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09.03.2020

Tags: Belgium Luxembourg, MSD, Clinical Trials, Manufacturing, Research

Brecht Vanneste,

associate VP and managing director of MSD in Belgium and Luxembourg, highlights the strategic significance of the affiliate as an important location for early-stage clinical trials and home to the company's Heist-op-den-Berg production facility, a key manufacturing site for the global group. Vanneste delivers a strong message about the company's aim to partner with local health authorities to ensure that local patients have continued access to innovation.

What were the priorities you put into place for yourself and the affiliate as a first-time managing director when taking on the role in 2019?

I have been with MSD for the past 20 years which is always an advantage when starting a new role, especially in leadership. Having known my colleagues for a long time, I can say that the priorities set in place were a reflection of the entire MSD leadership team's direction and goals.

MSD is in a good position not only globally, but here in Belgium as well. As a company we are focused on developing, manufacturing, and promoting breakthrough drugs – a mission that we reflect locally within the affiliate. Innovation comes out of our pipeline at a fast space which we then deliver to patients as quickly as possible. As MSD, our vision is to innovate with a purpose, making a difference in patients' lives and the lives of their families. This is the number one priority

of MSD across all countries and divisions.

Secondly, we are looking at new ways of reaching patients and by optimizing our go-to-market model. Seeing how the industry is evolving in the face of external challenges, we must consider how to better deliver our solutions to the market by incorporating the latest trends such as digitalization, data, and analytics.

At the same time, we have core operational values that are high on the MSD Belgium agenda. We want to make sure our employees are engaged with ample opportunity to develop themselves and their career. Moreover, we strive to be an inclusive company that values diversity and offers these growth opportunities to people of all backgrounds, gender and age.

What is the scope and scale of MSD's footprint in Belux?

Within the company's 130 years of operation, MSD has been fortunate to be able to benefit the lives of many patients thanks to the very significant investment we put into R&D year after year. Looking back ten years ago, we were very strong in general medicine (cardiovascular and diabetes) with some specialty drugs, for example in HIV. Today MSD is one of the leading oncology companies with a breakthrough drug in immunotherapy that helps to save the lives of patients who before had little to no hope.

Considering that immunotherapy against cancer was not even in our conversations ten years ago, it is truly remarkable to see how our scientists have invented and pursued this breakthrough to help so many patients and families to the point that the mechanism of action was even awarded a Nobel Prize recently.

Later this year MSD will celebrate the 55th anniversary of its presence in Belgium. We are currently second in the pharmaceutical market of Belgium and number one in Luxembourg. While of course financial performance is a benchmark for investors, we are most excited by the patients behind these figures that we can make a difference for. Therefore, we work with different stakeholders, be it the ministry of health, sickness funds, and scientific leaders and researchers, to ensure we can continue bringing these breakthrough innovations to patients every day.

How does the Heist-op-den-Berg production facility in Flanders attest to the strategic significance of Belgium for MSD?

This site is not only important for our presence locally but also for MSD’s global operations. It represents our footprint as a company in Belgium and the commitment we have to the community – economically and socially. The facility employs more than 800 workers which is greatly impactful for a city like Heist-op-den-Berg.

The fact that in Belgium we can develop, manufacture, and package drugs locally is important because it shows that MSD is a company that invests in the full product life cycle, not only focusing on commercial success. The Heist-op-den-Berg facility speaks to the entire ecosystem we have built as an industry as people typically forget about the time and effort it takes to develop just one life-saving product. A drug is often seen as a cost to the healthcare system, but our operations here show that development is, in fact, an investment into society, next to the many benefits for the whole healthcare system.

From Belgium we export to over 140 countries which solidifies the importance of our country as a pharma valley in Europe. Belgium is centrally located with solid logistic pathways via air, sea, and land. This is just one of the key elements we have in the ecosystem and it is very beneficial to have a government that is supportive of this environment. Heist-op-den-Berg is one of many facilities that helps to continue building this ecosystem and ensuring a healthy trade balance for the country.

MSD also invests locally in R&D – 34 immuno-oncology clinical studies in patients and approximately 25 studies in healthy humans are carried out in Belgium. Why does MSD have such a strong research footprint in the country?

Phase I trials cannot be carried out without a strong scientific development team and MSD is a company with a focus on early discovery and development. Thanks to our strong clinical network, a vast majority of our early discovery that happens across the globe is sent through Belgium: about 90 percent of all MSD “First in Human” studies (first clinical trials in humans) are carried out in Belgium The country has many university and clinical centres active in phase I-IV trials and over the past decade, the affiliate has established close partnerships with these external stakeholders. Furthermore, the government has also created an enabling regulatory environment for early and late-stage clinical trials, meaning we have quick approval decisions while maintaining compliance with all the necessary policies and procedures. This makes Belgium very attractive for a company like MSD to bring innovative concepts to humans in a matter of weeks compared to perhaps several months in other markets. All Belgian stakeholders are aligned on delivering new solutions

to patients as quickly and safely as possible.

What differentiates Belgium from other European markets, ensuring that Belux is not seen as a “periphery region of France”?

At MSD we are structured into regions and Belgium falls into the EUCAN (Europe and Canada) region which contains the smallest markets like the Balkan States through the largest like France and Germany. This also speaks to the importance of the European Union for MSD as a coalition that supports R&D for the benefit of patients. Within EUCAN, the Mid-Europe region comprises of all the small to mid-sized markets, excluding the EU Big Five and Canada.

While Belgium is not the biggest, we are known to be an innovative market with strong capabilities in clinical development, not only in phase I but II and III as well. The strong academic landscape of the country is well recognized and MSD Belgium itself has a superb clinical development unit. The ecosystem of academic and industry cooperation is a unique strength of Belgium.

Additionally, Belgium is a market where the conditions of access have been improving over the past decade. In the past, we were a market that was lagging in the time from gaining approval at the European level to reaching patients locally. Just within the last five years we have had a ministry of health that has been supportive of innovation and breakthrough drugs. Looking at immuno-oncology drugs, Minister De Block made the decision to ensure patients could access these treatments by accelerating approval timelines and awarding reimbursement for breakthrough solutions, especially in areas with a significant unmet medical need.

Calculations by Professor Lieven Annemans from the University of Ghent demonstrated that this fast-tracking of immuno-oncology drugs will result in a gain of more than 9,600 quality-adjusted life years just within 5 years whereas the usual longer procedure would have gained only 5,900. These political decisions have a tangible impact on patients, and I believe it is essential to maintain this environment that is supportive of innovative solutions.

What is the primary challenge being faced by the Belgian healthcare system when it comes to access to innovation?

Every country in the world is struggling when it comes to affordability of innovation. The top priority of the system is how can we create sustainability over the long-term. However, if

authorities continue to see innovation in healthcare as a cost rather than an investment, the ongoing debate will be difficult. However, most of the population sees healthcare as a priority; investing for their future and the future of their children to lead longer, high-quality lives.

In Belgium our system is very socially responsible, and the diagnosis of a serious illness does not come with the same social or financial burden as other countries like the US. While taxes are high, as citizens we have many benefits in return. Therefore, we hope to continue having a government that sees healthcare as an asset for the wellbeing and prosperity of our country rather than a cost or burden to society.

What do you see as the necessary factors for ensuring access to innovation without having costs get out of hand?

Looking at the pharmaceutical spending of Belgium, less than half of the budget is dedicated to innovative drugs which are still protected by patents. As an innovator, we have an incentive to bring our drug exclusively to the market. After a time, this incentive disappears as generic and biosimilar competition enters the market – a fair system. Drug development is very high risk and costly, so there should be mechanism to ensure the same long-term investment in R&D.

In Belgium, once a patent expires and generics and biosimilars enter the market, this is usually paired with steep price cuts which creates oxygen in the system that can hopefully be used to once again fuel the new innovation entering the market. This is where we are trying to collaborate with the Belgian life science stakeholders; where can we reduce the costs and prioritize investments. We must reduce the costs of off-patent products to continue creating room for innovation.

It is an ethical responsibility that we must ensure that patients have access to the newest life-saving treatments as soon as possible. Looking at Belgium’s almost five-billion euros drug budget, more than half is still supporting products which are no longer considered innovative. We must find savings in this segment of the market to continue ensuring access to innovation. This is not a story for MSD only, but for the entirety of the industry.

Furthermore, if we look at generic drug prices across Europe, there are many differences. We must make prices more universal in this off-patent segment. Even as MSD we understand that once our patent expires, the incentives we had will disappear and we take the hit – this is not the area in which innovative companies should be competing.

Being a partner is not only about collaborating with authorities, but also about supporting patients and healthcare providers. How is MSD Belgium keeping patient centricity as a value of its operations?

Unlike in the US, there are regulations in Europe that limit direct contact with patients, which I believe makes sense for how we should be interacting. Nevertheless, patients are at the centre of everything we do at MSD. As our founder, George Merck, once said, “We try never to forget that medicine is for the people. It is not for the profits. The profits follow, and if we have remembered that, they have never failed to appear.”

At the same time, we must work with patient-centred organizations on how we can bring the patient voice earlier in the development phase of drugs. Today, many clinical trials are conducted in the framework of the European Medicines Agency evaluation criteria. However, the patient-reported outcomes (PROs) of those who suffer from a disease are sometimes focused on very different attributes, such quality of life. Therefore, at MSD we try to consider patient concerns earlier in the R&D process to ensure we develop a product that will respond to what patients are looking for and go beyond simply the rigid outcome perspective that sometimes regulators have.

One we have developed a drug that responds to patient needs, we work on how we can communicate this in the best possible way because what a physician wants to know about a product can also be very different than a patient. While doctors want to understand the mechanism of action, patients want to know how their life and disease will be impacted. Very often information about a product is given through the voice of a healthcare professional, but we must work with physicians to ensure that together we can “speak the language” of our patients.

What are your objectives in leading the affiliate during your tenure as managing director of MSD Belgium?

Simply put, our ambition is to keep bringing life-saving innovation as quickly as possible to patients. There are a lot of new developments coming out of the pipeline for MSD in oncology, vaccines and infectious diseases. Internally, we aim to become an even more efficient and effective organization by implementing our “new ways of working”. This means creating an environment where employees feel engaged and inspired on a daily basis. If I look at the MSD I joined 20 years ago compared to today, we work in more agile teams where silos between division are broken down so that we can come together around patients and make a difference in their lives.

Looking at how quickly the environment around us is changing, we must also continuously learn and adapt. The way of working that existed two decades ago has become obsolete as we are in a digital, data-driven environment. Within MSD we have a responsibility to be as agile as possible and respond to the modern needs of authorities, healthcare providers, and patients. Therefore, it is important to create partnerships with all stakeholders to remain a sustainable organization within the Belgian healthcare system. This is not something we can do alone, and I believe we have a strong industry association that aligns between the different innovators. Nevertheless, our external partnerships are highly valued and will become even more important going forward.

You have been with MSD since the start of your career in pharma for over 20 years. What has kept you so loyal to the company?

I am proud to work for a company that has been continuously evolving for the past 130 years, making a difference in the of lives patients and families. I enjoy working with and learning from my colleagues every day in an environment which is diverse, innovative and inclusive. The words of our founder George Merck on how patients must come first, resonate closely with me and I believe it is this mission that has made MSD a sustainable and respected company within the industry. The fact that I can work at a company which invents solutions that improve the lives of people on such a major scale is very important to me and is what gets me out of bed each morning.

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