Interview: Jaroslav Duba – CEO, OAKS Consulting, Czech Republic



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The founder and CEO of OAKS Consulting Czech Republic reviews his success story, starting with the change in pricing and reimbursement legislation in 2007, and explains what is needed to gain market access today. Furthermore, he describes the Czech regulatory system as transparent, predictable, and fair—if managed correctly.

You founded OAKS Consulting in 2009, what was the rationale behind opening your own consultancy?

In 2007 the pricing and reimbursement procedures, at that time still based on decisions of a categorization committee, were completely remodeled because the system was neither predictable nor transparent. New legislation was prepared and amended to run starting January 2008—changing how to approach the topics of pricing and reimbursement from the perspective of pharmaceutical companies completely. The roles I inherited during my time in the pharmaceutical industry were always either business or sales roles and I had no knowledge about the skills and methods involved in pricing and reimbursement procedures, which was up to the point of change in legislation simply not needed. In the ‘old’ system there was a single point of contact in between the individual pharmaceutical companies and the categorization committee, in the new system, however, many people had to start dealing with the regulatory authorities. Realizing the need of knowledge due to my own situation, I had the idea to construct and e-learning platform for

everything needed to excel in regulatory procedures. By the end of 2007—right in time for the legislation change—we sold this e-learning platform to nearly every pharmaceutical company in the country. After the system worked, clients came back to us and asked if we could help them with their submission and reactions to the former of the State Institute for Drug Control (SUKL); that was the beginning of OAKS Consulting.

I started the operations from scratch with my laptop from home. Working on projects for two pharmaceutical companies, I had close contact with many former peers form the Industry and some of them were interest in joining. Today OAKS Consulting has 15 employees and business is running really well. The major reason behind our success is that all my employees have extensive industry experience, we're not just academics and theorists but have practical know-how. Our approach is to deliver real value, and not just consult for the sake of consulting.

Since you've started you grew quiet rapidly. What was the strategy that led to this rapid growth?

Indeed, we've enjoyed quite rapid growth. Interestingly no marketing activities were necessary to achieve this. The segment as such had—and has—significant demand and we simply keep fulfilling our clients' needs to full satisfaction and the projects' keep coming.

The only standardized product we have is what we call 'market access management outsourcing'. The SUKL and the ministry of health publish documents relevant to the different pharmaceutical stakeholders online and delete these documents after a five-day period. Many of my clients face difficulties of keeping track with these documents due to the nature of their own commercial activities. So we have a team which keeps track of all the documents provided by the SUKL and the ministry of health, writes summaries and together with action recommendations these are send to our clients within 24 hours after the documents have been released. These are also accessible online via an application we have developed for our client's convenience. Five of our 15 employees are solely responsible for that. Today, we enjoy providing services to almost 30 companies including a majority of leading MNCs from the pharmaceutical industry.

As longstanding expert on the Czech pricing and reimbursement system, to what extend do you think the dual system limits the Czech market attractiveness?

I'm not convinced that there is something that limits the attractiveness of the Czech Republic as a market. Indeed, you often hear lamentations of expatriates or corporate headquarters outside of the Czech Republic about low prices in the Czech Republic but that really isn't the realistic picture.

The Czech Republic has a dual regulation system in place, one for ex-factory maximum prices and the other for price reimbursement. The ex-factory price is referenced to the average price of the lowest three prices in a basket of 19 EU-nations—and to surprise to many, the lowest prices come from countries such as the UK or France rather than the CEE. And quite frankly, if pharmaceutical company manage their Pan-European pricing strategy correctly, they can avoid a “price surprise” in the Czech Republic. The price here can only be low due to the low prices in another country.

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The reimbursement procedures are slightly different. Reimbursement in the Czech Republic is assessed on the basis of therapeutic interchangeability, which means a pharmaceutical company should have a comprehensive analysis of the segment it plans to enter with its product and especially innovative molecule. The therapeutic model needs to be precisely described according to how it treats and what other options are available for patients now and then place the new product there deciding where they have EBM supporting data and where they want to be based on their corporate strategy. Will your product be placed where it serves unmet needs or will there be competition? That is the question to ask and if the latter case exists your treatment should be compared to those in terms of safety, efficacy and cost effectiveness and the reimbursement will be determined on similar level. If the product is not interchangeable, then the reimbursement level depends on Pan-European price management of the particular product.

What are the characteristics that make the Czech Republic an attractive market?

Its highly predictable, transparent and stable. Frankly, the only downside I identify is the predictability of timing. Generics and biosimilars are quite safe and are usually on the reimbursement list within 30 days because there is a fast-track procedure established which works quite well. The crux lies in the timing for new products. The legislation demands a time-span of 165 days, however, realistically it takes approximately one year to be on the reimbursement list hence why you can’t be certain when exactly you will enter. Nonetheless, the rest is highly predictable.

Crucial parts of assessment in the reimbursement procedure are health economic and budget impact analysis. Here it is important to pay attention to comprehensive analysis of the segment it plans to enter, development of therapeutically model and identification of all potential interventions which are currently used and are relevant for comparison. Mostly the only outcomes from registration clinical trials are not sufficient as comparators in those trials was either placebo or therapy which is not at the date of submission “standard of care”

Are there any plans to expand OAKS Consulting internationally?

The thought of expanding beyond the Czech boarders has been a frequent consideration and we concluded that this is not the right move for us. There were few—yet significant— reasons for that conclusion: the regulatory environment in each country is significantly different and in our segment one must have high expertise to excel. Secondly, I know from past experience how difficult it is to manage other branches especially in such a sophisticated segment such as ours. Our solution to expand our reach is a different one.

We have trusted partners in different countries across the region which offer the same portfolio we do with equally high quality and expertise. All of us often have international consulting companies as clients which got the contract from the pharmaceutical MNC and pass that on to the individual counterpart in the countries across the region. My partners and I want to bypass these larger firms and offer our services directly to the pharmaceutical industry. We're currently working on establishing one common presence through which we can offer our services for the whole region, with each partnering company taking on the responsibility for their own country. We will be able to offer added value to pharmaceutical MNC's and bypass the third party involvement.

How would you assess the competitive landscape in the Czech Republic?

The competition in the Czech Republic is rather limited as there are only few other market access service providers.

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Considering many years of our experience in the area of market access, when we prepared documents for more than 350 administrative procedures and a professional team of 15 specialists who have both the required education (medicine, pharmacy, statistics, mathematical modeling) and experiences with providing market access services, we believe that we are able to process required orders in the highest quality. Most of us have longtime working experience on the positions of regulatory, marketing, sales and top management in different pharmaceutical companies and therefore we bring a unique benefit and added value to our clients because we know from our experience the company processes including planning and pricing.

Where do you think your work impacts patients the most?

If we do our job right, we are significantly contributing in ensuring affordability of health care for patients through standard procedures and early access programs. We always see patients as the key subject in each project what leads us in our work and its successful completion.

What does your staff mean to you?

One day I will have to leave the company not because I want to have more time for myself, but rather because I realize I simply will not be able to deliver the added value to our customers which I am delivering today, nonetheless I would like to see OAKS Consulting keep growing as significant player in the field of market access. Therefore, my employees are the most valuable asset I have and I invest time, energy and money in them, so that one day they can replace the senior staff—including myself. Even now, all we do is only possible due to my employees and they are the reason why OAKS is able to deliver valuable solutions to our clients, without my people I couldn't do that.

Where will you have led OAKS Consulting to by 2020?

I believe the pharmaceutical industry will change completely in the coming years ahead. Autoimmune therapies and personalized medicines will change the global pharmaceutical landscape. More patients will be treated with better outcomes, however, this will be costly. And the big question is who will pay for these innovative treatments and drugs and I can see OAKS Consulting developing into this segment; decisions will be made differently and on the basis of different decision criteria.

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