Interview: Vladimir Afenliev – Chief Director Business Operations, Strategic and Organizational Developments at Sopharma, Bulgaria

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08.11.2017

Tags: Bulgaria, Sopharma, Generics, Manufacturing, Pharma, Internationalization, CEE

Vladimir Afenliev, chief director business operations, strategic and organizational developments at Sopharma, explains the great success of the strongest Bulgarian pharmaceutical company in the country as well as the upcoming strategies to further grow Sopharma in the region.

Sopharma is the most important pharmaceutical group in Bulgaria with activities spanning from manufacturing to distribution and exports. Could you please start by introducing the importance of the group in Bulgaria's pharmaceutical landscape and economy?

Sopharma Group is a fully integrated pharmaceutical group, with roots 83 years ago as a local manufacturer. Amongst the top ten pharmaceutical companies in Bulgaria, Teva-Actavis and Sopharma are the only two generic players, with Sopharma in fifth or sixth place in terms of market share by value and first place by volume.

After the privatization of the company back in 2000, we have never stopped developing our business. Indeed, within Sopharma group, Sopharma Trading is one of the Top Three wholesalers in the country and three years ago we inaugurated the most modern and brand-new facility in the country.

In parallel, we are working on developing our human capital as well as our expansion in the region. Indeed, we are strongly proud about being the only company with prevailing majority Bulgarian Ownership in the top players but, being realistic, we have to look abroad to continue driving our growth. Therefore, we aim to become a mid-cap regional pharmaceutical player, especially in the CIS as well as CEE regions, and our strategy is very simple: produce high-quality medicines that are affordable to patients. On top of that, Sopharma is developing a portfolio with first products that will be launched in the USA and some Western European countries.

You joined the company five years ago after a long career with pharmaceutical multinationals. How has Sopharma Group changed over this period of time?

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Since I arrived in 2012, the company has managed to keep its positioning in the Bulgarian market while steadily growing in foreign countries. Indeed, in Bulgaria, we have been regularly introducing new generics to the market on a yearly basis combining our own portfolio and in-licensing agreements. In addition, we have managed to keep our ranks within the top-six players by value meaning that our loss due to price erosion has been balanced with our increasing volume.

Moreover, Sopharma has a well-defined internationalization strategy based on flexibility and diversity. We are quite prepared and we do not fear to go to markets in Eastern Europe and CIS where the reimbursement systems are not fully implemented and transparent. In this front, Sopharma Trading acquired one of the biggest wholesalers in Serbia and Moldova. Sopharma AD has its presence as marketing company and a manufacturing plant in Ukraine for instance. We are being aggressive with inorganic growth strategies that have helped us to grow a lot in international markets.

In parallel, our daughter company is also investing in the innovative model of a small chain of pharmacies – based on best practices in the sector available in developed countries like UK for instance. The chain is called ‘Sopharmacy’ and patients can receive pharmaceutical treatments as well as basic care services. It is quite new for the Bulgarian market but we are looking forward to the first results.

The capacity to export is closely linked to manufacturing standards. Can you tell us more about your manufacturing capacities today?

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Our main strength is that we are the one of the few serious manufacturers of ampoules in Bulgaria and one of the few in the European Union. If you look at the European manufacturing landscape, there are not any producers of liquid forms and ampoules and we have forecasted steady growth from this segment – we will potentially reinforce our footprint in this area with the construction of a new facility.

Moreover, Sopharma is a very well reputed manufacturer of pharmaceutical products based on herbal extracts. We have been growing the herbs ourselves as well as extracting the essences in our all-equipped facility that transforms them into APIs to subsequently develop the drug.

We have also recently fully integrated a company 'MEDICA' for medical devices (previously Sofarma had a majority stake), which gives another competitive edge to our offer to market and customers. Indeed, merging both companies will create economies of scale that will help us to better manage our resources and diversify our manufacturing capabilities.

When discussing with key authorities in Bulgaria, some have mentioned the will to establish more "pro-generic" policies. What is your opinion on this new focus of the government?

There is an illusion that Bulgaria is a pro-generic market. All politicians are talking about implementing pro-generics policies but they are only focusing on few elements of a bigger matrix, which strongly limits their impact, and sorry to say, they do that before elections. Reality is a bit (or even "bitter"). For example, the NHIF is fully reimbursing some important treatments to target oncology, diabetes and other lifesaving treatments for around 500,000 patients; but, for another 3.5 million patients that need more daily doses, the institution is only reimbursing up to 50 percent of the treatments and this leads to a huge amount of co-payment. Discrepancies in logical and rational drug policy in Bulgaria were notified many times, last time in a special report from the World Bank by order of Ministry of Health of Bulgaria, and there are clearly stated recommendations such as generic substitution or even INN prescribing, which unfortunately till today are not implemented.

Moreover, there is a misunderstanding in the term "pro-generic" policy as it does not mean "in favour of the generic industry" but it is defined as favouring the use of cheaper generic treatments to create economies to be used for more expensive innovative treatments, based on the fact, that once authorised on the market generics have same quality, efficacy and safety with the reference product and they are fully interchangeable between them and with the off-patent original. Exactly such policy can help to reduce the financial burden, while increasing the access to healthcare

treatments. I believe that, by implementing the proper drug policies, we could create stronger impact in terms of government savings and market access. We were happy to hear declared intentions in that direction by the new team in Ministry of Health, so let’s hope they will have the courage to do it.

How are you integrating the biosimilar revolution and what are the investments planned in the future to support your ambitions?

For the moment, there are still some doubts about the success of biosimilars in the European landscape. As a kind of “biological generics”, their development as well as manufacturing is more complicated and expensive than the usual generics. Moreover, the legislation is clear concerning definition of generics vs the patented reference product, while biosimilars’ regulation needs to be further developed. But biosimilars are also very important tool for saving money and increasing access to healthcare, that is why governments should support their development and remove institutional obstacles for their normal market penetration. For the moment we do not have plans of developing biosimilar portfolio, however may be in the future, with the right partners, this question could be put on the table.

How can regional companies like Sopharma compete with global groups like Teva-Actavis, Sandoz or with Indian and Chinese companies?

Indian and Chinese manufacturers are divided into two categories: the ones that have a positive name in Europe and that are meeting all requirements and the others that are facing problems almost every year. Sopharma is a European company with very competitive prices formed by skilful staff with solid professional experience in the industry.

Additionally, Bulgaria also has a strong tradition in the manufacturing of pharmaceutical products and this expertise is strongly reflected in Sopharma, which also offers high quality contract manufacturing services. Indeed, ten percent of the European generic manufacturing industry headcount is working in Bulgaria.

While the regions know the company’s reputation very well, it might not be the case in the rest of the world. What do you want the company’s name to be associated with?

It is important to remember that Sopharma is a modern pharmaceutical manufacturer in Bulgaria, not necessarily big in size but strong in content. We are already well known in Europe and we are now aiming to be well positioned for entry in the US as well.

Sopharma is also very important company for the economy of Bulgaria by itself. We offer a chance for young Bulgarian professionals to develop themselves here in the country and in a leading company. In this regard, we would like to attract again all those Bulgarian medical professionals that have left the country through offering an attractive opportunity for them in Bulgaria.

Looking at the statistics, it is true that Bulgaria is one of the most important markets of our business but the generic price erosion in joint with a strong competition obliges us to look abroad as well. In this direction, we are looking forward to developing partnerships for contract manufacturing, especially with companies wishing to enter the European market.

Additionally, we are also a part of the “preliminary waver of manufacturing”, which is an initiative of the generic industry that aims to negotiate with the European Commission in order to allow the patent-free distribution of European valid patented medicines in third countries – as on average, these medicines can only enter after three to five years in these markets.

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