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Improving the evaluation process is crucial to ensure that real breakthrough innovative therapies can pass this stage and enter the pricing discussion

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Gábor Sztaniszláv talks through the global relevance of Belux to Amgen's operations, some of the challenging market access conditions at play - especially for orphan drugs -, and how the company's biosimilar portfolio has the potential to contribute to significant savings for the healthcare system.

As the general manager of Amgen BeLux, what were your first impressions of the healthcare ecosystem after transitioning from Central Eastern Europe? What personal motivations did you have?

I arrived in Belgium almost three years ago, having spent most of my life and professional career in Central Eastern Europe. It was a special moment as we arrived between the first and second lockdown and only a caretaker government was in place. Despite these challenges, the country was able to operate quite well in the fight against COVID-19, which speaks to the strength of the healthcare system and how it is established. On a personal level, it was also quite challenging because everything was closed, and we couldn’t even go out to a restaurant or invite anyone into our home. However, I found and still find Belgium to be a charming and enjoyable country with a rich cultural history and friendly atmosphere, and I am excited to be here.

One of my motivations to move to Belgium was that, despite its relatively small population size, Belgium is an attractive environment for innovative healthcare companies. Our local branch in

Belgium and Luxembourg is twice the size of the one in Poland, where I had come from, even if Poland has around 36 million inhabitants, while Belgium and Luxembourg together have around 12 million. This is a testimony to the importance of the healthcare industry in these countries.

However, Belgium is a rather complex country. It has three regions and three communities (French-, Flemish-, and German-speaking) with their own governments. The distribution of competencies across these governments is complicated, especially when it comes to public health. In total, there are nine ministers charged with some aspect of health policy. I professionally find such complexity a great challenge to embrace. Additionally, this is the first Western European market that I am directly managing, which made it even more attractive from a personal career perspective.

What is the positioning of the Belux affiliate among Amgen's European operations? How has the local organisation been performing over the last few years?

Amgen BeLux is an important affiliate for the company. Although we are of a modest size, we are one of the most important mid-sized European markets commercially. Last year, only the Netherlands and the Swiss affiliate had a bigger turnover than Belgium from this group. Another strong aspect of our operations in Belgium is the clinical department which covers Belgium, the Netherlands, and Luxembourg, making it the fourth biggest clinical trial hub within Amgen outside the US. We also have various global roles based in our Brussels office, given the proximity of important European institutions. Hence, our affiliate serves far more than just the Belgian market.

In terms of the local organisation in the last few years, we successfully implemented a remote way of working in the middle of the COVID pandemic, which received highly positive feedback from our employees. Amgen has announced that we will continue to work in 'flex-space'. Although it's not mandatory for people to come to the office anymore, face-to-face interactions are still necessary for certain meetings.

We have around 130 colleagues at the affiliate and more than half of them work for the commercial part of the operations. We have followed the trends with digital communication and omnichannel marketing approaches and have put in place completely new types of roles that focus on partnerships with hospitals and customers, putting a strong focus on patient outcomes. We try to offer solutions for healthcare providers or directly to patients, and we see ourselves as problem solvers, not just a commercial organisation bringing products forward.

How would you characterise Amgen's portfolio in Belgium?

As an Amgen affiliate, we have a portfolio consisting of innovative products in our historically strong areas of oncology and haematology. However, one of our key molecules is for bone disease, with an indication in oncology and osteoporosis. We also have a growing inflammation portfolio and innovative products in nephrology and cardiology. In addition to our innovative products, we have our own biosimilar portfolio, which we offer to Belgian patients to contribute to the savings of the system. Overall, our portfolio brings a nice balance of new, innovative brands and biosimilars.

A significant portion of our portfolio, as well as our future pipeline, consists of orphan drugs. Unfortunately, the success rate for reimbursement of these drugs in Belgium is rather low compared to other types of medicines. My understanding is that this could be further impacted by policy reforms that are currently taking place, which are looking for more standard types of health technology assessments for orphan drugs. As we are talking about a very low number of patients, this may have limited impact on a broader society but could be critical and lifesaving for the impacted patients. This is a challenge not only for Belgian authorities, but for Europe as a whole.

Having come from markets where it can be challenging to budget for the newest innovative therapies, what is your perspective of the Belgian market access conditions, in a country that has one of the highest GDP per capita in the EU?

Belgian market access conditions are becoming more and more challenging. Historically, Belgium was an open country for innovation and had a nice ecosystem between its R&D capabilities and market access – where reimbursement was not the fastest but still done in timely manner. However, in the last couple of years, this has been slowing down. Compared to countries with similar economic power such as the Netherlands, Finland, France or Austria, access in Belgium is getting narrower. The majority of products that got a negative reimbursement decision in Belgium are available in these EU countries and the waiting time between marketing authorization and reimbursement has put Belgium below the EU average. Another problem is that, once reimbursed, the approved reimbursement criteria are often much narrower than the product label itself. A high number of products do get reimbursed, but usually at very low price and with a restricted patient population.

I believe Belgian patients deserve the same access to breakthrough innovations so we should continue our tireless work and maintain the dialogue with the decision makers and the scientific community in order to change this trend.

Early access is one of the areas of the Ministry of Health and the payer are looking to seek legislative improvements. Do you have any opinion about their roadmap?

In my opinion, the proposed reform goals could be a positive evolution for improving access and making the process clearer for the industry, but there needs to be a more usable mechanism in place for earlier access to breakthrough therapies. The current system doesn't allow for temporary or partial reimbursement before the official reimbursement decision is made. The majority of the EU countries have well-working mechanisms in place which grant early access to real innovations for the patients and the costs are not solely charged to the manufacturer as is currently the case in Belgium. From my personal point of view, the real impactful development would be to significantly improve the quality of the scientific evaluations. It's problematic that sometimes products with real added value and critical impact on patients' life receive negative recommendations already at a very early stage of the process. The involvement of the scientific community and experts in the evaluation process would be a positive improvement to determine if a product presents a significant added value compared to the standard of care and to let it pass the stage and enter the discussion to agree on a price.

I believe that involving specialty professionals who are knowledgeable in a particular therapeutic area would allow a more accurate and objective evaluation of whether a product has a significant added value compared to the standard of care. This would enable promising products to enter discussions on agreeing on a price. However, in the current system products often do not reach this stage, resulting in many promising products falling out of the system too early. Therefore, improving the evaluation process is crucial to ensure that real breakthrough innovative therapies can pass this stage and enter the pricing discussion.

Can you tell us about the involvement of Amgen in clinical trials, especially Phase I trials, in Belgium?

I believe that the country is attractive for early-stage trials due to the fast approval process of the trials by the authorities and the presence of important universities and clinical centres with proper scientific knowledge and background. There are also enough centres that are qualified for conducting Phase I trials. As for Amgen, we try to participate in as many trials as possible. However, Phase III trials, especially for chronic diseases, present a big ethical dilemma because we have patients who are treated with our Phase III trial, but then after the marketing authorization is

granted we often have to wait too long for reimbursement. In some cases, we are asked to provide the product for free post-approval, and this can be challenging to sustain. Additionally, the unpredictability of whether the product will be reimbursed or not makes it difficult to decide if we should bring certain trials to Belgium at all. Some manufacturers have even halted clinical trials in Belgium, which is a concerning tendency.

We hope that decision-makers understand that there is a government-supported intention to bring more innovation and clinical trials to Belgium. However, if this is not linked to openness in the post-approval period, it can work against the goal of bringing more innovation.

Where does Amgen stand in Belgium in terms of its biosimilar portfolio?

Amgen decided to invest in biosimilars because of our significant expertise in biologic products. We recognized that it would be a mistake not to leverage this knowledge when these products are off-patent. Our manufacturing background and biotechnology expertise allow us to provide reliable and high-quality manufacturing and supply, which is a big advantage for payers and countries.

We focus on the most used biological products, and their patent expiration, and try to be among the first to bring biosimilars to the market. This is critical because it allows us to create an advantage by not just providing these products at an affordable price, but also ensuring supply reliability. We have a good track record in this respect.

When it comes to savings from biosimilars, it’s important to keep the price reasonable. In some countries with big national tenders or one winner takes-all type of systems, prices can be pushed down dramatically, which often leads to supply challenges. While it’s important to have a certain price incentive for biosimilars, the price should still allow the manufacturer to make a profit. We believe this is important, and we strive to strike a balance that benefits everyone.

We currently have three biosimilars on the market in Belgium, and we plan to launch almost every year another one, in the next three to five years. This is an important part of our strategy.

How are biosimilars received by Belgian stakeholders, whether professionals, patients, or the payer?

I feel there is a growing acceptance towards high-quality biosimilars in Belgium. However, some topics like switching from one product to another in the biological field should be carefully

considered. Even though we have conducted switch trials for some of our products and found no difference in efficacy or safety, there is still some resistance.

Finding the right balance between incentivizing the use of lower-priced products and avoiding unreasonable price spirals that could lead to supply issues is a challenge that is not specific to Belgium. It is important to allow new players to enter the market gradually and for doctors to gain experience with the new products before making broad use of them. If doctors have good personal experiences with biosimilars, they are more likely to use them in the future.

Amgen is well known for celebrating diversity and inclusion and also trying to fiercely preserve its biotech agile culture. How do concepts unfold in the BeLux affiliate?

In Belgium, Amgen places a strong emphasis on community and diversity especially due to the cultural diversity of the country. One recent example of this is our support of the Special Olympics in Belgium. Amgen not only supports the organisation as a company, but many of our colleagues also volunteer to help organise the national games of the Special Olympics this year. This is just one of the many ways that Amgen demonstrates its commitment to community and diversity.

Another way Amgen reflects the importance of community and diversity in Belgium is through its focus on gender balance and cultural diversity of its workforce. We continuously monitor different levels of our organisation to ensure we have the right balance of genders and cultural backgrounds. There is a strong belief that having a diversified workforce brings more value and creativity to the company.

While Amgen’s culture is important, it can be challenging to maintain as it has grown from a small biotech to one of the top pharma companies in the world. The company now has a presence on all continents and is opening new affiliates around the world. However, Amgen’s unique operating model allows local leaders to make decisions that fit best with the local market and cultural environment. This gives us a lot of freedom on a local level.

What goals do you have for BeLux and how do you hope to contribute to Amgen’s global success?

As a global company, Amgen has historically had a strong presence in the US, with a smaller portion of its turnover coming from overseas operations. However, in recent years, there has been

a shift towards a more balanced distribution of its sales, with the biggest potential growth coming from Latin America and Asia. Despite this, Europe remains a strong contributor to the company and has shown growth year over year.

In Belgium and Luxembourg, the goal is to achieve sustainable growth. While there may be other regions with more attractive growth opportunities, the team is committed to delivering on their goals and promises, while also remaining realistic about what is achievable within the local environment and the larger system. With a strong portfolio of innovative and biosimilar products, we are confident in our ability to contribute to Amgen’s global footprint and improve outcomes for patients with serious illnesses.

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