

# Vladimir Sayenko – Partner; Anzhela Makhinova – Counsel, Sayenko Kharenko, Ukraine

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*Vladimir Sayenko, founding partner, and Anzhela Makhinova, counsel, of the leading Ukrainian law firm Sayenko Kharenko, give an overview on the Ukrainian pharmaceutical industry in 2017 and explain the expansion of the firm into new practices in order to further respond to the needs of its clients.*

**What has changed in terms of the importance of the pharmaceutical industry in Ukraine to Sayenko Kharenko since we last met you in 2012?**

*“In the past, we did a lot of transactional work with our clients but these days, we are a lot more focused on regulatory and compliance requests, which means day-to-day interaction with local management and a better understanding of the client’s business.”*

The importance of the pharmaceutical industry for Sayenko Kharenko has grown since 2012. There has been a change in the nature of the work to be done for pharmaceutical companies, which reflects the current changes in the market. For example, in the past, we did a lot of transactional work with our clients but these days, we are a lot more focused on regulatory and compliance requests, which means day-to-day interaction with local management and a better understanding of the client’s business.

We have also experienced the growth of our IP practice, which is traditionally important for the pharmaceutical industry. We strengthened our team in 2014 and since then this practice has been doing quite a lot of work for the pharmaceutical sector.

**In 2012, you were full of hope for the implementation of reimbursement reforms, which is currently underway. Could you provide us with an overview of the current reforms and explain why they are so important for the overall reform plan?**

We are still full of hope that medical reform in general will reshape the industry, create new opportunities, and produce numerous benefits for Ukrainian society. The reimbursement system is one of the elements of this reform. It is too early to evaluate these reforms, as they started last year on paper and the key pieces of legislation only came to parliament in July.

In respect to the reimbursement issue, needless to say, it is crucial for Ukraine to set up a reimbursement system, especially in the current economic situation when many people cannot buy the medicinal products necessary for their treatment. Therefore, the first pilot reimbursement project in respect of medicinal products against hypertension was very important for Ukraine. The results of the project have demonstrated the following problems that have negatively influenced the overall project efficiency.

First, in Ukraine it is only possible to obtain reimbursement based on doctor’s prescriptions received each month. Lack of doctors, especially in some regions, resulted in lots of queues in hospitals. Therefore, many patients have not been able to receive prescriptions or have faced refusals and thus are unable to take advantage of



reimbursement.

Second, as of today there is no electronic register of patients. Therefore, now everything is done in paper form i.e. prescriptions are issued by doctors in paper form, pharmacies make their reports to the municipal agencies in paper form, and the responsible municipal agencies verify all these papers. In practice, this paperwork not only creates an administrative burden for doctors, pharmacies and municipal agencies, but also makes it very difficult to control the funds reimbursed to pharmacies.

Third, there are some problems with reimbursement to pharmacies (i.e. considerable delays or even absence of reimbursement), which results in reluctance of the latter to participate in any such programs. Unfortunately, these problems have not been fully resolved. Therefore, some experts are very skeptical about the success of the new reimbursement program that is currently being implemented in Ukraine in respect of cardiovascular diseases, diabetes and bronchial asthma. Moreover, one of the most important stumbling blocks influencing successful reimbursement in Ukraine is insufficient state funding. Even though in the state budget of Ukraine for 2017 allocated UAH 500 million for reimbursement, the above amount does not suffice, as according to the analytical pharma agency Proxima Research, it represents less than 1% of the annual turnover of the medicinal products on the Ukrainian market, estimated at UAH 60 billion.

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**You mentioned in 2012 that some pharmaceutical sector problems could easily be resolved through discussion between industry and the government. Has this line of communication improved?**

Indeed, the current government is a lot more open to communication with business and this is probably one of our firm's biggest success stories. In 2013, we launched our government relations practice. At that time, it was run by Andy Hunder, the current president of the American Chamber of Commerce in Ukraine. He was the main driver behind this initiative. With the Euromaidan Revolution in 2014 and all the changes taking place in the country, the tremendous success of this initiative cannot be overestimated.

Many of the current government personalities are our former clients or colleagues who decided to leave business and spend some time in the government to help change the country. However, when entering the government and realizing the different bureaucracy it implied compared to private business, they understood that they did not have the proper resources to achieve their objectives. They often turned to us with their ideas and we helped to draft legislations and other initiatives as a pro-bono activity to help shape the future of the country. We were also available to help them as in 2014 we were less busy because the investment climate was rather low during the active phase of war in the east of the country. This large investment in pro bono activity wasn't particularly good for our legal business in the short term, but it had a positive impact in the long term as now we have a strong relationship with many members of the government and they continue to rely on our experts. In the end, the government relations practice offers a good platform for our clients to be heard.

However, there are still improvements to be made in the field of cooperation between government and the pharmaceutical market. Unfortunately, some regulations, for instance, on reference pricing or technical regulations on medical devices, have been adopted very unexpectedly without prior discussions with the industry. Some legal acts should be improved in order to be fully in line with DCFTA requirements. Therefore, businesses are still struggling to adapt to these changes.



## **Despite boasting very low production costs, closer collaboration with the EU and a great geographical location, mergers and acquisitions are still rare in Ukraine. Why?**

Even though a lot of reforms have already been implemented, geopolitical uncertainty is still a major factor for international investors. In terms of new market entrants, we hope that having read your report, investors will understand the risks better and will consider the opportunities that the Ukrainian market now presents. We receive numerous requests from companies that are already evaluating such opportunities, so the interest is there. Recently, the volume of M&A activity has picked up and we hope that this is a trend.

To help multinational businesses that are not familiar with the Ukrainian market, we have just launched a new business alliance with an investment management company called UA Direct. This company operates separately from our law firm but we work closely together to provide seamless practical solutions to clients. UA Direct offers a range of services including support for companies entering the market, building their business strategy correctly, and introducing them to key local contacts needed for the business to be successful. This may be particularly relevant for the pharmaceutical industry, where there are a lot of regulatory concerns and a need to build up relationships with hospitals and other major consumers. With the assistance of UA Direct, Sayenko Kharenko can go beyond the classical offering of legal services and truly help clients achieve their intended goal. We feel like it is a general trend for the legal market to be more business-oriented and to provide our clients with solutions instead of process support.

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## **Since we met you in 2012, how would you say the firm has changed?**

In 2012, we were already one of the two largest law firms in the country and we have been growing since then. Thanks to the creation of the GR practice and strengthening of our IP practice, and later a Tax practice, I assume that we are now number one. Many of the international law firms are withdrawing or downsizing in this market as for several years they did not see their traditional source of revenues. They are also looking at this market's financial results through foreign currencies, which, after the recent hryvnya devaluation, do not match their expectations.



In this difficult market, we are still seeing opportunities that are not in traditional practice areas. That is why we created our government relations practice, co-invested in UA Direct, and expanded in international trade and various niche areas. For example, we are now focusing on corporate security, which combines knowledge and experience from the dispute resolution practice and an outside team providing general security services (physical security of assets and premises, personal security of company's owners and officers, security of communication, cyber security). We also engage business consultants to provide a full picture. Our strategy is to conduct comprehensive due diligence of a business to understand its weaknesses and all the issues that could affect the company's operations, not only from the legal perspective but also from the purely business perspective, and to find proper legal solution to protect the business from all these risks.

For example, the major weaknesses of doing business in the pharmaceutical industry are government intervention, including through registration procedures and regulatory inspections. We recently helped one of our clients who was dealing with a criminal investigation that resulted in a delay in the registration of their products leading to their incapacity to import to Ukraine. It has become one of our success stories. After a year of legal fights, the prosecutor's office closed the investigation and apologized publicly to the company. Therefore, the corporate security practice is a comprehensive solution that allows clients to decrease the risk of their operations from various angles.

**If you were to pinpoint one main achievement of Sayenko Kharenko over the past five years, what would it be?**

The greatest achievement for Sayenko Kharenko is that we have a unique and diverse team of talents and experts in each core field, who work together efficiently. On the one hand, the firm is very decentralized, based on a unique model that allows a large firm to operate like a collection of boutiques, where each practice can fully realise its potential and develop deep knowledge. On the other hand, all practices work seamlessly together, when a multidisciplinary team is formed for every client matter. All practices adhere to the highest standards of the legal profession and quality controls are unified across the firm.

**We have also heard that you have been appointed as Vice President of the Ukrainian Bar Association. Could you tell us what new responsibilities await you in this position?**

The legal community feels that now is the best time for changes in the country. There is also a good opportunity for public organizations and various institutions of civil society to make themselves heard by the government and we do not want to miss that opportunity. When it comes to lawyers, the Ukrainian Bar Association (UBA) is the best vehicle for this purpose, as it unites all branches of the legal profession.

Therefore, we allocate a lot of our time to pro bono activity within the UBA in order to contribute to society and change the operating environment for Ukrainian lawyers. One of our first goals is to protect the rights of lawyers, for example, when it comes to protection of attorney-client privilege that really matters to our clients.

Personally, as the Vice President of the UBA, I concentrate on international relations. We want the UBA to be more active and more visible internationally, to promote exchange of experiences among lawyers from various countries, and to implement international best practices in the legal profession.

**What would you like to achieve in the next five years?**

In the next five years, we are likely to see some major changes in the way the legal profession operates. I believe the most important changes will come from the overlapping of the legal and IT industries. Most likely, some computerized solutions based on artificial intelligence will be used in the legal practice to make the delivery of legal services more efficient for clients. At present, no one can predict precisely how the industry will evolve. As our firm wants to stay ahead of the market, we are already investing into research and development in this area. We want to have the capacity to seize future opportunities in this area and gain experience as we test various innovative solutions.