Interview: Ludmila Bezpalko – CEO, BCPP, Ukraine



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21.07.2017

Tags: Ukraine, BCPP, Pharma, Manufacturing, R&D, Partnering, Export, Internationalization

Ludmila Bezpalko, CEO of Borshchahivskiy Chemical Pharmaceutical Plant (BCPP), a top 10 domestic pharmaceutical company in Ukraine, documents the development strategy she has been following over the past two decades to ensure BCCP now proudly stands as the Ukrainian leader in terms of international standards and quality certifications. She also provides insights into the company's eye-catching portfolio of in-house developed original products and how BCPP is actively looking for international partners to jointly bring these promising products to the most advanced markets in the world.

Could you provide our international readers with an overview of Borshchahivskiy Chemical Pharmaceutical Plant (BCPP), one of Ukraine's historical and leading pharmaceutical companies, and walk us through some of the company's main milestones?

Our company was founded in 1960, and I have personally been at BCPP all along the way, starting here since the age of 18, before ultimately becoming BCPP's director in 1976. Looking back on our company's history, it has truly been an amazing journey.

Three years after the fall of communism, in 1994, BCPP withdrew from the pharmaceutical association Darnitsa and was bought by a consortium of owners. For the first time in its history, BCPP then became a private company, which actually opened a new historical era for our organization. At the time, this concept of having privately owned companies was rather foreign to Ukrainians in general, so – initially – trust between the company's owners was a hard to come by.

These years truly marked a turning point in our company's history, as, in 1995, we also established our research and industrial center, combining our company's research and development entity with its manufacturing departments. This center has then evolved into one of BCPP's main assets and now stands as a clear differentiator within the local pharmaceutical landscape.

Since then we have gone from strength to strength and are improving every year, and we now have established ourselves as one of Ukraine's top 10 domestic pharmaceutical companies, holding representative offices in several countries including Vietnam, Croatia, Serbia, Montenegro, Belarus, Kazakhstan, Moldova, and Uzbekistan.

Overall, our main activities are the research and development, production, distribution, contract manufacturing, and exports of both generics and original pharmaceutical products. We now hold a comprehensive portfolio of more than 100 products in nine therapeutic areas. Our portfolio is moreover perfectly aligned with Ukraine's main morbidity and mortality causes, and products for cardiovascular and metabolic diseases as well as antimicrobial drugs make up a large share of our company's revenues. Additionally, we have recently opened branches of dietary supplements and veterinary preparation, from development all the way to production.

From economic and geopolitical standpoints, nobody can deny that Ukraine has been through challenging times over the past three years. However, we see that some local companies have been able to keep up with double-digit growth rates despite the crisis. Commercially, what is the current situation at BCPP?

From a commercial perspective, we have been growing at an excellent rate, with sale volumes in 2016 increasing by 12.6 percent and profit by 100 percent, which allows us to further invest into the development of BCPP. To the difference of many other domestic companies, our company's original products based on herbal raw materials proudly stand as strategic growth drivers and make up 28.5 percent of our overall sales. Besides strengthening our market share in Ukraine, our goal is now to increase our exports, as well as finding partners to manufacture their licensed drugs through contract manufacturing services.

Within the Ukrainian healthcare industry BCPP prides itself, above all, on being the first Ukrainian company, in 2003, to have received Good Manufacturing Practices (GMP) certification. This led us to have an efficient European system based on innovative, modern production and to hold a diverse range of leading experts who are guided by European and international standards. Without any doubt, we want to continue this upward trend of high quality European production and we have recently invested UAH500 million [around USD 19 million] into increasing our production capacity

and replacing our ageing manufacturing equipment.

You mention that being a company holding the best international standards is the most important area for BCPP. Could you please elaborate on this?

Meeting European and international standards is very important for BCPP as it allows us to gain a reputation of quality throughout the world and create great possibilities for geographic expansion.

To understand the reasoning for global standards, we need to look back to their history. The idea of quality standards and certifications in the healthcare industry, whether they are FDA or EU related, were first put in place as a “preventive measure” to stop external companies from bringing lower quality products into regulated markets. In the meantime, these standards also protect local companies from increased market competition and massive market entry of foreign competitors.

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When the Ukrainian government told our country’s companies to start shifting towards European certifications around fifteen years ago, many local companies were confused with the steps to take. BCPP actually first began the march towards European standards in 1992 and we have clearly been a local frontrunner in this process, which also means we were left with no choice but to figure out by ourselves how to step up our quality standards – at a time where accessing external advisory services was particularly difficult.

In a way, adapting these quality standards, which were initially designed as a preventive measure by regulated markets, has allowed us to upgrade our own practices and become a more competitive company – from both local and international standpoints. I now see this compliance process – which required us to invest significant resources over the past 25 years – as the perfect way for Ukraine to further advance its pharmaceutical industry and improve its quality in all facets of healthcare.

Obtaining GMP certification in 2003 was a great step forward in the company’s endeavor to be aligned with the best international regulations. Has BCCP implemented any other international industry standards since then?

Today our quality systems have evolved significantly since the first GMP classification of 2003. BCCP has since then implemented an integrated pharmaceutical quality system (IPQS) which encompasses GMP standards, good distribution practice (GDP), good storage practice (GSP), and good quality control laboratory practice (GQCLP). GMP was a good starting point though we found that only very limited information was used to cover every staff role, from mechanics to doctors,

and we felt we required other certifications to further improve BCPP's standards and ensure we were the number one Ukrainian company in this area. We therefore began getting ISO certifications, starting with ISO 9001 (quality management system) and then ISO 17025 (general requirements for the competence of testing and calibration of laboratories).

Like any other people, Ukrainians also want to continue living in an environment with beautiful trees and rivers and clean fresh air, allowing our people to enjoy healthier lifestyles. To enact this vision, we then looked at enhancing our company's environmental impact, and we now hold ISO 14001 (environment management system) certification. Furthermore, recent roblems related to the natural gas supply to Ukraine led to rapid increasing the price of gas. Therefore, we swiftly initiated the process to get the ISO 5001 certification (energetic management system), which resulted in a 40 percent reduction of energy used by our manufacturing plant. Overall, these certifications demonstrate our contribution towards going green by decreasing emissions and disposing of waste correctly.

For decades, my vision for the development of BCCP has been to create a little Europe in Ukraine, a place where people are happy to come and work for us. This is why we obtained an OHSAS Certificate (Occupational Health and Safety Assessment Series), so our staff are now safer than ever when they come to work. In the grand scheme of things, we see obtaining and continuing these healthcare standards, especially in the volatile Ukrainian healthcare ecosystem, as being like the process of natural selection, and we must evolve with the times to continue growing internationally.

BCPP now proudly stands as one of the most advanced Ukrainian companies when it comes to international standards and quality certifications. How do you plan to leverage this great asset to further expand your international footprint?

In parallel to our remarkable alignment with the most stringent international standards, our company's second great asset undoubtedly relates to its R&D capacity, which is second to none in Ukraine. Again, this unique expertise takes its roots into our country's history. In Soviet-Ukraine, scientists used to work for government organizations, whose funding eventually dried up at the independence of our country – prompting them to join leading companies like BCPP to pursue their research.

When it comes to R&D activities, we focus on cardiovascular diseases, diabetes, respiratory, CNS, and infectious diseases – and we are particularly proud to see that some of our in-house developed original products have revealed themselves being truly life changing. For example, we recently

obtained strong clinical evidences that one of our herbal cardiovascular treatments can significantly decrease the risk of developing primary diabetes – a great outcome that will undoubtedly draw the attention of patients and physicians all around the world.

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Unfortunately, previously performed Ukrainian clinical trials cannot be used to register products in the EU or in the US, because Ukraine's preclinical and clinical sites still operate within a different regulatory framework than those in regulated markets. As a result, we must perform again our trials, whereas our products have been thoroughly tested and in some cases used in Ukraine for quite a long time already. As a result, we are now actively looking for international partners to join forces with us and collaborate on the advancement of these international trials, which truly stand as a risk-free investment, as well as participate in these products' distribution in key foreign markets. In terms of geographies, we remain particularly open to any new opportunities in Europe, Asia and Africa.

In the grand scheme of things, our partnership approach goes beyond product registration and we are ready to collaborate with international companies that would be eager to work on the joint improvement of our existing original drugs and on new projects. Overall, we view drug development as an exciting step into the international spotlight, and we definitely offer eye-catching value in this regard.

Being an international company with aspirations to grow internationally and into the EU market in particular, what has been the impact of the long-awaited Deep and Comprehensive Free Trade Agreement (DCFTA) between the EU and Ukraine, which was provisionally applied in January 2016?

One of the first positive aspects we have observed relates to the easing of imports, specifically if the goods carry the EUR.1 certification, which has allowed BCPP to more save substantial time and resources when importing pharmaceutical equipment and spare parts, particularly substances for producing medicines, packaging materials, and basic raw materials (API).

On the other hand, the introduction of the free trade agreement has also brought challenges around the intellectual property rights of products in Ukraine. The DCFTA notably required Ukraine to modernize its copyright rules and geographical indications standards. Although the current legislation is already particularly comprehensive, it still holds some strategic rooms for improvements, especially with regards to the independence, non-disclosure, and confidentially used for obtaining permission to introduce a new drug onto the market.

Finally, the DCFTA has also greatly contributed to improve the transparency of our country's public procurements. In this regard, ProZorro, an electronic procurement system, was recently established and BCPP started participating in these new tenders with great results.

What can we expect from BCCP within the next five years?

International expansion is something we have been looking at for many years and is now on the horizon. We have ambitious plans to register not only generics, but also some of our original products in the most advanced markets globally. We hope that our company's unique R&D capacity, which has been developed according to the best international standards, will be of interest for foreign investors and international partners, and that many patients all around the world will be able to access our high-quality, life-changing treatments within the upcoming years.

In the meantime, our international ambitions will never overshadow our commitment to Ukrainian patients, and we will tirelessly strive to bring new treatments onto our domestic market and consolidate our leadership position in Ukraine.

Whether it relates to expanding our international footprint or consolidating our domestic leadership, the most critical success factor to the fulfilling of these two fundamental objectives will be our staff. When I began working here at 18 years old, almost all staff originated from the same Ukrainian village and many people were even related – the company was like a large family. Now, being 70, I am proud to be heading such an amazing organization, and I absolutely want to preserve this family atmosphere and further promote our company's culture of hard work and kindness, which contributes to making BCPP a harmonious ecosystem. Our overarching objective is to drive BCPP to new heights and we must forever view our staff as our most important asset, continuously nurturing the development of our people, like my managers did with me many years ago.

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