Interview: Andreas Woitossek – Head of Strategy & Outcomes CEE, Janssen-Cilag, Hungary

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The managing director of Janssen Hungary, Andreas Woitossek, depicts the valuable role of real-world evidence in enabling the affiliate's consistent double-digit growth over the last four years, while highlighting the advantages of using Hungary as a strategic hub. He also shares his vision for Janssen Academy—an institute set to become a collaborative learning center for medical innovation.

What have been the most pivotal decisions you've made since taking over as managing director and how have they impacted the company's performance?

In 2012, a healthcare reform was introduced, which made substantial cuts to the drug budget. That unfortunately led us to reorganize the company, resulting in a more than 20 percent cut in our workforce.

We decided to set up our collaborative learning center for medical innovation, we call Janssen Academy—an institution for medical education. This is a new facet of our business model and the goal of this initiative is to invite the customers to us and ultimately become the facilitator of important discussions and education surrounding our innovations. We are using Janssen Academy as a physical meeting point, but we also have virtual classrooms to provide knowledge and medical education to our customers through more convenient mediums.

On the topic of our business model, we have invested much more in market access to enhance our product propositions and truly demonstrate the value of our products. The key point, which we're very proud of, is using Hungary to generate real-world evidence. There's a unique opportunity to access data that encompasses the whole population covered under OEP (National Health Insurance Fund). Through this data, you can see how patients are developing through the system, but you can also see the performance of your drugs in market. With studies supported by real-world evidence, you have a much stronger position to show the added value of existing products for the patients, while gaining a much better understanding of which patient population would benefit the most of our new product launches.

We have built here a small center of excellence for real-world evidence with six people who are working here on the Hungarian database, not only for us as a Hungarian company, but also EMEA and global structures. For instance, if there is a question for the development of a new Janssen product, we use this database to determine how specific patient flows through the system, identify the breaking points, and also ascertain which treatment options are administered and with what outcomes. These understandings essentially aid us in developing our drugs in the right direction.

In light of all these organizational changes, how would you now evaluate the affiliate's current positioning and trajectory?

We are back on track, having consistently experienced double-digit growth for the last four years. So, we are performing very well. Compared to other countries, our nominal growth is relatively good, but we're slightly disadvantaged when it comes to profitability because that taxes and burden of payback are much higher in Hungary than even in other countries in CEE region. There are exorbitantly high sales rep fees, coupled with 20 percent and even upwards of 30 percent tariffs on revenues. As such, the profitability potential of Hungary when compared to other countries is seriously limited.

Consequently, there is a bit of misalignment. Our levels of investment in the country are certainly high by relative measures, but our revenues after taxation are comparatively smaller. Hungary loses its competitiveness when it comes to this consideration. I'm aware of many companies that are hesitant to invest in the country given the rather unfriendly business environment when it comes to taxation and rep fees.

However, we do see long-term potential, as we've partnered with the right stakeholders that will help mitigate risk and ultimately enable our development now and moving forward. We created a logistics center in cooperation with UPS (courier service) and we are physically distributing our

products to a bigger part of the EU from there. And last but not least, Janssen also sees Hungary as an important hub for clinical trials.

Beyond commercial prospects, clinical trials, logistics, and real-world evidence are all examples of how we're trying to keep Hungary on our company's investment map as a committed partner with long-term ambitions, despite all extra taxes

Many of the fundamental characteristics you mentioned can also be said about other markets in the CEE region. So what defining qualities truly distinguish Hungary?

Starting with clinical trials, Hungary has well-trained doctors, giving us very reliable data through transparent systems, all at a favorable price. This is certainly one of Hungary's competitive advantages compared to other countries—a feature that we're currently under discussions with government to maintain.

Hungary also has very good infrastructure in logistics and a good network of highways. You're much better positioned when sending out physical goods from A to B in Hungary, as opposed to Bucharest or Prague. All the major regional hubs can be easily accessed from Budapest.

Last, but not least, the unique opportunity of real world evidence. In Hungary, we have access to roughly 10 million people, who are all covered under one insurer. This is invaluable as we can access this data to better understand diseases and configure our product strategy, to better meet the patient needs. This simply can't be accomplished in Poland or Romania.

So we see Hungary as having clear competitive advantages in all three of these areas.

In terms of product offerings, how has the portfolio been adapted to effectively address the clinical needs of Hungarian citizens?

The clinical needs of Hungarian citizens are very similar to the more developed countries and from global product development point of view belonging to the developed word. However the pharma financing is still significantly legging behind the western part of EU, but hopefully will converge together with the economy convergence.

As a company, we have one portfolio strategy with innovation at the center. We strive to be a transformational medical innovator. Our drug selections are driven by this criterion.

So, the portfolio consists more or less of the same products offered in Germany. However, we are operating in a country that's much poorer. We have to devise market access strategies for drugs that are on the edge of leading innovation at corresponding price points, which serves as the

primary challenge.

The biggest part of our portfolio is still in Neurosciences, namely schizophrenia, where we have real-world evidence to demonstrate their added benefits compared to other products available on the market. Prospective market opportunities for us lie in oncology—specifically prostate cancer—and hematology, where we've already launched one product, with two others in the approval pipeline. There's probably more of a specialized portfolio composition when it comes to these two therapy areas, otherwise our therapeutic focus remains constant.

How are you using this concept of real-world evidence to communicate the broad value that Janssen brings?

We put this real-world evidence data in front of customers to demonstrate what is really happening in the market and broader healthcare system. We are also using this data to create a better understanding for the disease. We have done it very successfully in prostate cancer. We had a broad study about all the prostate cancer patients, their flow within the system, who is treating them with what, and if you understand the disease and treatment of a whole country better, then you can more easily identify the gaps where treatment is not consistent. With these discussions, we're able to help stakeholders pinpoint efficiencies or areas of improvement —ultimately creating a dialogue, and in turn, a completely new platform to obtain broader access to patients for the innovative solutions.

Together with Sweden, we are seen as frontrunners in the Janssen organization when it comes to this real-world evidence approach. With our small center of excellence, we are closely cooperating with our Swedish colleagues, who are closely collaborating with Karolinska University, to push this initiative forward.

What would you consider the main pressures that the regulatory regime poses today?

As is the case with many other innovators, the process for obtaining product reimbursement is simply too long. The other point is the high level of extra taxes and paybacks. We, as an industry, are required to finance the country's drug consumption. And from a broader standpoint, the lack of acknowledgement of our investments in the country is a common sentiment.

For example, the Hungarian government is more focused on production, so the industry's HUF 90 billion (USD 325 million) investments in clinical research aren't valued appropriately. But it should be understood that in the modern pharmaceutical world, creating clinical data and development is the most costly and important part of the pharmaceutical value chain.

Creating more awareness will inevitably yield more foreign direct investments from big companies. This would also lead to rippling benefits across the sector. Doctors would be less likely to leave the country because they're getting trained in new therapies as a result of clinical trials and receiving added compensation accordingly. The money that goes to hospitals could then be re-invested in maintenance and improvements of infrastructure. And Hungary would increase its attractiveness to the medical world. So, understanding the added value of these investments is imperative.

Given the lack of value that the current reimbursement framework places on innovative medicines, what would you define as Janssen's differentiating factor that has enabled its commercial success over these past few years?

Very early on we were able to engage with key opinion leaders and payers to determine exactly what kind of value our products show; then use real-world evidence to more effectively depict that value. We have also developed strategies to identify specific patient groups that would benefit from a proposed product.

If you look into oncology or hematology, for example, we were able to get market access, but to a patient population of the smaller size than other countries. Not only because Hungary is smaller, but because only the patients with the highest or most pressing need would be eligible for the drug. Our aim of course is to widen that gap. But a lot of patients that would be able to get the drug in countries like Austria or Germany would not be able to obtain it in Hungary because of the more stringent eligibility requirements.

In an open and transparent way, showing the value and identify patient groups that can benefit from our innovations, and following up with real-world evidence to demonstrate efficacy before and after launch has been pivotal. For instance, we have an important treatment option for psoriasis, which is administered only 4 times per year. Based on our follow-ups with patients, compared to competitors, our product has been able to boast better patient compliance with fewer side effects, adding to our value proposition and truly demonstrating that our drug goes beyond clinical studies and actually improves real-world health outcomes.

It was recently announced that the National Health Insurance Fund (OEP) will soon become integrated within the Ministry. How will this impact the way you go about approaching and ultimately securing reimbursements?

For Janssen, given our current strategy, our primary considerations focuses not only on having that access to real-world evidence staying the same after the integration, but perhaps even increasing. There's now this huge project surrounding e-health to match this data, which could very serve as a

competitive advantage for Hungary. If this data were accessible that would mean companies would invest more in the country, particularly when it comes to clinical trials.

They could, for example, generate phase IV, post-market data to see how their drugs are performing. Also in terms of drug development, if they have a drug in phase III and are able to see the patient outcome of the actual treatment practice, then the companies can identify where patients would benefit the most from new developments. So, if this data gives us even more information and with a wider scope, then that can only serve to improve Hungary's investment appeal.

That being said however, there's also the risk of moving from a relatively stable and calculable market situation, which at its current state is not the most ideal, but at least we have a clear partner to a situation where we don't have a solid understanding of how the new system will work and operate.

So, from a strategic point of view, would you say the level of uncertainty is what worries you the most?

Absolutely. I'm expecting the risk of going through longer phases without securing reimbursement. Some of company's new drugs are currently waiting for public procurement, and within a European framework, managing a public procurement process is a relatively complex task, not only from the legal side, but also medically. This requires a capable administrative apparatus. But now if everyone is talking about changes and this public procurement process does not start, because of the foreseeable changes, then we will not only experience a level of uncertainty, but also paralysis. Today, I don't see a blueprint for responsibility delegations, criteria frameworks, or budget allocations.

Furthermore, Hungarian hospitals are struggling with huge debt obligations, and now if you combine with multiple budgets, then no one will truly understand the underlying issues—especially given the potential decline in transparency and efficiency. Ideally, at the end of the transition I hope to have transparent and structured regulations with people who understand pharmaceuticals, so we can continue to open the market for innovation

Considering that you're soon moving on to a regional role, what is the legacy that you would like to leave at Janssen Hungary?

In terms of business, I want to leave an organization that is still growing with key products on the reimbursement list. I would also like to leave a team that is composed of people that we've hired in

the last two to four years, as well as people with more experience and collaborative mentalities.

Beyond economic indicators, I hope that we are seen as the leader in medical education, with Janssen Academy positioned as the collaborative center for the medical community when it comes to physical and virtual learning. I also would like to have Janssen seen as a true partner with patient advocacy groups, which we are just starting to work on today. And finally, I hope our efforts with real-world evidence becomes ingrained—essentially getting to a point where we run analyses on the Hungarian database for all major in-market and future products to truly demonstrate the value of our innovations.

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