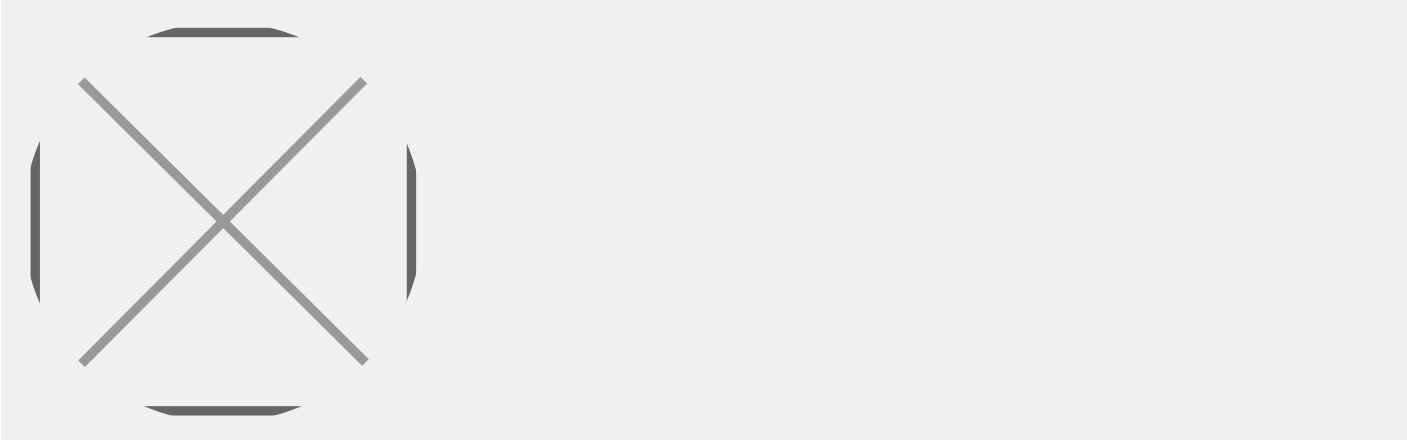
Interview with Luboš Chadim, General Manager, Astellas Czech Republic



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Mr. Chadim, after Astellas was formed from the merger between Yamanouchi and Fujisawa, it became your job to lead its Czech subsidiary. Tapani Sura, your colleague at Astellas Poland, has told Focus Reports that in Poland, Astellas' first year was a nightmare. "It is safe to say," he remarked, that "the company had experienced all possible problems within one year." Astellas turnover has since grown in Poland by 70%. What has been your own experience in forming and leading this subsidiary, and what growth trajectory have you enjoyed?

We also faced a number of major challenges in our early period, although our territory is different from Mr. Sura's in several ways.
The formation of Astellas' subsidiary in the Czech market was not particularly complicated from an integration standpoint, because Fujisawa was very, very small here—I believe they employed 4-5 people in this territory. They did, nonetheless, have an interesting product on the market: Tacrolimus. Yamanouchi CZ was then mid size company approximately 40 employees—but nonetheless larger than Fujisawa. I myself came to Astellas from Yamanouchi, and because of our larger size, it was clear from the beginning that we would build on Yamanouchi's existing Czech structure.

The merger between Fujisawa and Yamanouchi was a very logical step, and the combination of R&D programs made the company very efficient in terms of its future portfolio. Fujisawa was present in the hospital segment, while Yamanouchi was not—Yamanouchi was a pure primary care

and outpatient player. Fujisawa, finally, had a strong footing in the U.S., while Yamnaouchi did not. There were little overlapping redundancies, and it was truly a great merger that combined the strengths of both companies.

For me, the biggest challenge in our first year was to become familiar with the transplant segment. All of a sudden, 30% of my business was coming from this area. And it was a growing segment for us—at the time, the Fujisawa transplant product that I mentioned was not suffering from generics that time. The transplant segment was a significant growth driver for us. Today, despite generic competition, it continues to be a major part of our business.

Yamanouchi's pipeline became Astellas' pipeline, and continued to produce strong products in urology. In this segment, having already Omnic Tocas for treatment BPH, we launched Vesicare, followed by Eligard. The transplant pipeline then gave us Advagraf. 2005-2011 were very exciting years. We were able to offer our internal staff great opportunities and promotions—but more importantly, we were able to offer our patients great new products.

Our position in urology, both in Europe and in the Czech Republic, is very strong one. We are already a clear Global Category Leader (GCL) in this area. The same can be said about transplantation.

Meanwhile, the acquisitions Astellas made over the years have greatly strengthened our third major category – oncology. We are very close to launching our second oncology product (the first is Eligard for treatment of patients suffering from prostate carcinoma) which is expected to reach the European markets in next year.

You mentioned prior to the interview that the launch of new products is growing increasingly difficult in the Czech market. Can you expound upon this statement?

I believe that access to the market is getting more and more difficult. Astellas is increasingly moving from primary care to the hospital segment. Once you are there, you find that the market is not as disseminated as primary care—we are not looking at a range of stakeholders that include, say, 5,000 separate GPs. However, it is difficult to break into the hospital market, and the challenges are growing.

Between 2004-2006, there were many changes in how pricing and reimbursement are organized in this country. The system was simpler in the past, and, in principle, the Ministry of Finance dealt with prices, while the Ministry of Health (MOH) would set reimbursement levels. The authorities changed this, and delegated pricing and reimbursement decisions to a single body: SUKL.

On one hand, the MOH creates legislation, and passes it to SUKL for implementation. On the other hand, SUKL did not have the capacity to implement. The agency had a tremendous backlog, and is encumbered by complex procedural requirements.

From a budgeting perspective, the creation of SUKL was beneficial. However, the negative consequences we saw from the creation of this body ensured that many products were not launched on the market. Today, the doctrine of the MOH and of SUKL is to compare our reimbursement levels with the lowest prices for a final consumer in the EU27. This has significant impact on a) new product availability and b) parallel trade.

Every company that considers launching products in this territory is suffering because their headquarters will schedule Czech launches last in the schedule. Hence, Czech subsidiaries must wait. Once the product is, finally, launched, prices are low anyway, so profits are difficult. Furthermore, you will watch as your products are exported to higher-price markets, which will complicate the lives of your neighboring colleagues.

To escape this situation partly and hopefully for certain period of time, you can turn to the hospital segment. As I mentioned, this niche is difficult to break into—but hospital products enjoy relatively good prices, despite the presence of tenders. In these tenders, if your company has truly strong products that bring real added value, you can gain a good position. Fortunately, Astellas has such products.

Do you feel that Astellas receives a fair price for its products in this market?

For those products that we have on the market, I believe that we do. On the other hand, if we do not receive prices that we find economically workable, we do not launch the product here. This has been the case for certain drugs. It is very frustrating for us, because we must stand by and watch our neighboring subsidiaries succeed with these products. This is, too, quite frustrating for patients.

I believe that, if we would like to enjoy the same quality of care, in terms of product availability, as other European countries, then you should be ready pay for it. The Czech Republic is by no means one of the poorest countries in Europe—why, then, do we aim for the lowest prices in the EU27?

According to our conversation with Minister Heger, the capital is simply not available. Dr. Heger remarked that the Ministry is trying to spread the burden of payment, and to find greater efficiencies in the system via the implementation of health technology assessment—but more money is simply not forthcoming at the state level.

I can understand this position. But if we look at the situation fairly, we see that pharmaceuticals are always touched when it comes to cost-cutting measures. Equipment, for instance, has never been a real focus for cost reduction.

According to SUKL, this situation is set to change: a similar cost-benefit assessment framework will be put into place for medical devices as for drugs.

This is true, but I do not believe that the authorities will be able to easily compare prices in the medical device sphere. For pharmaceuticals, the system is simple, because the prices for every country in the EU are available on the Internet. Cost containment is therefore quite straightforward for the state. For medical devices, the situation is still, from my perspective, quite obscure. We know, moreover, that the leak of money from that sector is much more than we can see. Pharmaceuticals are very close to the people—everybody takes pills. However, patients do not know very much about the devices that were used in their treatment or what their cost should be.

For the last twenty years it has been quiet often told that pharmaceuticals comprise 35% of the cost of healthcare. This is true numerically, but the problem is that, while pharmaceutical prices were relatively similar around Europe, the cost of doctors (salaries) and hospitals (running cost) is far highger in a country like Germany. So there is no wonder that in the Czech Republic, we arrive at a number like 35%. If doctor salaries were akin to those in Germany, medicines would comprise only 15% of the total budget.

And yet, you have managed to find growth in this challenging environment—isn't that correct?

Yes we have. Astellas is doing well. One of the reasons for our success—not only in the Czech market but also in other countries—is the clarity of our strategy. Our Vision 2015 is founded on clear focus on a few therapeutic areas, among others. We do not try to participate everywhere; we take a limited number of therapeutic segments and try to be the best.

Our heritage is, as we discussed, urology and transplantation. Now, we have to look at which areas can deliver growth. In 2005, when our Vision 2015 was designed, our executives looked at where so called high unmet medical needs exist. We believe that those areas of unmet need will enjoy growth—and hence enjoy premium pricing. Unmet need areas today include niches like oncology, diabetes, pain -just to name a few. They do not include, say, cardiology: in cardiology, the market is already well saturated.

We implement the GCL strategy in the Czech Republic as well, and we are absolutely in line with our company KPIs. Comparing our sales in 2011 and 2006 we succeeded to double our revenues here in Czech Republic.

What do you expect to achieve by 2015, and beyond?

This is a good question, because there are several challenges that we must contend with. For one, we do not have basic patent for Vesicare in the Czech Republic and Slovakia. Therefore, unlike our other subsidiaries in Europe, we already face generic competition for Vesicare—a product that represents substantial part of our sales.

I believe that this year, we will again generate similar revenues like last year, but several products sales will increasingly suffer. We are not very much afraid of loosing market share from generic penetration; instead, competition has greatly eroded the price of the product. Under the new pricing system in this country, once a generic appears on the market, the pricing reference point is lowered. Thanks to our reputation as a company, we are actually selling far more units of our main products as we did prior to patent expiry, and we continue to enjoy unit growth. However, value is not growing accordingly—and value is the bottom line for a stock-listed organization.

The prices for our many products in the Czech Republic are currently on lower site those of Europe. We have two options: either improve our distribution strategy, or take the product off the market. Unit-wise, our products are market leaders in their therapeutic categories, which mean that thousands of people will not have access to our product if we are forced to remove it.

Looking beyond 2015, the future of our company is defined by our pipeline, and I believe that our direction is very clear. We are moving from primary care to specialty care and the hospital segment. Our strategic direction is clear that we must build up our next therapeutic area -oncology. We will continue to work within the GCL strategy.

Our product mix will change, of course. Currently, we have great number Phase I oncology projects. At least half will reach Phase II, and perhaps a few will reach approval. It is an exciting time to work for Astellas! I remember my time at Yamanouchi: I would not say it was boring, but the company was a bit stagnant. The same may be said of Fujisawa. If we had not merged, I am sure that each company would have failed, or been acquired.

In a 2007 interview with the Japanese Times, you mentioned Astellas' clinical trial efforts in the Czech Republic. You said, "The presence of clinical trials in the country is very important. Clinical trials enable doctors and administrators in local hospitals to see that Astellas is investing in local R&D and therefore giving back to the local medical community, which is very important.'' Has Astellas continued its commitment to clinical trials in subsequent years, and has this program continued to bring you such benefits?

Absolutely. This is one of the main strengths of Astellas in many of our markets. Our investment in this field is huge. All of our Central European subsidiaries enjoy an excellent reputation amongst healthcare professionals, and we have no problem attracting patients for trials, because there is still a huge need in these countries.

In the last years, the industry has increasingly been talking about the possibilities of personalized drugs. Astellas is betting on this approach: its R&D programs are directed not towards "Mass Medicine", but rather towards what it calls "Precision Medicine"—"offering highly effective therapeutic options for precisely defined patient populations based on molecular targeting and precision diagnostics." Do you believe that this approach of

moving beyond ‘one size fits all’ prescriptions is catching traction in the Czech market?

It must.

Look at the field of oncology. We currently have these huge pieces of equipment that non-discriminately kill not only tumor cells, but also body own cells. It is a matter of quality of life: what quality of life can a cancer patient enjoy when he has been subjected to such treatment? Precision medicine, based on tailored treatment and diagnostics, is the solution.

Another example is anti-infectives in the hospital segment. Again, we must make such drugs very, very targeted. Just yesterday, our newspapers discussed the ‘New Killers’ that are coming: for instance, a form of extreme diarrhea that attacks patients after a round of antibiotic treatment. In the UK, 8,000 people per year die from this disease. In the Czech Republic, we do not yet know the numbers, because no survey has been done. Hence, Astellas is undertaking a major pan-European project to understand the demographics of this infection, and we are on the verge of launching a new product that very precisely targets the cause of the disease. The benefit of this treatment is that it i very targeted, which does not damage any other microbes living in the intestine. Current antibiotics tend to kill everything in their path.

This approach is the future of our industry. If society does not recognize the importance of such concepts, then we are in a very poor position indeed. We must allocate money to this, instead of covering less significant areas . I know that the budget will always be limited—but we must decide where our priorities lie..

How would you describe your approach to your own position?

I understand my role as professional responsible for meeting company objectives.

What advice can you offer your fellow pharmaceutical managers operating in the Czech Republic about what it takes to be successful in an environment that you have largely described as quite challenging?

I believe that it is very important to, firstly, define where you would like to be, and to put your resources there and work as efficiently as possible. I believe that in today’s market, trying to be strong in 25 ATC groups is not a recipe for success.

At Astellas, for instance, we used to be present in the OTC and consumer goods market, but we sold out all. I know that diversity may be good from the standpoint of financial stability, but it will rarely put you on top. You must have a firm direction. Astellas decided that we would acquire or develop best in class or first in class products, and that this is the only way to ensure our survival.

Furthermore, those companies that believe they can just ‘sell a pill’ are deluding themselves. No—you must bring solutions. You must offer these solutions to the government, because the

authorities scrutinize each product that comes to the market, and they demand a great deal of added value. You cannot expect to receive a premium price for just incremental innovation.

This is my advice. I know that this approach is not possible for everybody—and therefore, the number of players in the environment will steadily decrease. Of course, we need ‘basic’ medicine. But do we need basic medicine because disease prevalence is high, or because we are over-diagnosing? I believe that in Central Europe, the consumption of products like antibiotics is much higher than in the rest of the world—it is our habit to expect a drug prescription when we visit a doctor. It seems that otherwise, we feel we have wasted our time. In the UK, only 2 out of 10 doctor visits are accompanied by a prescription; in the Czech Republic, the number is 6- 8. The Czech health care spends untold millions on this. I believe this scenario will change—and when it does, it will contribute to the market consolidation that I have described.

The Czech Republic is small market—about the size of Austria, Hungary, or Portugal. We have ten million people here. My vision is not to localize products specifically to this market. Instead, I believe in capitalizing on our global R&D investments and contributing to help patients to have better life –simply changing tomorrow.

Without good products, of course, we would have no chance to do this. Ten years ago, a lot of no added value products were sold on this market. There was little assessment or regulation. Those who were good in marketing sold an amazing number of products that like this. Today, those days are over: added value, premium price; no added value, no price!

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