Interview: Bojan Trkulja – Managing Director, INOVIA, Serbia

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Bojan Trkulja, managing director of INOVIA, Serbia's innovative drug manufacturers association, underlines the importance of cooperation not only between his members but also between all the key stakeholders of the Serbian healthcare and life science industry, concluding that the time for investment in Serbia is now and that the country has undiscovered opportunities waiting to be explored.

Where does INOVIA stand today and what are the priorities for 2017/18?

Our main goal has always been and will always be to improve access to innovative medicines in Serbia. We are aware that this is an ambitious goal as a lack of innovative medicines is a quite substantial issue here. We believe there is a need for more investment from the government in order to improve the situation. When focusing on per capita investment, if we divide the EUR 380 million of government expenditure between Serbia's 7.5 million people, it amounts to EUR 50 per person. We recently conducted a study comparing Serbia to neighbouring countries such as Bulgaria, Croatia and Romania as they are most similar in terms of economic indicators, and we concluded that our government medicine expenditure is 60 percent lower (per capita) than in Romania and Bulgaria. This is a crucial issue to look at as we want Serbian patients to have access to the most innovative and effective therapies.

One of the big steps that we needed to take in order to improve this situation was the introduction of the managed entry agreements. The process took almost three years, and the industry, the health fund and the government, World Bank after negotiations came together to support it.

First was the cross-product model where company has to achieve saving to Health Fund on the medicine that is already reimbursed, so that for the amount of saving they could get another product on the reimbursement list.

The second one was about the rebates, where the company would give a certain percentage of the yearly amount of the product for free as a rebate.

Currently we are working on the third model: the ‘hidden price’ model. The main characteristics of this model is that you are obliged to offer the medicines at a lower price than listed on the reimbursement list. This is hugely important as in Serbia prices of medicines are not freely formed. In Serbia, the government sets the prices, and the process is very lengthy and complex.

This is the main initiative that we are planning to implement here as we are aware of the investment situation. Moreover, we are trying to persuade the government to increase investment in medicines in order for us to catch up with our neighbours and make the market more sustainable, while fostering innovation.

Recently, you warned that there are very limited amounts of innovative medicines that are accessible for Serbian patients. How can the country balance the importance of access to medicine, while at the same time ensure that there remains a place for innovation and research?

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First, in order to foster innovation, procedures and processes need to be made more efficient. There are many bureaucratic issues and unnecessary procedures that stop innovation. The processes are too complex and untimely, making innovation simply no worthwhile for many companies. What we at INOVIA are pushing for is a change of regulation. We started working with the EU through a pilot project back in 2014 on amendments to the medicines laws and it still, in 2017, has not been completed. On the positive side, we are expecting to see changes in the regulation of clinical trials that will be aligned with best practices of the EU. Another thing we would like to see improvement on is the customs regulations, which is especially crucial for donations and early access programs, as well as the VAT being 10 percent on medicines, even on donated goods.

We believe that through regulation change, a change of the mindset will occur and help speed up procedures. Serious gains can be made and this market would make it much more appealing. It is the time for the government to realize the crucial need for innovation, especially in our industry.

How responsive is government to the conversation about improving the regulatory landscape as well as the need for innovation?

There has been a very significant improvement in the last few years. I believe that being accepted as a candidate for the EU had an enormous impact on that. All the regulations now that we have prepared in Serbia need to be prechecked by the EU, which is an insurance policy for Serbian people that the regulation is there to help and is aligned with Best Practice Guidelines (BPGs). We are part of the conversation, and the government is realizing the importance of the industry working together, so there are many joint initiatives INOVIA and other key stakeholders were a part of.

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Being part of the conversation and cooperation is crucial, but what is still missing is direct action behind those talks. The improvements we agreed upon are not being implemented, so this needs to be improved in order for us to move forward.

What will EU accession mean to your members and to the pharma ecosystem in Serbia?

While we are not part of the EU, we need to have local marketing authorization as well as EU marketing authorization in order to start the process. According to the law, for drugs to be registered by centralized procedure it should take up to 150 days, while for others it should be 210 days. On average, procedures are 80 days late. It is much better than it was five years ago, but we are aiming to shorten it to 90 days. Medicines going through the centralized EU procedures should be gaining access immediately. Looking at the complexity of the pricing procedure, it should also be made more efficient in order for us to fit with EU standards. Furthermore, we are pushing for the abolishment of the maximum price because of the lengthy process that is not regulated enough, as the government does not have a deadline to give you the price. It can be tomorrow or in three years. The reimbursement procedure is facing the same issues. It is unfair to innovative companies as they can only submit the application once in March while other companies can do it throughout the year. This is the time for the changes to be implemented and the industry believes the EU accession will be the power behind it all. The outcomes will allow for easier and much faster access to innovative medicines for the nation.

In the 2018 ‘Ease of Doing Business Report’, Serbia improved from 91st position in 2015 to 43rd. With FDI predicted to reach approx. USD 420 million by 2020, what would your advice be to a CEO of a company looking at Serbia as an investment destination?

When talking about Serbia you are talking about the opportunities. We are not the biggest market in this part of the world, but the potential is there. Industry, government and key stakeholders need to realize the potential that is here, waiting. Serbia has such agreements and tax laws with the EU allowing us to import and export goods without paying customs. Serbian government has similar agreements with Russia, Turkey amongst others, allowing the current businesses and any potential investors to have opportunity to reach largest markets. Also as the country of seven million people, we are not nearly at the level of potential in terms of pharmaceutical market as other nations. Additionally, when we look at the situation in Bulgaria which is also 7.3 million people, their pharmaceutical market is almost twice as large as ours.

The potential is definitely there. The government is going to be better and better year by year. The fact is that Serbian GDP is low; even a high growth percentage is not going to be enough to catch up with the neighbouring countries. On a positive note, public debt is on the downward path, unemployment is decreasing and it is a good signal for the companies looking at Serbia. Many of the big names are already realizing this potential, including Fiat, Swarovski, Bosch amongst others. Expected growth in expenditure on healthcare, a better regulatory landscape and positive changes related to EU accession have already started shaping the bright future of Serbia.

I believe we could do more to attract investment, as there are many fields, not only pharmaceutical, that have enormous potential waiting to be explored.

On a personal note, throughout your tenure as managing director of INOVIA, what have your proudest accomplishments?

I am most proud of INOVIA being recognized as a stakeholder and partner in the conversation with the government. We have done a lot of things together in changing the bylaws, introducing managed entry agreements where INOVIA played crucial role, advising on policies and working together toward a better future. We are also proud of our collaboration with the Serbian Drug Agency, and the improvements we have implemented in order to shorten the delays in approval times, such as variation initiative. We have implemented the initiative on variations that is now in its third year upon which all the industry is sending the list of priority variations that are not approved yet. Those variations then are treated as priority, in the quarterly periods and the companies have the predictability when it will be solved.

Furthermore, for over five years we saw that no innovative medicine was being reimbursed, so it was a huge milestone when we achieved that by introduction of the managed entry agreements. Amongst the small things, the alignment of our members and being able to bring them to the table to work together toward the same goal I consider even harder than negotiating with the government, yet so rewarding as we are working towards the better future of the nation. I am very proud that I managed to do so, and that is why I have been here for seven years and enjoying my responsibilities immensely.

Where will we see Serbia in the next five years?

I would like us to be if not a member then a candidate with a clear date to be associated with the EU. Further I would like to see the regulatory landscape be filled with laws and policies aligned with BPGs. I would like Serbia to catch up with the region in terms of access to innovate medicines, and become the heart of the region that we were prior to the wars of the 1990s. The nation still believes we are able to regain this position.

As the managing director of INOVIA, how would you convince an innovative company to choose Serbia as an investment destination?

First and foremost, I would highlight the unmet medical needs of the country; making Serbia a perfect place for a pharmaceutical company offering innovative therapies. The patients are here. Further, the mindset of the government is changing and the industry is expecting increased funding, starting next year, as the government is setting up a National Strategy on Medicines, strategic plan outlining the changes to be implemented in Summer 2018. The small wheels have started to turn and the big wheel will turn very soon, the change is happening. In order for companies to greatly benefit, they need to choose Serbia now and be a part of the process. If you look at the economic indicators, increasing healthcare budgets, increasing reimbursement, and everyone who is interested in this market, innovative players should not miss this train. The time is now!

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