Interview: Novyk Anatoliy – President, Ecopharm, Ukraine



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Anatoliy Novyk, founder and president of SMC Ecopharm, the only Ukrainian pharmaceutical company to be exclusively focused on its own original drug development, provides insights into Ecopharm's promising expansion strategy, which should be significantly propelled by the company's upcoming GMP-certified manufacturing plant. He also provides an in-depth look into their own new drugs made on the basis of the active substance proteflazidum that can be successfully used in the treatment of diseases caused by DNA and RNA viruses.

Could you introduce the company that you founded in 1998 to our international readers as well as the main milestones achieved throughout the years?

In fact, Ecopharm was founded on the basis of a pharmaceutical development that was presented to a group of investors including me and my partners. This pharmaceutical development concerned the active substance extracted from two herbs — tufted hair grass (Deschampsia caespitosa L.) and bush grass (Calamagrostis epigeios L) — that demonstrated good results in specific antiviral action study during a primary laboratory research. For the five years from the Company foundation, we have conducted more than 30 pre-clinical trials, studying the specific antiviral action and toxic properties of this substance, using the following virus strains: influenza, adenovirus, herpes, hepatitis and HIV. We have also studied the action mode of the bioactive substance, and the obtained results turned to be very promising, as it was evidenced by the experiments that this substance had direct active antiviral action on DNA and RNA viruses, as it was an inhibitor of virus

specific enzymes synthesis – thymidine kinase, DNA and RNA polymerase and reverse transcriptase.

Then we proceeded with the creation of new dosage forms based on this substance *proteflazidum*. Our first medical product that entered the market in 2002 was drops for internal use. The development thereof allowed us to start clinical trials, which we have conducted in all nosologies indicated in our patient leaflet: diseases caused by the herpes viruses, human papilloma viruses, influenza, ARVI, as well in complex treatment of Hepatitis B and C, and HIV-infection. As of today, Proteflazidum® drops medicinal product takes the 4^{th} place on the Ukrainian market in value terms within its segment of direct action antiviral drugs, according to the data of all international rating agencies, and competes with all global brands presented locally.

In 2007, we introduced to the market our antiviral syrup for children Immunoflazidum® that today is among the top five medications in Jo5 and L03 of ATC classification measured in value terms. Furthermore, we introduced Proteflazidum® suppositories indicated for local application in diseases caused by Herpes simplex virus (1^{st} and 2^{nd} type), human papilloma virus (including oncogenic strains) and virus-bacterial mixed infections in 2016.

We have been developing steadily, as initially I, as an investor, was engaged in several projects simultaneously. However, at the time I realized what this active substance truly represents, I focused on Ecopharm exclusively, and since 2007 an active stage of company’s development began. In such a way, throughout the 10 years of the active development stage, we managed to achieve annual sales of nearly $7 million in Ukraine with the portfolio of three medicinal products. Furthermore, we have invested more than $5 million into construction of our own pharmaceutical facility that will be certified by the European GMP standards and will, according to the schedule, start operating just in the first half of 2018. However, we are not complacent and plan to continue our active development into the future.

For this project, Ecopharm received a EUR3.4 million [USD3.8 million] loan from the European Bank for Reconstruction and Development (EBRD), the largest international financial investor in Ukraine, whose due diligence process is particularly stringent. How did you manage to convince them?

It really was a rather difficult process for us that had taken about 1 year and half. We were inspected in numerous areas of our activity and fulfilled all the conditions precedent the EBRD set to us. In many aspects, these terms were new to us. Nevertheless, we are very happy that the Bank believed in us, in our potential, and taught us new approaches in planning and managing the

manufacturing, which laid a foundation to credit partnership with such a large and reputable investor. During this time we have learned a lot, realized what approaches should be used in collaboration with the European partners and we will follow them.

Will the new manufacturing plant allow Ecopharm to diversify its drug portfolio?

We are planning to diversify our portfolio with the launch of our pharmaceutical plant, but, in the first place, we expect that our new certified manufacturing will allow us to enter the new markets. We believe that our drugs based on our active substance will be of great demand in any market, as the diseases that we deal with are spread worldwide. And here our goals are very ambitious – enter the European, Chinese and, prospectively, the U.S. markets, as our antiviral medicinal products can compete with popular brands by all key applicable criteria: efficiency, safety and affordability (estimated by the treatment course price).

The crisis in 2013 had a significant effect on a large percentage of the Ukrainian healthcare market. How does Ecopharm stand after all this?

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Nobody feels good after an acute phase of a crisis – it is like after having a disease: a recovery period is needed during which you have to adjust your plans. I believe that we would have been able to launch our pharmaceutical factory by own means, if there were no 2013 crisis. However, I can state that we coped with the crisis phenomena rather quickly and continue to increase our figures and even improved our positions in the market ratings. Our company’s staff is also growing: if in 2015 we were only 125 people, now we are 177, and after the launch of our facility we will be more than 300 people.

Ecopharm is the only company in Ukraine that exclusively produces original products. What obstacles have you faced thus far?

This is rather hard to anybody to do marketing of only own original drugs, because one needs to convince the medical community and patients that its products have certain benefits in comparison to other well-known medicinal products (the majority of which are generics) which have been traditionally prescribed by the doctors, are well elaborated and known.

There are three main generally accepted criteria, by which pharmaceutical products are assessed: safety, efficiency and affordability (in other words, the treatment course’s price). A pharmaceutical product is viable if it offers the market an advantage by at least one of these criteria, and we believe we have advantages when looking at every single one of them.

In terms of safety, our products are indicated to pregnant women and newborns and any possible side effects are much less meaningful in comparison with many competitor's products. Second, the efficiency of our products is evidenced in 220 published studies, including clinical trials and clinical observations, in which more than 20 000 patients took part, of whom 3560 are children aged from 0 to 12 and 1250 are pregnant women of I-III trimester of pregnancy. The results of such studies are statistically meaningful wherefore the meta-analyses performed testify, showing high efficiency and solid safety profile of our medicinal products. Finally, affordability, as the market price per treatment course with our drugs is lower than that for well-known antiviral brands of our competitors.

Are there any comments you would like to highlight showing this lack of support of the Ukrainian authorities toward science-driven domestic companies like Ecopharm?

It might in some way be the feature of our mentality: any tendencies coming from abroad are taken up quickly and easily unlike the ideas and projects developed inside the country. But it is possible to challenge the mentality by setting right goals. If the authorities are eager to develop a healthcare system that would provide for the well-being of citizens and healthy future generations, they should set the goals to: find and maintain innovative pharmaceutical developments, make them available and affordable to people, contribute to a dialogue between the owners of the innovative pharmaceutical developments, on one hand, and the medical community, on the other. For such to have place, there should be worked out special state programs, which is something that, unfortunately, we could not observe so far.

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As a result, are you looking for international partners to collaborate with Ecopharm on this product?

We would be very glad to engage an international partner to tap the new markets, and we stay open for a dialogue. Nowadays we are making steps that can make us more attractive for a partnership: finishing the construction of the facility that will manufacture GMP-certified products which is a necessary requirement to be present on any pharmaceutical market. In our view, the fact that our active substance has a direct action against many types of viruses increases the window of opportunities for potential partnerships, however, as we can judge from our own experience, the fact that our medicinal products are produced exclusively from bioactive botanical substances, on the contrary, limits the possibilities for potential partnerships, as large pharmaceutical companies prefer chemically synthesized substances to the natural ones.

Ecopharm is a scientific based company, but many larger companies, domestic and international, are strongly investing into their R&D branches. What sets Ecopharm apart from the competition?

As far as I know, the pharmaceutical development market is organized in such way that the discovery, research and synthesis of new molecules is being conducted by specializing companies, while R&D departments of pharmaceutical companies develop ready forms based on the molecules they purchase.

In our case, Ecopharm's R&D is ''two-in-one'': we discover the molecules of natural origin ourselves and do re-synthesis of the molecules discovered in our own chemical laboratory. We have certain exploratory works on chemical synthesis of our botanical molecule. The company's R&D departments is rather big — accounting for about 12.5% of the total staff — it employs scientists, qualified specialists in the field of biochemistry and chemical synthesis.

You are a founder of Ecopharm, so have been part of the journey all along the way. What image would you like to build for Ecopharm in the future?

The company's image is created by people who work here, do the decision-making. An image of accompany should reflect a certain idea. The idea of our Company stays unchanged throughout already the second decade of its existence: 'The substances extracted from plants should be closely examined and applied. The solutions for many problems arising in a human body can be found while studying bioactive substances extracted from plants. These substances have been created as a result of natural biochemical processes taking place over hundred million years of evolution'. And our bioactive substance of natural origin is a clear evidence thereto. In the years to come, we will direct our efforts at search and discovery of new active substances of natural origin and fulfill our mission which is 'Power of Nature — to the Well-Being of People'.

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