Interview with Tamara Tomovic, General Manager, Janssen Serbia

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Janssen Serbia

How does Janssen view the Serbian market today, and how has company built up its presence here in the country?

Previously we were working through distribution channels and in 2003 we started to operate as a part of Johnson & Johnson in Serbia. As you know J&J has three parts: medical devices, consumer products and pharmaceuticals. In 2003 our drugs were not registered in Serbia so we had to re-register them. It was a difficult time because there were no reimbursement lists for several years. However, in 2005 our products entered the reimbursement lists and then Janssen started to increase its business in the country. We began to experience good growth and started to work with physicians. We felt as though positive changes were taking place in Serbia, and that the Serbian government and authorities had started to be sensitive towards innovation. Unfortunately, this attitude stopped three years ago, but before this they had started to take positive measures to bring structure to the industry here. Of course the system was not perfect, and there were still many issues to be addressed, but at least things were going in the right direction.

Although many people complain about the challenges faced in the Serbian market, every country has its issues. In Serbia, positive steps are being taken, but every change needs time to be established. We just have to be very patient as a group and take the right steps to promote innovation. We have not been very successful at this until now, but I have high expectations for the future.

How are you going to take those next steps? We know that the last few years have been quite tricky for the market as a whole so what strategy have you adopted as general manager in order to take Janssen beyond this troubling period and put it well in the future?

We have to wait for the national strategy. I do not believe that the current strategy of trying to tackle corruption is the right approach. Really we want to aim to improve health, the health system and how to bring access to new drugs. In this current situation where the media is concentrating on scandals, for the pharma industry it is not so easy.

How am I going to position our company really depends upon what happens in the future. We will work with INOVIA, the Serbian innovatorsâ?? association, and try to establish an appreciation of innovation, and then we shall see. It is not possible to invest heavily in innovative drugs and sell them in the country that requests generic prices for them.

For us it will be a great shame if the Serbian people do not have access to these innovative treatments in the near future. New therapy for the patient is here, but I must say Janssen as a company has a focus on psychiatry and this is one of the most vulnerable population parts. We were lucky that one of the our more expensive and innovative drugs Rispolept Consta, our long acting anti-psychotic drug, was placed on the special reimbursement list and in Serbia 1300 schizophrenic patients can today receive this drug. The fact that this drug was placed on the reimbursement list showed that perhaps the government had a sense that they need to treat schizophrenia in an innovative way. Since the product was launched in Serbia we have heard very enthusiastic stories about the results. Maybe this is the start.

There has been nothing new added to the reimbursement list since 2008. It is extremely difficult for us to explain how we can develop and what we can offer. But I hope that other companies, not just Janssen, can together show the benefits of anti-psychotic drugs for patients to have anti-psychotic drugs. Sometimes it is better not to have competitors and sometimes, like in this situation, it is a disaster when you do not have competitors because you do not have anything to compare with.

Has Janssen played a role in education over the last few years?

This is really our basic business. We put all our efforts into medical education and we have played an extremely important role in medical education.

We are beginning to help people understand and recognise the problems. And if the problems are identified at an early stage the cost of treating them will be much lower. Sufferers will not have relapses â?? in schizophrenia for example.

We were talking to Martin Selles of Janssen Spain who was telling us that one of the biggest challenges he was facing in the Spanish market was the lax IP protection which means he was facing a lot of competition from generic products as Janssen products come to the end of their lifecycle. Is that a problem here in Serbia?

Now Serbia has good IP protection legislation since the IP protection law from 2004 is harmonized with EU regulations. But in the past, this area was not so well regulated and Janssen did not protect its older products here. When we entered the market, we did not have time to build our business and start to focus on our other groups of products since we experienced generic theft immediately.

For some products we do have patent protection and for others their lifecycle is expiring and generics are lowering their market price, but this is normal in the lifecycle of a drug.

In addition, there is also data protection of 10 years, defined under Serbian Drug Law. But this 10-years period is suspended only for domestic manufacturers who can register generic product only six years upon registration of an innovative drug. However, once Serbia joins the EU, this will be extended under EU law.

I do not like the idea of small producers offering drugs to the market at low prices, but the government has at least realised that quality standards have to be set at a certain level, and they are leaving the original drug on the reimbursement list.

One thing we have seen in the reports that we have done on Eastern Europe is the problem of counterfeiting. When we did the report on Russia, counterfeiting was a very large issue. How is the situation here? Is it a threat to innovative companies?

We have many measures protecting our products and today Serbian anti-counterfeiting law is changing. For the first time Serbia has introduced mandatory control labels that will be applied on

each product released on the market. We are pleading with the ministry to wait for EU laws as they could be implemented here immediately, but convincing them to wait for the EU is difficult. And we are ready; we have the new labels ready to be placed on our products. Personally I do not believe these new measures will solve any problem, but I did not think we had a problem in the first place. This is something the Ministry of Health requires and since we are a company that follows the law, we shall comply. INOVIA was active in trying to explain that this new holographic label is not an ideal and necessary measure as Europe is currently testing new anti-counterfeiting measures, but still the Serbian government is moving ahead with their own plans.

How attractive do you believe Serbia is for clinical trials?

Although the atmosphere is very positive in general for clinical trials in Serbia, there are still some limitations, such as that Principal Investigator can be only a person with academic qualification i.e. Professor or Docent. It is something we didnâ??t expect, and has limited the amount of clinical research able to be done in the country. However, it does ensure that those involved in the clinical trials are good clinicians and that the patients will be treated in most proper wayâ?¦ This is helping convention in that you can enable â?? in a very limited but a very constructive way â?? new drugs to be tested in Serbia.

Today, Janssen does not have a clinical trial office in Serbia, but rather our studies in the country are carried our through CROs. We currently have ongoing studies in oncology, a psychiatric study, and we have had a lot of successful studies. However, we are not so successful in neighbouring countries.

However, conduction of clinical trials has been hit recently because patients are afraid to take part due to negative coverage in the media. Additionally, as a result of the legislation many excellent clinicians are not able to participate, because they do not have required academic qualifications. But I believe this will change. The government will realise eventually that this is not the right way to proceed because clinical studies are have such a huge benefit for the patients and for the country.

Apart from clinical trials, we also have so called name patient programs through which we donate novel drugs to patients that have no further treatment options with therapies currently available on the market. There are two HIV drugs that we have now been donating in Serbia for three years through such programs, We also have ongoing named patient program for patients with psoriasis, which is recognised in Serbia only as a cosmetic disease. However, it is a very serious disease that attacks internal organs. The sufferers are so stigmatized that they canâ??t wear short sleeves all their lives for example. Severe forms of psoriasis require biological drugs, but at the moment such drugs are not on the reimbursement list for this disease. So these sufferers are not considered important. We are now planning a named patient program for prostate cancer and one for Hepatitis C.

As a Serbian citizen yourself, you are obviously very passionate about promoting Serbia. How do you convince headquarters that the country is a good place to invest? How do you encourage them to put more effort into the Serbian market?

To be honest, at the moment I am not encouraging them too much because we are at the waiting stage. Serbia has 7.5 million people, while Slovenia has a market of only 2.5 million. We are not such a small country. We have a highly educated people and we are at the beginning of the development of a health system. And before the crisis we were a country with a rising GDP. I believe this is a country of potential.

For Serbia, having exports is something that will really increase GDP. Serbia is a country that is located in the center of the Balkans; a transit country that I believe wonâ??t be forgotten even in the

EU context. Now as a company we have to be patient and not invest too much otherwise we will have disappointments and the business will be forced to close. We have to be positive. We have to be cautious and wait for the right moment.

Does headquarters understand the position in which you have decided to place the affiliate? Do they understand that you are playing a waiting game, a long-term game?

Janssen recently organised this region into the Europe South region, which is basically the former Yugoslavia without Macedonia, but including Croatia and Serbia. It is much easier when you are talking about more countries; showing how one is not going down, one is growing, and showing that Croatia is not stabilized as much.

Headquarters are trying to encourage this kind of activity; to be ready, have knowledge, do something in shaping the environment, and try to persuade key decision makers that innovation has value. Saying we are not investing is not correct because we are investing a lot in medical education.

As far as medical education is concerned, we have to follow our internal Code, Policies and Procedures that are extremely strict. We have to report when we are meeting a doctor and what we talk about. It is very difficult and in the pharma industry you have to be very cautious.

We are part of INOVIA, the Serbian innovative pharmaceutical association. They are trying to make their member companies sign an agreement about how they should run their businesses and which stipulates that money should have to go to medical education and not into grey areas.

Looking at different ways to add value to what we do here, from education to clinical trials, is the way that Janssen is now working in Serbia. We are committed to the market for the long term, and as soon as the time and the atmosphere are right, we will make the next leap into Serbia.

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