. Our products are very unusual, and even paradoxical to a certain extent. The authorities have worked with us, and our products are no longer listed as ‘homeopathic’ in Russia. This has given us a chance to integrate ourselves not only into the OTC segment, but also into the vital and essential medicines list.

Many years ago, we raised the bar for ourselves in a manner that no other homeopathic company had done before us. We demand more from our operations. We conduct serious experimental work. And it is not limited only by experimental pharmacology, as is the case of other manufacturers of original drugs. We also have to perform fundamental studies in the field of molecular biology, and even physicochemical studies in order to prove the physical phenomenon we discovered.

When we were listed as “homeopathic” manufacturers, we did not invest significant economic resources into full-scale clinical trials. Since this label has been removed, we have created a very strong in-house clinical department, and this year, we will likely be the leaders in clinical studies on the Russian market—amongst Russian companies certainly, and perhaps amongst all companies on the market. For one of our products, if trials go as planned, it is possible that we will apply for registration with the U.S. FDA.

Materia Medica aims to be an exporter and a truly international player. Do you believe you will be able to similarly convince healthcare professionals in foreign markets as well?

It is tough question for us. On the one hand, we appreciate the unique opportunity to create a new class of drugs adopted from homeopathy. But on the other hand, the image of homeopathy undoubtedly holds us away from physicians and a portion of patients. But when physicians see that we can treat severe diseases using our new approach, we overcome their skepticism. We simply gain their acceptance by our results, without dipping into descriptions of complex mechanisms of action.

We are now registering our products in other developing markets. We are investigating the possibility of registration in America and Europe. I believe that if we look beyond the notion of business and economics, our products are socially significant. They provide new avenues for therapy. For this reason, our shortcomings are our greatest assets.

Ultra-dilution of our substances is necessary not to reduce their toxicity, but to attain new possibilities for therapy. We have proved that the efficacy of our products is not lesser than that of well-known drugs, such as insulin, rosiglitazone, glibenclamide, interferons, tamiflu, azidothymidine, losartan, xenical, diazepam, and amitriptyline.

What do you then see for the future of this company?

The future of the company depends on the reaction of foreign authorities to our products. If we manage to get an acceptance from regulatory authorities and prove that our products are not homeopathic, then we will have the opportunity to become a truly multinational player. In some

countries it is easier to register our medications as homeopathic drugs, rather than explain why we are different. This is certainly a big difficulty for us, and right now we are forced to delegate much of our energies not only to clinical study, but, as I have already said, the the validation of methodologies to judge the quality and quantity of the material within our tablets.

Thus, as always, our organization remains in development. Business is a hunt and its results are hard to preconceive, but we are optimistic that our hopes will be realized.

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

In the Soviet Union, there was a very prominent slogan: “Proletariats of all nations unite!” We want to be a part of the international pharmaceutical market. We want for this market to accept us and to accept our products. Our products are needed. We want the pharmaceutical community to see us as we are: the producers of original pharmaceuticals using nontraditional methods, but with demonstrable mechanisms of action.

In pharmacology there is a crisis in the field of new drug discovery. I think that in medicine as a whole, and in pharmacology in particular, interesting ideas are needed. Niels Bohr said that ideas must be crazy enough. Our idea is crazy enough; and at this stage, it is proven to work.

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