Interview: Petro Bagriy – President, AMMU, Ukraine



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Petro Bagriy, president of the Association of Drug Manufacturers of Ukraine (AMMU), which gathers seven of the leading Ukrainian pharmaceutical companies, provides insights into the internal workings of the association and the interaction with the government, the future direction and strategies of AMMU as well as how the new reforms have influenced the actions of the AMMU members and the Ukrainian healthcare system in general.

Could you please elaborate to our international readers why leading Ukrainian pharmaceutical companies came together to form the AMMU in 1996?

Many years ago, the leaders of the Ukrainian pharmaceutical world desired to move into the European market, expanding on their sole domestic market. The initial goal of the association when we were established in 1996 was to implement GMP standards across the board, allowing companies to build around a EU-inspired quality system. In this regard, AMMU's members truly were frontrunners among the Ukrainian pharmaceutical ecosystem, as GMP certification only became obligatory in 2012 in Ukraine.

It is interesting to note that companies that initially were against GMP have now come to the realization that it allows domestic companies to sell products all around the world. As a consequence, Ukrainian companies now distribute their products to 56 nations, compared to pre-GMP years when they only exported to Post-Soviet states.

To summarize, our role is to implement European norms in Ukraine, with our main task today to promote – and hopefully adopt – European legislation in all areas across the pharmaceutical value chain.

What levels of the pharmaceutical chain are you pinpointing most at AMMU?

We do not focus on a specific area in particular and our efforts encompass pharmaceutical development, clinical research, laboratories, production, distribution and pharmacies – in short, from production to consumer.

Already we have European standards implemented around production, including all facets related to this area. We however clearly understand that drug quality is not all related to production. If tomorrow we provide a distributor with a perfect drug, but do not allocate the said distributor with the correct storage facility, the drug is now useless. This is the same in the pharmacy setting, so we must also improve Ukraine’s distribution standards, and step by step we will achieve this goal.

Secondly, clinical trials are another key sector to be revised. We need to ensure trials are done correctly and under the ideal conditions to ensure results are accurate and usable in other countries.

In summary, we need to break down the steps one by one along the levels and impose our will to ensure we have European standards throughout the entire value chain. Currently all companies in the association take part in this process and help fund the proceedings to change the legislation.

It seems that AMMU and its members have done a lot by themselves. What has been the government´s influence throughout this process?

I see the pharmaceutical industry as a diamond in the economic crown of the country, but the government is not very supportive. In this context, Ukraine’s pharmaceutical sector truly stands as a high-tech export orientated industry without sufficient national backing. If we take the example of GMP implantation in 2012, the government did assist; otherwise, not much else has come our way.

I would also like to highlight that the Ukrainian pharmaceutical industry never insists on exclusive rights compared to foreign companies – on the contrary – we look to establish conditions that would interest international companies and investors in developing partnerships with domestic companies.

Given the government’s ambitions to improve Ukraine’s health system, what would you highlight as the most important reforms recently implemented in this regard?

Product pricing in Ukraine is a hot topic with each subsequent government and president. The market always feels pressure from regulatory bodies to reduce prices as Ukraine is the only country in Europe where around 90 percent of all medicines supply comes as out of pocket expenses. Many reforms have been talked about, though in reality only the recently implemented but limited reimbursement mechanism *[covering so far 21 INNs in the cardiovascular, asthma, and diabetes areas, ed.]* has had an impact on producers, doctors and patients.

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The government has invested UAH 750 million (around USD 29 million USD) into this reimbursement scheme, which represents less than one percent of the total value of Ukraine’s pharmaceutical market. Pharmacies are also required to complete complex report systems for purchased medicines, and many are not willing to participate in the program due to low margins. Furthermore, retailers do not fully trust the government reimbursing them, as, in 2012, when a similar program was first attempted, some pharmacies did not receive government payments. All this results in a program that functions slowly. Nevertheless, I am still confident that we are on the right track if the government can prove it is reimbursing effectively.

Finally, the effect on pharmaceutical producers has resulted in companies reducing prices to participate in the reimbursement program. AMMU will continue to give full support to the government as we go forward in this reform. Ultimately, it will lead to patients having more access to medicines, and this is the most important.

2016 was also marked by the decision of the Ukrainian government to outsource centralized public procurement of medicines to three international organizations, the UN agencies UNDP and UNICEF as well as UK-based Crown Agents, a system which has been maintained in 2017. What is the association’s position on this particular reform?

The association has two problems with it. Initially, only pharmaceutical companies holding WHO qualifications could participate in these tenders, which no domestic companies currently carry, although many hold German GMP certification for example. We criticized this approach heavily and convinced these international organizations to relax these requirements, hence allowing domestic producers to take part in the tenders.

Secondly, VAT rulings have created an unfair playing field between domestic and international producers. The laws state drugs delivered to Ukraine are VAT free, while drugs produced in Ukraine are imposed with a seven percent VAT rate; therefore, domestic companies are tendering with elevated prices and cannot compete fairly.

This situation is particularly strange for local companies as we pay all our taxes to the state but still receive discriminatory treatment. We have been in open discussion between organizations and the government to resolve these issues, especially as domestic pharmaceutical companies are paying among the highest taxes and wages in Ukraine.

Do you believe that Ukrainian companies will soon be able to distribute across the EU?

Absolutely, as we see leading domestic companies are already selling their products in nations such as Germany, Poland and Bulgaria. For example, a company like Farmak *[Ukraine's market leader and largest domestic company, e.d.]* has already forged a long-standing experience in the development of new products and formulations and use modern production methods, which allows the company to successfully compete in some European markets. For example, Farmak sells X-ray contrast agents in Germany, the homeland of these drugs, and they now proudly stand as a serious competitor in this market, as their products are in no way inferior in quality but remain affordable.

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Nobody expects us in the EU as each market protects itself to foreign companies, a system we do not employ in Ukraine. All European countries have extremely tough regulations, which is understandable: in the end, we are talking about people's health. In this regard, Ukrainian companies are left with no choice but to adapt themselves to the rules of these new markets.

The Ukrainian pharmaceutical industry remains particularly fragmented. Would uniting together benefit domestic companies?

Historically in Ukraine there have always been a large number of domestic producers on the market, and this continues in the present day. Ukraine has encountered three separate, deep crises since the country's independence, with each crisis throwing the pharmaceutical industry backwards and stunting its growth. As a matter of fact, we are still struggling to reach the sales levels of 2012-2013, before the annexation of Crimea and the beginning of the war in the east of the country.

Despite all this, processes are moving forward and I expect companies will consolidate their position in the future. The peculiarity of the Ukrainian market is that it is still characterized by very

low prices, and medicines in Ukraine are on average four times cheaper than in Europe. Therefore leading domestic companies are also attracted by more mature markets because of the elevated price of products, while in the meantime expanding into developing markets like Vietnam, Brazil and African nations.

In domestic companies' endeavor to continuously improve their processes, what would be the importance of partnering with international players?

We already see very interesting examples of collaboration in this regard. Farmak, for example, has been partnering with foreign companies in the production of insulin for a long time. This collaboration has allowed them to step-by-step improving their processes and sharpening their expertise. In the meantime, we believe the Ukrainian market stands as a great opportunity for international companies because it is a growing market with a significant, untapped potential. Finally, I am convinced that increasing these win-win interactions between domestic and international companies will ultimately benefit to Ukrainian patients.

In terms of acquisitions, Switzerland's Acino Group, recently acquired Pharma Start, a large domestic company. This is great news as behind this acquisition will come new technologies, new knowledge and increased competition, which contribute to upgrade our overall capacity.

What is your final message to our international readers as President of AMMU?

First and foremost, I would like to highlight that Ukrainian companies are fully operating according to European standards. Overall, our companies are open to cooperating at all times and are able to solve any challenge, striving to above all benefit doctors and patients. In the grand scheme of things, we have to remember that European and worldwide standards were not only implemented for the sake of improved medical production, but to bring life-changing, high-quality treatments to the people.

It is my task as president of AMMU to push our members to put in place these standards, building on the leading market positioning that many of them have gained in Ukraine throughout the past years. A new era is starting in Ukraine and our organization as of the 14th of June 2017 has become a member of the Medicine for Europe organization, represents the European generic, biosimilar and valued added pharmaceutical industries. This exemplifies our approach to people, medicines and treatments and proves our real intention to move together towards Europe.

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