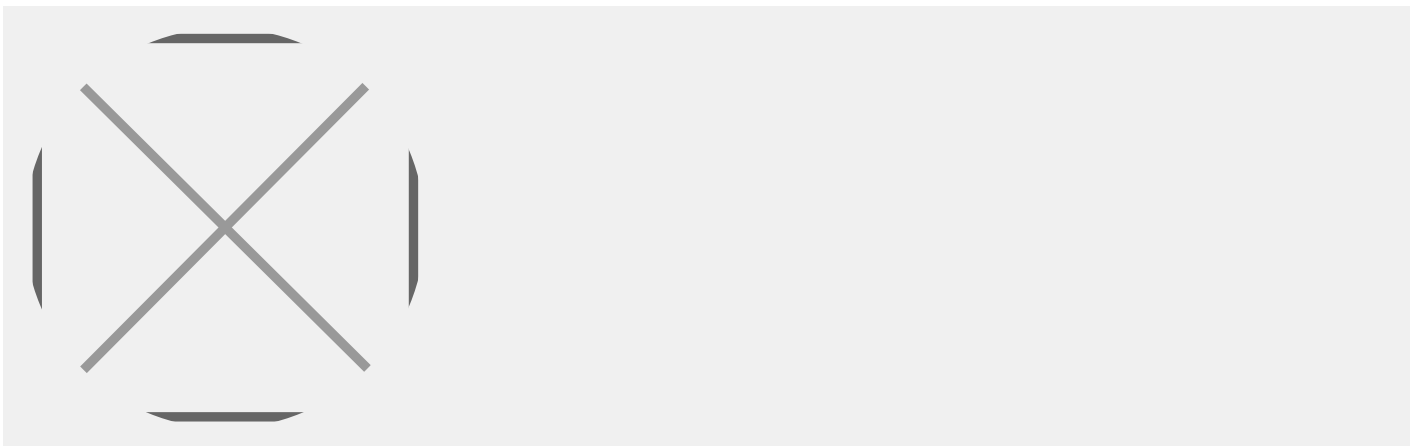


Interview with Jean-Philippe Duc, Country Manager, Amgen Czech Republic



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Mr. Duc, you first worked in the Czech Republic in 1997, as an Oncology Business Unit manager for Pierre Fabre. The '90s in this country have been described to us as a 'wild' time, with little regulation and easy growth. Since then, the Czech pharma market became much more complex from a regulatory standpoint, and it became considerably harder to grow here. Mr. Pfannenschmidt, head of Boehringer Ingelheim CZ, told us, "People were not prepared for these changes. People working in the industry for 10 to 20 years being used to the constant growth of the market struggled to handle the business under different rules." How would you compare the market of today to the one you say in 1997, and do you believe the pharmaceutical industry is approaching the Czech Republic with the correct strategy?

There have of course been major changes in the market between the 1990s and today. This has partly been driven by the broader economic environment, because when you are riding an economy that is growing by double digits or high single digits, you are in quite a different situation than when you find yourself in an economy with low single digit or even negative growth.

In the '90s, pharmaceutical companies did indeed enjoy economic growth. Many companies were entering the market, and bringing innovation. Amongst Czech society, there was a strong need for modern medicine.

There are also major differences between the way we worked in the '90s, and the way we work today. In the past, bringing a new product to market and demonstrating its clinical efficacy was sufficient to drive success. Today, authorities are much more scrupulously looking for value and

quality if they are to spend money on pharmaceuticals. This trend has become even more pronounced in the last three years, in light of the global financial crisis—there are increasing barriers, and an increasing need to demonstrate the value of your latest innovations in order to get the price and reimbursement levels that you targeted. Like in other countries, the major difference between the '90s and today is hence really a question of market access.

Furthermore, today we find an increasing trend towards transparency and ethical practice, and better regulation of the way we conduct business. This is of course the right direction for the market. Our industry is, obviously, different from many other industries, and it is necessary for us to work within an ethical framework. Every country in the CEE is taking this path—it is a big evolution in the environment.

Where does Amgen stand on this market today?

We have been present on the Czech market since 2004. Our first priorities were to bring our existing portfolio to a new territory, set up operations, and ensure that healthcare professionals have access to our products. I believe that since our early years, we have reached a stage where our portfolio has become more established, and the products that we launched at that time have now gained solid positions.

Our objective today is to ensure that we continue to bring innovation to this market. In the past three years, we have launched several new products. For instance, just last year, we launched a new molecule indicated in the treatment of osteoporosis; We are also expanding our oncology franchise with new products and indications.

We are trying to maintain growth on this market—which, in the current climate, is challenging. The market at large is growing at around 1% in value. This year, Amgen is growing above this level. We will see at the end of the year where we land, but we are going in the right direction. We have a dynamic portfolio.

We are competing well against our competitors, but our company values center around more than competition: they center on collaboration, communication, and ethics. We do compete, and we want to win, but within the bounds of our code of conduct as AIFP standards. I am proud to say that Amgen has one of the highest industry standards of compliance and ethics.

The IMS has noted that access can take up to three years longer in the Czech market, relative even to close neighbors like Austria.

Three years is perhaps on the higher end, but we definitely see a delay in comparison to some of the countries in the EU zone. A period of 12-18 months to reach reimbursement can be common.

Of course, payers want to ensure that they pay for the right value and the right quality, but at the same time, one can argue that patients need quicker access to new therapeutic options.

Another difficulty we observe is that companies develop their product for a particular indication, and this indication is harmonized across EMEA. Afterwards, locally, payers decide whether to accept to pay for the full indication. The more we move forward, the more we can see that payers seek to be more selective in the base of payment.

A second challenging dimension that I see at the moment is that once you pass the barrier of receiving a reimbursement price from SUKL and the insurance companies, you may then face situations where local budgets are sometimes not ready or sufficient to access innovative medicines. Getting reimbursement is not the end-all; you also need to demonstrate the value of your product locally, to hospitals and other local healthcare providers. You need to ensure that they have organized their budget in a way that gives space for innovation.

In our recent conversation with Mr. Zahradnik at Teva CZ, he mentioned that a market needs to display three characteristics to be labeled 'attractive': the first is transparency; the second and third are sustainability and predictability. How would you rate the market on the latter two elements?

In terms of predictability, I would say that if we compare the Czech Republic to other countries in the region, we see a positive difference. The situation in the market is not entirely predictable—there are always some surprises—but overall, compared to our neighbors, the Czech market is a considerably more stable environment. And, because of increasing transparency, we can reasonably anticipate changes in regulation.

Of course, we would like to have predictability on a longer timeline. I don't think we can expect any major surprise in the next one or two years; but, in a business such as ours, we would like to have at least 3-5 years of visibility. In this sense, I believe that the country can improve—but, again, we are doing better than our neighbors.

With regard to sustainability, I believe that this factor is really driven by the greater economic environment and whether countries can deal with financial turmoil without any impact on elements of their spending. The level of national debt in Poland or the Czech Republic is not as dramatic as other EU countries. Nonetheless, authorities are very reactive in balancing their budget—if they see that the economy is on a downward path, they quickly adjust their expenses. This creates difficulties in both the predictability and sustainability of our business, because healthcare is part of that equation.

When you spoke about predictability as a function of market attractiveness, you compared the Czech Republic to other countries in the CEE; however, many compare the healthcare

standard in this country to Western Europe—and, in fact, the country seems to be striving for a Western European standard. So should the Czech Republic be held up to greater scrutiny in terms of market attractiveness, as well?

This is a fair point. However, for all of its successes, this is still a new country, and it is still not yet at the level of a nation like Germany in terms of the organization of the healthcare system. But as we discussed, the market is improving a lot—and there are additional reforms coming to spur further evolution.

As a long-term goal, I believe that yes, in terms of things like predictability, the Czech market should look to compare itself with Western Europe. This is where we are going. However, I believe that it is unfair to the country to expect change in such a short timeframe. If we look at the evolutions that have taken place here in only 20 short years, it is quite remarkable.

Returning to Amgen: this company has increasingly been making forays into the generics sector, by teaming up with Watson Pharmaceuticals to develop biosimilars. Amgen has largely escaped the competitive pressure faced after patent expiry on chemically-based drugs—however, with the rise of biosimilars, does Amgen expect that times are changing? What will be the effects of this new strategy in the Czech market?

As an innovation-driven company, our primary focus is to continue discovering, developing, and commercializing new medicines—however, we also believe that biosimilars have a role to play in providing an important option for some patients, provided that they are safe and effective. Amgen is well positioned to enter this field because of our proven capability to develop and manufacture biological products. On that perspective, it makes sense that Amgen takes this direction.

Regarding the potential launch of biosimilars in the Czech Republic, we have not yet announced our global commercialization plans, so I cannot comment on that.

Conversely, regarding biosimilars competing with our products: this is something that will certainly come. Actually, we have already this experience, with Neupogen—several biosimilars have been launched on the Czech market in recent years.

Our best strategy in the face of competition, in the end, is really to continue to bring innovation. In the past, Amgen was a two-product company in this market, but today our portfolio is much more diverse.

Is there anything that particularly excites you about your pipeline?

It is difficult to select what excites me most! We have a really fantastic pipeline—particularly in oncology. We have several oncology products that are in the midterm testing period and look very promising.

The interesting thing about Amgen is that we are now expanding into new therapeutic areas—beyond our traditional niches of nephrology, oncology, and bone. We have a product in our pipeline, for instance, for hyperlipidemia. It is quite exciting in terms of mode of action, and the way in which it can help patients.

Amgen is an historic company in the biotech industry—this is the company that launched the sector’s first blockbusters, and was for many years an ideal that was emulated by many other biotech players. In the 1990s, Amgen was one of a handful of biotech companies that was able to achieve critical mass without selling out to a big pharmaceutical company. However, some analysts are now saying that, as the biggest of Big Biotech, Amgen is losing its innovative culture and focusing on Wall Street, by engaging in complex stock buybacks and paying its first dividends. As someone that has worked at Amgen for close to a decade, what can you say to those claiming this company is looking more and more like the Big Pharma companies whose mold it always tried to break?

Globally, Amgen has been growing quite impressively over the last ten years. We developed our portfolio, and we developed our geographic presence. Ten years ago, the share of our business in European countries was much smaller, and today these markets contribute to a sizeable and continuously expanding proportion of Amgen revenues. If we look at our pipeline, moreover, it has never been stronger, and it is recognized as one of the best in the industry.

I will not comment on the opinions of the analysts you mentioned. But as someone looking at this company from the inside, I truly believe that it has retained its core values and its focus on innovation. We are really focused on driving science forward in places of unmet need. This has never changed.

Obviously, we are growing, so we need to adapt. We cannot work in the same way that we worked when there were 1,000 employees in the organization. But in terms of nimbleness, and capability to adapt, I am quite impressed with how we are able to move despite our size. I believe that we are actually much quicker to make decisions than we were some years ago.

Amgen entered the Czech market in 2004. When you celebrate ten years in 2014, where would you like to be in the marketplace?

I would like this company to remain on the path of growth, and fully adapted to the environment—meaning continuously bringing innovation and capable of demonstrating its value to Czech stakeholders.

Amgen in the Czech Republic will remain a company with a strong medical footprint. We have a strong R&D entity here, and this will remain an important element of our strategy. About two thirds of our Czech staff work in R&D. This demonstrates the strong long-term commitment of our company to the Czech Republic.

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