

Interview: Anatoliy Reder - General Director, InterChem, Ukraine



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Tags: [Ukraine](#), [InterChem](#), [Pharma](#), [R&D](#), [Manufacturing](#), [Internationalization](#)

Anatoliy Reder, founder and general director of InterChem, provides insights into the heightened international ambitions of this leading, science-based Ukrainian pharmaceutical company, which plans to leverage its unique R&D and manufacturing capacities to bring to the EU and other international markets their in-house developed, original products, which proudly stand as some of the largest selling and most reputed brands in Ukraine.

Over its 25 years of history, InterChem has managed to establish itself as a cornerstone household brand among the Ukrainian pharmaceutical industry and now belongs to the top 10 domestic companies in the country. What sets InterChem apart from other local pharmaceutical manufacturers?

The true core of our company has always been its scientific expertise. Actually, the history of InterChem is quite unique, as it started as a chemical company with a very small group of postgraduate students from the National Academy of Sciences, before we decided to concentrate our efforts on the development of finished products and implemented our own R&D unit at the end of the 90s. Twenty-five years after our beginnings, we have proudly managed to design and launch four original products - an antiviral, two anxiolytics and a sleeping agent. These four products have already gained a remarkable brand reputation in Ukraine and in CIS countries, with two of these original products being ranked among the 50 largest selling pharmaceutical products in these markets. In Ukraine, the sales of our original products amount to around 45 percent of our

domestic revenues, which are complemented by a strong and ever expanding portfolio including 33 high-quality generics and eight active pharmaceutical ingredients (API).

Building on the increasing reputation of our original products, InterChem has followed a rapidly ascending growth trajectory throughout its history, constantly outperforming our domestic pharmaceutical market – even before the 2013 crisis, when the Ukrainian market was growing more than 20 percent a year. Local and international players included, we now proudly stand as a top 20 company in Ukraine.

However, we do not plan to rest on our laurels and are actively advancing the development of three new molecules (two pain killers and a neurotropic drug), which we plan to launch in Ukraine in the near future. Unfortunately, our country's regulatory framework remains more favorable to generics products and registering locally developed original drugs still stands as a lengthy, tedious process.

InterChem has historically concentrated its efforts on the Ukrainian market, but we now see many leading domestic companies looking abroad to nurture their long-term development. To what extent does InterChem fall within the same trend?

As a company, we successfully survived the 1998 crisis *[a particularly difficult year for Ukraine, which suffered from the financial crisis in Russia and also struggled to overcome a political impasse between the government and the Parliament, e.d.]*, and the 2008 Global Financial Crisis, but the 2013 Revolution has had an unprecedented impact on the Ukrainian healthcare sector in general and the pharmaceutical market in particular. All companies operating in Ukraine were strongly hit by currency devaluation *[the exchange rate of the Ukrainian hryvnia versus the US dollar decreased more than threefold between the beginning of 2014 and mid-May 2017, ed.]*, and all players' turnovers significantly decreased when expressed in US values. In this regard, market studies revealed that international and domestic companies followed very different approaches to cope with currency devaluation. For example, data shows that the average price of foreign pharmaceuticals increased by 100 percent in 2014, while local manufacturers only raised their prices by 21 percent on average, which probably explains why domestic companies' market share has increased from 63 to 78 percent (in volume) over the past three years.

Nevertheless, the impact of the Ukrainian crisis and the significant drop of our domestic market's value did lead us to accelerate our international expansion. In this regard, we have already localized the production of two original products in Kazakhstan, where we have setup a joint venture with a local partner and conducted a technology transfer to overcome regulatory barriers.

Looking forward, we want to bring twelve additional products into this promising market within the next two years.

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In the grand scheme of things, our strategic vision is to steadily enter higher value, regulated markets, such as the EU, which would mark a historical, but challenging, milestone for our company.

What are the main difficulties you encounter when it comes to bringing your original products to the EU?

Since the independence, Ukrainian companies have – successfully – developed themselves within a regulatory framework with standards inherited from the Soviet era. More importantly, these standards, which are completely different than those in force in the EU, used to shape our entire pharmaceutical ecosystem, from clinical research to product registration. Ukraine has however been rapidly catching up over the past decade, and our country’s regulatory and certification frameworks are more and more being aligned with those of European markets. However, changing our country’s overall regulatory system stands as an enormous task which cannot be completed overnight, and – in the meantime – Ukrainian companies still suffer from these structural discrepancies.

Let me give you an example. Ukrainian preclinical laboratories and clinical sites have not yet been certified by EU regulators, which does not mean that they display a significantly lower level of quality in comparison to their European counterparts – but only that they operate within a different regulatory framework. Unfortunately, this specificity means that clinical data obtained in Ukraine cannot be used to register locally developed original products in EU markets.

As we performed in the past most of our original products’ preclinical and clinical trials in Ukraine, we now must duplicate our clinical studies in EU certified laboratories, which consumes valuable time and resources. In this regard, we understand that all markets try to protect their domestic companies from foreign newcomers while looking to ensure only safe products are marketed. Nevertheless, from an external perspective, the level of data duplication required by some of our targeted markets is hardly understandable – especially given that our products have been used in Ukraine for a substantial time already.

How do you plan to overcome these regulatory barriers and fulfill your international strategy?

Over the past nine months, we have been diligently searching for the right international partners to guide us through this tricky regulatory process. We discussed this proposition with over 30 interested companies and ultimately picked an American company based in Czech Republic, which we believe will assist us to more swiftly distribute our products in the EU.

With regards to the three original products in our R&D pipeline, we then plan to follow differentiated registration approaches, using Ukrainian data for domestic and CIS markets, while looking to obtain EU-certified clinical results for our targeted EU markets. In the same vein, we also plan to enter some African and Middle Eastern countries, as we believe our products can offer a particularly eye-catching added-value to these countries' patients and healthcare professionals.

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In the grand scheme of things, InterChem is really at the frontier of a new era, as we truly aim at building an international company. Our expansion strategy does not only encompass the marketing registration of our existing products in foreign markets, as we are also interested in the joint development of new original products with international partners.

On the other hand, we see that Interchem has been continuously upgrading its manufacturing capacity, and, in 2015, you started the third expansion of your production facilities. Could you tell us more about this new production line?

This USD 48 million development project uniquely stands as the company's largest ever investment into a single project. This new production facility has an annual capacity of over one billion tablets and ten tons of APIs per year, while covering a total area of 15 thousand square meters. This new production and laboratory complex was moreover designed in accordance with Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP), and it has increased our overall production capacity fourfold, contributing to double the volume of our exports.

Throughout our successive expansion plans, we have paid special attention to continuously upgrading our facility's laboratory. The latter now provides us with a level of precision that is particularly impressive. This laboratory is probably closer to a R&D center than a standard production laboratory, which leads us to consider that we hold one of the most advanced laboratory capacities in the country. Second, this expansion plan has allowed us to further modernize and automatize our production process, while implementing digital technologies to guarantee the traceability of our products and further enhancing our cost-efficiency ratio.

Finally, the expansion of our production facility lead us to hire of 139 new employees, bringing our total headcount to over 700 people, while, we plan to employ another 260 employees by 2020. Given the economic difficulties our country has encountered over the past years, we pay very special attention to our social impact. In this regard, InterChem's average salary is 1.7 times higher than the annual Ukrainian average and 1.9 times higher than the average in the Odessa region *[where the company's headquarters and production plant are located, e.d]*.

Although Ukraine probably holds one of the most advanced domestic pharmaceutical industries in the region, these companies have developed themselves without receiving any direct support or funding from the government. Do you feel that the government's approach is evolving?

Ukraine indeed holds remarkably advanced pharmaceutical companies and devoted professionals; in fact, the European partners who visited our production site were particularly impressed by its high level of development, especially given it is less than three decades old.

Evidently, it is true that domestic companies have never received any direct support from the Ukrainian government. In this regard, we are not asking for direct funding or financial support, but only to ensure inadequate or obsolete requirements are removed or updated and do not slow us down any longer.

In May 2016, Ukraine's Prime Minister Groysman attended the opening of our new manufacturing plant, which became the opportunity to hold a high-level meeting with other members of the Associations of Medicines Manufacturers of Ukraine (AMMU). When we started to discuss opportunities to set up dedicated development programs that would foster the development of local pharmaceutical companies, Prime Minister Groysman explained that the government was favoring a market development approach, ruling out the option to directly support a specific part of the value chain.

Coming back to InterChem, what can we expect from the company within the next five years?

We will naturally remain committed to the Ukrainian market, servicing our country's patients and healthcare professionals with the utmost attention. Actually, InterChem's slogan translated in English means *"the medicines from those who care"*.

Nevertheless, our fundamental objective is to greatly increase and improve our presence outside Ukraine and in the EU in particular, as many regulated markets could benefit from our life-changing, high-quality treatments. All in all, we want to further build on our company's reputation

and ensure InterChem is synonymous with innovation and science beyond the Ukrainian borders.

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