Frederic Clais – Country Manager, Eli Lilly Belgium

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Eli Lilly Belgium's Frederic Clais discusses the potential impact of upcoming reform of the country's access and reimbursement system, the country's enduring relevance to the company as home to its European Clinical Trial Services (ELECTS) division, and his aim to reach 200,000 patients in Belgium with Lilly treatments before the end of his term as country manager.

In addition to acting as the country manager of Eli Lilly in Belgium, you also hold the position of chairman for pharma.be. What made you want to take on this extra responsibility on top of managing a strategic affiliate?

Alongside my responsibilities at Eli Lilly, I have been a part of the pharma.be industry association board for several years as the vice president. When the position of chairman became vacant, I saw this as an opportunity to drive innovation and ensure that it reaches patients in Belgium. My motivation for taking on this additional responsibility is not solely from a company perspective, but to bring positive changes that benefit the wider community. It is energizing for me to focus on this objective, and I put all my efforts into achieving it.

In your opinion, how much of the Belgian healthcare system’s ability to transform and change depends on the current government that is in place in the country?

The Belgian healthcare system's flexibility is certainly dependent on the government in place, as it plays a vital role in setting policies and budgets for the healthcare sector. Every four years, a new government is formed, and during this process, specific elements related to the pharma industry may be discussed and stipulated. Even though there are some basic principles that do not change, budgetary discussions always take place, and new investment plans and reimbursement procedures are typically evaluated by each new administration. This is a logical process considering the speed of innovation in the industry and the continuous emergence of more targeted therapies. It is essential to adapt and adjust reimbursement and access policies to the latest technologies to meet the evolving needs of the healthcare sector.

There has been a significant decrease in both Belgium's overall healthcare budget and the share of medicines within it. What is your opinion on what have been the driving forces in this reduction?

The drop in Belgium's overall healthcare budget and the decrease in the share of medicine budget can be attributed to various factors. The automatic increase in salaries due to inflation is one such element that impacts our budget share. However, this decrease indicates that there may be an inclination towards perceiving innovation as a cost element rather than investing in it. With an ageing population and the introduction of new treatments that are much more targeted, it is crucial to maintain our share of the medicine budget. Instead of taking this approach, the regulators need to have a clear and long-term view of our medicine budget to ensure that there are enough resources allocated for upcoming innovations. Belgium's heavy infrastructure for health with a significant number of doctors and hospitals is also a contributing factor to this budgetary restraint. This is a yearly struggle, which is understandable, but there needs to be an open discussion around investing in better health outcomes for the population. Overall, we need to view healthcare spending as an investment and prioritize the allocation of resources to ensure better health outcomes for all.

What have been the impacts of COVID in these discussions of health and infrastructure investment?

In my opinion, we would have taken more learning lessons from the impacts of the COVID crisis in both Europe and Belgium. Although there has been a huge investment in handling the COVID crisis, including treatment, screening, and testing, it has also created a budgetary gap that needs to be

addressed. In terms of healthcare management, there has not been much learning from the COVID period, and there is a missed opportunity to improve the system. While there were some positive developments, such as quicker access to vaccines and increased digitalization in healthcare, there has not been much building on what was learned during this time. In fact, there are not many concrete examples where the government has established new practices or built on what was constructed during COVID.

Do you foresee the recently announced New Medicines Deal having a significant impact on patient access in Belgium?

The “Spearhead Note”, as it is called officially, aims to provide better access and reimbursement for innovative medicines. The current reimbursement process in Belgium is challenging, some medications receive reimbursement in other EU countries but not in Belgium. This situation is difficult for Belgian patients, who should have equal access to high-quality care and treatments. Although university centres and physicians have access to research and development through the large number of clinical trials conducted in the country, this is not reflected in the final access for patients.

However, with this reform, the government has committed to improving the evaluation of the value of medical innovation, which should be reflected better in the evaluation process. There is a potential scheme to allow earlier access to innovation, even as early as following EMA approval. Hopefully, this can address the biggest gaps in medical evaluation, which needs to be approached more from a value perspective rather than a cost perspective.

The industry and the government should work together to ensure that Belgian patients have access to the best possible quality treatments and high-quality care. This is essential for the sustainability of healthcare in the long term. As healthcare stakeholders, our common goal must be to give access to Belgian patients. The government has committed to improving the evaluation of the value of medical innovation, but it remains to be seen how this will work in practice. This new reform needs to be an engagement from both sides, giving new opportunities to deliver innovation in the Belgian environment.

Naturally when making these kinds of policy adjustments resources have to be rearranged and reallocated. One of the ways of doing this is the proposed changes in

patent rules within the EU to allow generic manufacturers earlier opportunities to create their own formulations. Is this something that innovators are willing to compromise on?

The importance of innovation in the pharmaceutical industry cannot be overstated. Without innovation, there would be no new medicines, and therefore no generics. As such, it is important to give innovators the necessary space to launch their products in a country.

Restricting intellectual property (IP) may seem like a solution to reduce costs, but it is not the right approach. IP is crucial for investment, especially for chronic diseases, and any restrictions on it may put the EU at a disadvantage in attracting investments compared to the rest of the world. From the perspective of the pharmaceutical industry, IP is certainly a concern, both locally and across Europe. Therefore, it would be risky to limit IP protection time compared to other parts of the world, as it may reduce the incentive for innovators to bring new treatments to Europe and therefore impact health outcomes.

While policy adjustments may require the reallocation of resources, limiting IP protection is not a solution. Instead, the EU should focus on providing a supportive regulatory environment that promotes innovation, allows for faster access to new medicines, and encourages fair pricing. By doing so, it can strike a balance between the interests of innovators, generics manufacturers, and patients, and ensure that high-quality healthcare remains accessible and affordable for everyone.

Having spent almost a quarter of a century with Lilly and approaching your ninth year as Belgium country manager, what has kept you engaged and motivated at this one company for your entire working life?

I joined Lilly in 1998, right after completing my studies as a pharmacist followed by an MBA program. I started as a sales representative, where I learned the importance of communication and proximity to physicians. Over time, I worked my way up through different roles, from brand manager to sales manager and head of business unit. For almost a decade now, I have been responsible for Lilly’s operations in Belgium and Luxembourg.

What motivates me to work at Lilly is twofold. First, being able to help Belgian patients from a health perspective is a huge motivator for me. Growing up in a family of pharmacists, I saw firsthand the struggles of ill patients, and this drove me to enter the pharmaceutical industry. My ambition is to achieve better health outcomes for patients, and I get frustrated when we fall short

of that goal. Second, Lilly’s culture aligns with my personality and values. Lilly was founded over 150 years ago by a pharmacist with a vision to make things better. That philosophy resonates with me and serves as a strong motivation.

Finally, working with excellent people at Eli Lilly is another big motivator. We have a mix of experienced professionals who know the culture very well, and younger people who challenge the status quo with fresh insights and a willingness to drive change. This combination of experience and new perspectives works quite well for us as a company. Our culture is built on excellence, integrity, and respect for people, and I am proud to be a part of it.

Eli Lilly is perhaps best known as the first company to commercialize insulin for diabetes patients 100 years ago. How would you characterize the company’s role in combating the diabetes epidemic in Belgium?

Diabetes is a disease that has been central to Lilly’s DNA, and it started with the company’s groundbreaking commercialization of insulin 100 years ago in 1923. While Lilly remains active in both diabetes type 1 and type 2, the disease still presents a significant challenge today as more and more people are living with diabetes globally, including in Belgium. Even in Belgium, many patients are still living with pre-diabetes or are undiagnosed. For those who are treated for diabetes, it remains an evolving disease that can be difficult to control.

As a company, Lilly is committed to researching and developing new treatments to help control diabetes. With more insights now available on the human body, Lilly is creating new medicines to help control diabetes and other factors that can contribute to the disease, such as weight gain. Lilly has recently developed an innovative medicine to decrease blood glucose in type 2 diabetes patients, which has been approved by the FDA in the US and the EMA in Europe. However, getting access to the medicine in Belgium is still a work in progress.

Looking to the future, Lilly is continuing to innovate in the diabetes space and has many novel treatments in the pipeline. Despite these advancements, diabetes still presents significant challenges and requires continued efforts to improve patient outcomes.

Oncology is another crucial area for Lilly, and the company has stated its aim to improve patients’ lives by treating rare tumour types, leveraging precision medicine, and finding new ways to improve existing treatments. What are the priority areas

where you feel Lilly can have the biggest impact on cancer patients in Belgium?

Lilly's focus on oncology is indeed a critical part of our portfolio. We aim to improve patients' lives by developing precision or targeted medicine and finding new ways to improve existing treatments. Our current treatments and pipeline include precision medicines that target specific types of cancer, such as breast, gastric and lung cancer. We recently obtained reimbursement for breast cancer with a high risk of recurrence in Belgium. We continue to search for solutions for patients affected by cancer from a larger perspective. The fight against oncology is ongoing, and there is still much to be discovered in the field of oncology. Nevertheless, Lilly is proud to be a part of this research and development within oncology, and we will continue to work towards improving patients' lives through our treatments.

What does the current product launch experience look like and how receptive are Belgian stakeholders to the kinds of innovation that Lilly is bringing forward?

The current product launch experience in Belgium is challenging due to the lengthy reimbursement process, even though it has legal timelines and the quality of some evaluations. The evaluation process in Belgium is thorough and requires a lot of support from clinicians. We are very happy to see that our treatments have strong support from the clinical society and physicians.

In order to bring the medicine earlier to the patient, we also have the possibility to install a medical need program, but they are entirely funded by the industry, and there is still the risk that the drug or indication will not be reimbursed.

Overall, the launch of new products in Belgium is heavily dependent on reimbursement. While it is frustrating to wait for reimbursement after EMA approval and clinical trials, it is essential to evaluate the benefits of each innovation thoroughly. The New Medicines Deal, described in the Spear Head Note, reform may put more emphasis on worldwide evidence in the evaluation process, which would be helpful. Belgium has strong data, but it is not always utilized to its full potential.

Digital transformation is on the lips of both governmental and industry leaders today, but seamless adoption is not always easy. To this end, Lilly has made significant investments through its 'Connected Care', the patient outcome-based next phase of insulin management. In a country looking to join Europe's elite in terms of healthcare digitalization, how important is this to you? Where are the most significant digital gaps

within Belgian healthcare?

Digital transformation and healthcare digitalization are important topics, and we are hoping to lead the way through our ‘Connected Care’ initiative, which is focused on improving patient outcomes in insulin management. In the United States, this type of connected care is well-established, but it is still emerging in Europe. While it has the potential to improve patient monitoring and management, digitalization is about much more than just this one aspect.

One crucial aspect of digitalization is data collection, which can provide valuable information for decision-makers and pharmaceutical companies. However, there are still significant gaps in digitalization and data optimization within Belgian healthcare, compared to countries like Denmark, Finland, and other Scandinavian countries. While the Belgian government has some data collection systems in place, there is still much room for improvement.

To address these issues, our affiliate is actively involved in the Belgian Diabetes Forum, which is a multi-stakeholder platform focused on improving healthcare for diabetes patients. Digitalization and data registration are key areas of focus for the forum. While connected care is important for individual patients and healthcare providers, broader data collection efforts and the creation of worldwide evidence should also be considered. One challenge is to determine what data should be collected and analyzed from the beginning.

What is Belgium’s relevance to Lilly?

Belgium is an important country for Lilly as it is home to both an important mid-sized European affiliate and its European Clinical Trial Services (ELECTS) division. From a clinical trial perspective, Belgium is quite important to Lilly and the company invests quite a lot in clinical trials there. It is important to maintain a strong position in Belgium, both in terms of regulatory compliance from a European level and in terms of access to patients for clinical trials. The ELECTS division coordinates all clinical trials and manages all clinical material across Europe, Africa, and Asia, due to Belgium’s historical track record in managing clinical trials. We also have strong partnerships with local logistic partners in Belgium who help distribute the clinical material across the world. This shows the strong investment of Lilly in Belgium. We hope to maintain our investment in the country to continue Belgium’s strong position in clinical trials.

Looking forward, whenever the time does come for you to move on to new ventures, what would you like to have achieved with Eli Lilly in Belgium?

In terms of future goals, the ultimate achievement that I would like to reach with Eli Lilly in Belgium is to increase the number of patients that have access to our treatments. The current number of patients being treated with a Lilly drug in Belgium is 145,000, and the goal for next year is to increase this number to 160,000. My ambition is to reach 200,000 patients treated with a Lilly drug before my time ends as country manager. This goal is driven by my desire to improve access to treatment and the innovative drugs that we develop. Ultimately, I believe that success is measured by the number of patients being treated, and my goal is to make a difference in the lives of as many people as possible.

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