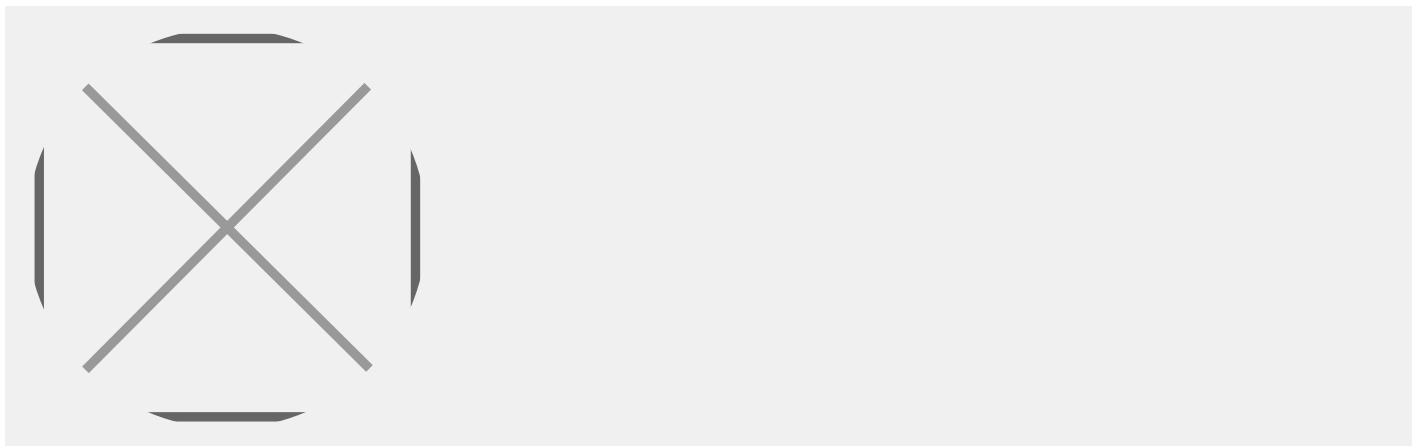


Interview with Berthold Cvach, Managing Director, Astellas Austria



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Whereas most General Managers are exposed to different countries during their professional career, you have chosen to dedicate yours to the Austrian market. What is it in this country so unique that has kept you here over the years?

It is a very good question. Since 1974, I have worked for six different companies. I started my career as a sales representative, and can certainly say today that I know every angle of the Austrian pharmaceutical industry. I have seen practically every hospital in this country – perhaps not all the doctors! – I have been active in many areas; I have learned how relationships are built; and I have become familiar with the different health systems, including the very complex reimbursement system.

Although I may have missed in my thirties the opportunity to go abroad, for example to Germany, I am happy with my choice, as I have been able to offer this company extensive Austrian knowledge and know-how. I find this much more valuable than being a managing director in different countries for short periods of time without being able to get a full grasp of each market.

Because I have the background of a pharmacist, I feel I need to know what I am doing. I am interested in natural science, and therefore I am not a manager solely geared to economics. I am a firm believer that the cultural aspects of each and every country are not given enough credit. Especially in Europe, each country has its own specificities.

Has it been challenging to create in Astellas Austria a unified company culture and management style, after the 2005 merger between Yamanouchi and Fujisawa, considering this affiliate inherits from a family owned and traditional Austrian business – Klinge pharma?

Actually, there was any particular challenge for me when the merger took place, because Yamanouchi was not present in the Austrian market before 2005. Therefore, in the country, it was only necessary to convert the organization to a modern global company. We were also fortunate in the sense that no one was afraid to lose their job during the merger.

I started in 2000 with Klinge, which was a local, very cosy and traditional family business, based in Munich, with a robust business base through subsidiaries in Switzerland and Austria.

When Fujisawa came to play, the company's focus did become a bit different, but the real global aspects came with the creation of Astellas. From this moment on, I focused on opening the minds of our people to the new areas that we were moving into, and on the company's new organisational concepts.

Indeed, Astellas brought a different approach to the way a company is organized, which I find very professional. It has a matrix structure, whereby all managers, i.e. the regulatory, financial, marketing, clinical and other managers, do a functional reporting to European headquarters, and often attend international meetings, hence getting exposure to international strategies.

I value very much the fact that Astellas understands, and it is worth mentioning, that there are differences in the German and Austrian work cultures, although the same language is spoken in both countries. And believe me, not all companies make this difference! Austria is not a small Germany, or the 17th German federal state; it is a completely different market, both in terms of its healthcare system and of its people's mindsets.

At Astellas, I feel myself very much at home, and at the end of my professional career, I find Astellas has been the best company I have ever worked for. The company's products are excellent, the pipeline is promising; our managers give us professional support, understand that Austria is different, give me room to operate, and provide me with a lot of trust.

What is the management approach towards delivering sales results?

Astellas Austria ranks around the 21st or 22nd position, hence we are in line with the global performance.

Japanese companies are working on a sustainable business, which marks the difference with American companies. A few years ago, I worked for Abbott as a division manager for the pharmaceutical business in Austria. Every quarter, I had to deliver new record results, and I

thought this was too short thinking for the pharmaceutical industry.

Of course, Tokyo also wants to see results, and is very demanding in that regard. But the difference lies in their ability to think in the longer term. This fits to the European thinking as well, and to keep business to a medium to long term sustainability.

In 2005, the company's vision for 2015 was established, and we are really living for this. We have our own vision for Austria as well, with adapted objectives.

In its vision 2015, Astellas aims to become a global category leader. Are you reaching this point for your target areas in the Austrian context?

We have already achieved category leader status for transplantation. For urology, as Yamanouchi was not present in the Austrian market before the merger, we had to launch the portfolio from scratch in 2006. In a couple of years, I expect that we will be leading in this therapeutic area as well.

Dermatology was originally one of the focus areas with Fujisawa, although it is a small franchise. In Anti-infectives, we launched Mycamine in 2009, and this year we launched Difclir. Mycamine should generate 1.5m+ Euros in sales this year, which represents a 15% to 20% market share. Austria is amongst the top European affiliates to have successfully launched Difclir.

As for oncology, I can only make predictions, but I am very confident. We will introduce the molecule enzalutamide (called Xtandi in the US), which is a significant breakthrough and is expected to become a blockbuster drug. Astellas's strengths in oncology are based on the company's urology experience.

While the global innovative pharma industry faces LOE issues, and is forced to find alternatives to its model, Astellas has 30 major projects in Phase 3 or pending approval, and more than 50 projects in early-phase clinical development. How do you envision the next couple of years in Austria? What is the growth potential for the Austrian affiliate?

I am looking at the future of Astellas' presence in Austria very positively. Astellas' way of thinking is that first, the products must be superior, and then you can get a price for them. However, in Austria, to obtain reimbursement on your products, you have to prove to the Austrian authorities that your products have a certain innovative, clinical and economic superiority over the other candidates. I am very confident that the next four or five products we are launching in Austria will have these attributes.

Moreover, the hospital market in Austria is not as regulated as the other European countries. Therefore, we can present a product with a price around the average European price, notify it to the Ministry of Health, and then we can sell this product in hospitals. This applies to our

commercialization strategy for anti-infectives, and also concerns part of our oncology portfolio. Hence these two areas benefit from a fast entry to the market. In Austria, hospitals are organized in holdings, so we need to approach these holdings to have our products purchased, which is a much easier process than having doctors prescribe your drugs.

How do you assess Astellas' capacity to resist generic competition in Austria?

Generic competition is one of the main issues I have faced here. For instance, the patent for Prograf, which was the largest product in our portfolio, expired in 2009, and last year the first generic came in. In the Austrian system, when the first generic comes in, the Sick Fund demands a price reduction of 30%, and by the time the third generic is in, your price has to be reduced by 60%.

Therefore we can still keep market share in volume, but of course we lose a lot of margin.

How is this situation seen from outside Austria by your colleagues?

In other markets, for example Germany or the Netherlands, generic competition is much more fierce because they are not only losing price, but also volume, due to the system demanding a higher generic usage.

It depends on the therapies: in certain areas, it is often a matter of how the product is trusted and how many lives it has saved, as patients do not risk changing a trusted brand for another generic which they do not know anything about. It gives us a high possibility to keep sales volume high.

Just like in Ireland or in the Netherlands, Austria has been incentivizing the research sector by creating a favourable tax regime allocated to companies investing heavily in R&D. In Austria we have seen the development of life science clusters and research centres or institutes. Can Astellas' next research centre in Europe see the light in Austria?

It is part of Astellas' strategy to run clinical trials in all major markets, in order to get physicians and clinicians familiar with the new molecules and therapies very early on in the process. This is what we took up, and in Austria we have a small department with 8 people monitoring and managing clinical trials.

This also enables us to internally much better understand all the products. For instance, the product Qutenza is a pain medication in the form of a patch, which burns the nerves and regulates pain on the skin, and works for 90 days. Qutenza was in-licensed from a US-company and was a completely new concept. The Austrian doctors had never seen this product before, and it was important for everyone to become familiar with the product. Hence we tried very early to have our pain specialists exposed to the product.

How will you measure your success in the coming years?

The key for future success will be our ability to launch new molecules in Austria. This year, Dificlir is a good example, it is a new antibacterial for C. difficile infection causing diarrhoea. This is a huge problem in hospitals because of the recurrence of patient visits. The disease and its hazards are unrecognized. Dificlir clearly adds value when compared to the previous treatments, as even though it might be slightly more expensive, the rate of people coming back to the hospitals drops by half.

Therefore Dificlir needs a campaign to raise the Austrian public awareness about its added value. We do some public relations activities, and in one press conference, one of our specialists showed the outcomes of his research on the benefits of Dificlir. It tracked how many people were infected, and how frequently it would cause severe damages. This led to an inquiry in the House of Parliament, addressed to the minister of health, to find out if he knew the dangers of the disease. Today, we see this product increasingly prescribed in Austrian hospitals. I received a green jersey recognition for the first Dificlir ever sold in Europe.

Similarly, I see great opportunities in Austria for Enzalutamide. We will have this product enter the reimbursement system by demonstrating what it brings to patients. It is a therapy for Castration-resistant Prostate Cancer, which enables patients to live 4,8 months longer. This is a value which you do not see often in oncology therapy!

Austria's minister of health recently stated he aims at prolonging the lives of Austrian people by 2 years, which is an objective Astellas is totally aligned with, thanks to our innovative solutions.

Profits are not an objective, they are a result of our activities. If we put patients and values first, the profits come automatically. We apply this principle in our local situation, and under the guidance of Astellas Pharma Europe's new CEO Mr Ken Jones, who is the first non-Japanese President for Astellas, and whom I trust very much.

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