

# Interview: Gabor Stanislav - General Manager, Amgen Romania

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*One of the new generation of pharmaceutical general managers in Romania discusses the complexities of introducing innovative therapies on the market and explains how the country has become the 'to-go-to' destination for relocating pharma companies' support services.*

**Amgen has been present in Romania as far back as 2004. Can you please start by telling us how the company's interactions with the local market have evolved over time?**

Amgen is actually quite a young company established as recently as 1981. In the initial years the company essentially comprised a group of scientists with some investors behind them and without any products to sell so quite a unique and interesting business model that has positive implications for the corporate ethos even today.

The first marketing authorization was gained a decade later in 1991 for the "home" North American market. Then, twenty years ago, Amgen took the decisive step of expanding into the European markets to achieve critical mass, but central and eastern European countries were not yet prime targets. Amgen's first central European affiliates actually started being established approximately a decade ago with the Viennese office functioning as the local regional hub. In those days, Central and Eastern European markets were primarily driven by nation states such as the Czech Republic, Hungary and Poland. Then, when Romania and Bulgaria joined the European Union there was a decision at the global management board level that the markets were attractive enough to start

directly engaging.

European Union membership was in many respects a game changer in terms of investor attractiveness for Romania and Bulgaria, because being inside the EU club fosters the sort of firm legislative environment and politico-economic predictability that is sufficient enough for companies like Amgen to seriously consider establishing local affiliates.

We first launched products on the Romanian market in 2004 through two distributors. The strategic decision to open the affiliate was then made in 2009 with our local office physically opening its doors to business in 2010. We celebrated our fifth year's anniversary as recently as December last year.

**What would you say have been the main milestone moments for Amgen in Romania in recent years since you were appointed country director?**

The main milestones have been the increasing of our in-country workforce to close to 50 employees. We have also extended the number of personnel involved in phase III clinical trials and we have been investing and developing deeply in this direction to the point that it is now fair to say that Romania represents an important clinical trials destination country for Amgen.

Another critical milestone that has been met has been having our first products placed on the reimbursement list last year. Amgen is globally renowned for possessing a portfolio of pioneering medicines for therapeutic areas such as cancer, kidney disease and rheumatoid arthritis and this prowess is also mirrored at the local level on the Romanian market where we are registering a high performance for selected oncology and bone disease therapies.

**How strategically important, then, are Amgen's Romanian activities considered relative to the company's regional and global operations?**

Traditionally Romania has not been considered quite as strategically important as some other CEE markets such as the Czech Republic, Hungary and Poland though attitudes are starting to change as new opportunities open up. In terms of the market fundamentals there are quite number of positives: the country is vast, the population deep and the demand very buoyant both over the long and short perspectives. In this respect, the potential certainly is there for companies like Amgen to be doing a great deal of business.

On the other hand, the current climate is worrisome in the sense that our global management board invests where the market environment is predictable and sustainable and Romania has become one of the least in Europe on both counts. Companies like Amgen generally tend to

allocate investments in R&D and manufacturing according to how open a country is to innovation because at the end of the day we are research driven businesses that specialize in innovation. That is the core bread and butter of what we do. Having six or seven years delay to the reimbursement list is unfortunately a strong indicator that the country is not yet properly open to innovation and that has implications for making capital investments.

**Can you please elaborate on this deficit of innovation and how it comes about?**

It's a fact that the growth of the Romanian pharmaceuticals market is not coming from innovative high price products: a full 70percent of all units sold in Romania constitute generics. Ordinarily the generics and innovator sides of a pharmaceutical industry should work in tandem, in balance and in harmony. We consider it entirely natural and correct that cheaper, generic versions of branded innovations should be encouraged to penetrate the market, but ordinarily the savings generated from those cheaper generics would be reinvested back into healthcare and pay for the reimbursement of latest-generation innovative molecules. In Romania we are missing this second part of the equation. There is a national program that is promoting the use of generics, but little awareness at the public authority and governmental level of the need to be investing in bringing in new innovative treatments.

There is a misconception that for all medications there is a generic alternative that exists, is equally effective and more affordable. If there is a generic that is cheaper and available then, of course, we can unanimously agree on the virtue of having a system in place that favors the integration into the market of that cheaper but equally effective product. Sadly, however, there are a great deal of cases where there is simply not an alternative or the higher priced option is scientifically proven as possessing more effective properties. This leads to end outcomes where patients are unable to get the treatments they deserve.

The lack of access to innovative medicine also ironically drives the growth of clinical trials. Clinical trials represent an alternative, and sometimes the only, option for patients to have access to innovative, new-generation molecules when there are typically several years of delays in registering and ensuring commercially available new molecules. Doctors, for their part, tell us it is very frustrating to go to a scientific forum when their counterparts in other CEE countries are discussing products that they have been using for the past five years whereas they have no access to or experience of those products. The clinical trials, on the other hand allow them some exposure and Amgen is proud to be playing some role in this.

## **How can innovative medicines, despite escalating drug prices, contribute to the sustainability of Romanian healthcare provision?**

In Romania, healthcare is commonly considered from a purely fiscal point of view meaning how many euros we are spending on medicines and treatment programs. What should be factored in as well are the indirect societal consequences. If life expectancy remains one of the lowest in Europe or if the number of days spent on sick leave by workers remains abnormally high then this is going to harm the economy as a whole and translate into reduced productivity and a lower tax intake. There are a multitude of studies to back up the fact that under such conditions the end balance is a negative one. If you don't spend a sufficient amount on healthcare then it will have a negative impact on the overall state budget and the economic health of the country. This needs to be accepted and understood by the authorities.

Savings that are generated by allowing generics and biosimilars to enter the market once patents have expired should automatically and immediately be reinvested towards bringing in new innovative products because there are really amazing developments in some specific therapeutic areas that simply didn't exist five to ten years ago. I'm talking about state of the art products that don't merely prolong life, but can cure specific diseases. Reimbursing these types of products obviously involves some upfront cost in the short-term, but would reap an economic dividend in the medium to long term. There is absolutely no doubt innovative medicine can be drivers to healthcare sustainability. It just takes some big-picture analysis and an awareness of the nexus between health spending and the overall national economy.

Let's not forget either that more money in absolute terms should be allocated towards the local health sector. Today, the Romanian state spends substantially less than any other EU member on pharmaceuticals and less than most other non-member European countries as well. We need to swiftly align with countries that are on a similar economic footing. Unfortunately in the priority list of the citizens, healthcare isn't yet ranked as being in the top three. The picture is very different in Scandinavia, France and the UK. If we can change mind-sets at the level of the citizen and the weight that they ascribe to public health provision, then that will logically change the priorities of the government too.

**Amgen has spotted that Romania holds competitive advantage for situating some of the support functions of the company. I'm thinking especially of the relocation of your business security operations center (BSOC) capabilities to Bucharest. Tell us about this?**

This is a market segment where the taxation environment and employee incentives are aligned in the right way to really incentivize investment. Amgen essentially decided to relocate its entire information technology security department from California to Romania meaning the new center constitutes a fully global department with extensive reach dedicated to serving Amgen needs across the world.

Recognized as a hub for information technology services due to a legacy of strong and extensive engineering and IT education programs, a population with both a high level of technical skill and proficiency in diverse languages and competitive prices for services, Romania turned out to be the natural choice as host-country.

I actually view this as a shining example of what can ultimately be achieved in Romania when the different stakeholders put their minds to it. The country possesses a very strong labor pool in terms of talent, education and availability and when this is combined with a competitive fiscal environment it actually becomes a winning hand and magnet for investment. My hope is that, in time, local manufacturing of pharmaceuticals could be incentivized in an analogous manner. Were this to happen both innovators and generics companies alike would surely demonstrate great willingness to invest.

### **What are your future goals and aspirations for developing Amgen in Romania?**

A biotechnology pioneer since the 1980s, Amgen has grown into one of the world's leading independent biotech companies developing a pipeline of medicines with breakaway potential. We are, at heart, an R&D organization focused on a "biology-first" approach when the paradigm for this industry remains innovation. As such my vision is very much to position the firm as a primary conduit for introducing innovation to the local market that will generate a step-change in positive health outcomes for the Romanian patient.

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